PROPOSED STANDARDS FOR RELATIONSHIP TESTING LABORATORIES

16th Edition

Effective January 1, 2024

A Note to Readers

Individuals not familiar with the standards-setting practices of AABB should be aware of the following:

- Requirements, once stated, are not repeated. For example, standard 5.0 requires that all processes and procedures be validated. Therefore, it is not necessary to require in other areas that a specific process or procedure be validated.
- Words or phrases used in a way different from their usual meaning are defined in the glossary.
- The term "specified requirements" is defined broadly to include accreditation requirements, national, state, or local laws, and any other applicable requirement.
- Please note, that the Summary of Significant Changes to the proposed 16th edition begins on page 2 and runs through page 19. The proposed 16th edition begins on page 20 and runs through page 80.

Significant Changes to the Proposed 16th Edition of Standards for Relationship Testing Laboratories

Updated Quality System Essentials

The proposed 16th edition of Standards for Relationship Testing Laboratories is the first edition to incorporate the updated quality system essentials (QSE). This includes a number of updates to the chapters and the tone and flow of the edition.

Highlights of the updated QSEs include:

- All standards written in the active voice.
- Once a requirement has been stated, it is not repeated.
- Each chapter begins with a description of what the standards therein cover.
- Each chapter contains a list of examples of key terms that mirror the content of the chapter and that should be kept in mind when reviewing the standards.
- Each chapter contains a list of examples of key objectives that an assessor could look for during an onsite assessment, however, this list is not comprehensive, nor will it be assessed against by an assessor. It is merely for guidance purposes only.
- Each chapter now concludes with the record retention table for that chapter. Note a comprehensive record retention table still exists at the end of chapter 6**.**

Driving factors behind the revisions to the updated QSEs:

- Deliver a streamlined template that mirrors current quality concepts.
- Make it user-friendly to shorten learning curves.
- A top-to-bottom reworking of tone, formatting, language, and style.
- Preserve chapter headings and overall structure, to make it easier for users to follow and understand the core quality concepts.
- Maintain the exact same standards numerology for all core quality standards across all sets of AABB Standards.
    - Incorporate activity-based standards into that structure
- Responding to member needs and requests.
- Beneficial to facilities with multiple accreditations (uniformity of language and numbering).

Significant changes to the Standards are included below:

1.1.1.1 The laboratory director shall have at least 2 years of training or experience in relationship testing in an AABB **(or equivalent)** accredited 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. Where indicated, the laboratory director may delegate responsibilities to another qualified individual; however, the laboratory director shall retain ultimate responsibility for laboratory director duties.

The committee made this change to allow for greater inclusion of individuals that can serve in the role of laboratory director if they have the necessary qualifications but do not work in an AABB accredited laboratory.

1.1.1.1.1 In cases where the director candidate's experience is not in a laboratory accredited by AABB (or equivalent), exceptions shall be considered on a case-by-case basis by the Relationship Testing Accreditation Committee. Standard 1.1.6 applies.

The committee created new standard 1.1.1.1.1 to allow for individuals that wish to serve as a laboratory director but do not work in an accredited laboratory, to have their candidacy reviewed by the RT Accreditation Committee. This language is based on an existing standard in the Standards for Immunohematology Reference Laboratories.

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 ~~laboratories~~, the technical leader serving as a laboratory director for relationship testing purposes 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/ experience in relationship testing in an AABB **(or equivalent)** 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.

The committee edited this standard based on changes noted above concerning the equivalence requirement.

1.1.4.1 In cases where the director candidate's experience is not in a laboratory accredited by AABB (or equivalent), exceptions shall be considered on a case-by-case basis by the Relationship Testing Accreditation Committee. Standard 1.1.6 applies.

The committee created new standard 1.1.4.1 to allow for individuals that wish to serve as a laboratory director but do not work in an accredited laboratory, to have their candidacy reviewed by the RT

Accreditation Committee. This language is based on an existing standard in the Standards for Immunohematology Reference Laboratories.

2.2 Laboratory Director Oversight

The laboratory director shall oversee a maximum of 10 accredited facilities. No more than **5** ~~five~~ of those **facilities** shall be testing laboratories and the remaining may be collection/verification facilities.

Based on feedback from members of the AABB public, the committee replaced the spelling of "five" with the number "5"to allow for legibility. This, in matching with the number 10 in the previous sentence should make it clear that a laboratory director can only oversee 5 testing laboratories.

4.1.4 Laboratory testing and other services required by these RT Standards shall be performed in a laboratory accredited by either the AABB or ~~other~~ equivalent accrediting body.

4.1.4.1 When another laboratory provides genetic test results, that laboratory shall be accredited by the AABB or ~~other~~ equivalent, accrediting body for that activity. Reference Standard 6.4A, Requirements for Test Reports, I.7 applies.

The committee removed the clause "other" from standards 4.1.4 and 4.1.4.1 to mirror the language edited in chapter 1.

4.3.1 Results shall not be released before quality approval of new lots and shipments.

Standard 4.3.1 is new to this edition and was added to ensure that laboratory results are not distributed before they have been reviewed and approved by the quality representative. The new language in the QSE in 4.3 requires "received, inspected, and tested, as necessary, before approval for use" The language of the 15th edition was "before reporting of results". Subnumber 4) was added to allow the common practice of concurrent QC testing of new reagents with approval required prior to reporting of case results.

4.4.1 Review of Supplier Promotional Material

The laboratory shall ~~have a process to~~ review promotional materials of contracted third party administrators at defined intervals to ensure that the information complies with these RT Standards.

The committee elected to give standard 4.4.1 a title for clarity's sake. The committee, in line with the updated quality template, has removed "have a process to" for consistency.

4.5 Management of Supplies and Materials

The laboratory director or a designated representative shall ensure that the laboratory processes ~~that~~ address the availability, control, storage, handling, and transportation of critical supplies and reagents.

The committee removed the clause, "that" for tone and to mimic the updated quality template.

4.6.1 The facility shall ~~have policies, processes, and procedures to~~ evaluate and respond to possible altered or fabricated documents.

The committee, in line with the updated quality template, has removed "have policies, processes and procedures" for consistency.

5.1.10 Proficiency Testing Program

The laboratory shall participate in a proficiency testing program for each **locus or group of loci** ~~genetic system~~ used for reporting test results. Standard 7.2.5 applies.

5.1.10.3 When a formal graded external proficiency testing program is available for one or more of the **loci** ~~genetic system~~ used to report test results, the laboratory shall participate three times a year for each **locus** ~~genetic system~~ analyzed in the laboratory.

5.1.10.4 When no formal graded external proficiency testing program is available for any of the **loci** ~~genetic system~~ used to report test results, the laboratory shall use one of the following methods:

1) Test on a monthly basis known samples that were ~~from~~ **originally tested** when graded proficiency testing was available.

5.1.10.5 When formal graded proficiency testing programs are available for some but not all **loci** ~~genetic system~~, the laboratory shall test the **loci** ~~genetic system~~ not evaluated by a formal proficiency testing program using one of the following methods:

1) Test on a monthly basis known samples that were ~~from~~ **originally tested** when graded proficiency testing was available.

5.1.11.1 If proficiency testing is not available for all of the **loci** ~~genetic system~~ relied upon to report test results, the samples tested, if available, shall be stored for as long as records are maintained. Standards 5.1.10.4 and 6.2.1 apply.

The committee elected to replace the term "genetic system" with "locus or group of loci" for accuracy and matching the terms used in the industry by AABB member laboratories. Where the term "genetic system" exists throughout the RT Standards, it has been replaced by either locus, loci or group of loci where appropriate.

5.1.12.1 The laboratory shall release test results, **samples, or profiles**, only for purposes relevant to the relationship testing for a specific case. Otherwise, a court order or the written authorization of the individual(s) tested or the individual(s) with legal authority to provide consent is required. Standard 3.7.4 applies.

~~**5.1.13.1** The laboratory shall release an identifiable sample and/or profile of an individual only for purposes relevant to the actual relationship testing for which the sample was submitted.~~

~~**5.1.13.1.1** If additional relationship is requested to be evaluated, a court order or the written permission of the individual(s) who furnished the sample, or the individual(s) with legal authority to provide consent, is required.~~

The committee added the terms "samples or profiles" to standard 5.1.12.1 for completeness. With this inclusion, the committee was able to delete standards 5.1.13.1 and 5.1.13.1.1. This edit has not changed the intent of the standards.

5.2 Sample Collection for Chain-of-Custody Cases

The laboratory shall ~~have policies, processes and procedures for~~ **ensure:** ~~consent, collection, verification, and acquisition and maintenance of identification records~~.

The committee, in line with the updated quality template, has removed "have policies, processes and procedures" for consistency and added "ensure" for the standard to read appropriately. The committee also removed the list of terms included as they are all covered by the subsequent standards that flow from standard 5.2.

5.2.2.1 Collection materials shall **only** be sent directly ~~only~~ to collectors and/or witnesses. Collection materials shall not be in the possession of any of the tested parties either before or after collection.

Standard 5.2.2.1 is new to the proposed edition, however the content previously appeared as the second sentence of standard 5.2.2. The committee moved the term "only" in the standard for legibility.

5.2.2.3 The laboratory shall ~~have policies, processes and procedures to~~ ensure that **the individuals who perform** collect**ions**~~ors~~ are trained. Standard 2.1.3 applies.

The committee, in line with the updated quality template, has removed "have policies, processes and procedures" for consistency and added "ensure" for the standard to read appropriately. The committee also included the clause "the individuals who perform" for completeness and legibility.

5.2.2.4 Samples intended for immigration, visa, passport, and citizenship testing cases for the United States of America shall be transported directly from the place of collection to the testing laboratory.

Standard 5.2.2.4 is new to the proposed edition. This standard was added at the request of AABB's representative from the State Department to ensure that samples collected at an embassy or consulate are shipped directly to the testing laboratory instead of a third party.

5.2.3.6 The laboratory shall ~~have policies, processes and procedures to~~ identify and clearly indicate on the final report whether it is a chain-of-custody or non-chain-of-custody case. Standard 4.6 applies.

The committee, in line with the updated quality template, has removed "have policies, processes and procedures" for consistency and added "ensure" for the standard to read appropriately.

5.2.4.1 Printed name, alleged relationship, and date of birth of each individual tested ~~and untested person(s) signing consent for a minor child or legally incompetent adult~~.

5.2.4.1.1 Printed name and relationship of an untested person(s) signing consent for a minor child or legally incompetent adult.

The committee elected to separate these two concepts into two standards for clarity. The concern and need to split the standard into two is due to many states having social workers who bring the children for testing and do not wish to provide their date of birth. The creation of standard 5.2.4.1.1 allows for the individual (potential social worker) to provide consent and identification but removes the requirement to provide a date of birth for the untested party signing consent.

5.2.4.2 Race/ethnic background of **all the tested parties**, ~~each parent/alleged parent or other participant(s) being tested~~ with the exception of ~~the~~ **a** child **in parentage cases**.

~~**5.2.4.3** For non-parent-child relationship, the race/ ethnic background of the participants.~~

The committee elected to move the content of standard 5.2.4.3 to standard 5.2.4.2 for clarity, thus allowing the standard to be deleted. The intent of standard 5.2.4.2 has not changed.

5.3.1 ~~5.3.3~~ Autosomal loci shall be used to evaluate a relationship unless one of the following conditions exists:

1) Results for autosomal loci are not obtained.
~~2) Results for autosomal loci are inconclusive.~~
2~~3~~) Results for nonautosomal markers exclude the relationship.
3~~4~~) Autosomal markers are not **expected to be** informative because the hypothesized relationship is beyond second order.

Standard 5.3.1 previously appeared as standard 5.3.3. The committee felt that this more general standard would fit better as the initial standard in the flow of the section.
Former subnumber 2 has been deleted as it was deemed redundant to subnumbers 2 and 4 where the concepts are included.
Subnumber 3 has been edited to include the clause "expected to be" as a means to ensure that subnumber 2 and 3 support the removal of former subnumber 2. This allows for the concept of there being an inconclusive result, while acknowledging that inconclusive results can at times be informative.

5.3.2 When autosomal markers are tested, a minimum of 8 independent loci shall be attempted.

~~**5.3.2 Testing Requirements for the Null Hypothesis and Alternate Hypothesis**~~

~~**5.3.2.1** When the null hypothesis is that a child inherited its parental obligate allele (POA) from a person with the genotype of the alleged parent and the alternate hypothesis is that the child inherited its POA from a random person in the alleged parent's population, the laboratory shall test three or more independent autosomal loci.~~

~~**5.3.2.2** When the null hypothesis is that a child inherited its POA from a person with the genotype of the alleged parent and the alternate hypothesis is that the child inherited its POA from a person who is related to the tested alleged parent, and there is a failure to exclude, the laboratory shall test eight or more independent autosomal loci.~~

New standard 5.3.2 was created by combining the former content of standards 5.3.2 and 5.3.2.1 into one standard. By combining the requirements and requiring a minimum of 8 loci be attempted, the standard can accommodate both relatives of the tested individual and random individuals. This editing to the content does follow the flow of normal work processes in a laboratory. Of note, the elements of former 5.3.2.1 were being maintained in the previous editions to cover situations where a laboratory still conducted RFLP testing. However, at this time, acquiring RFLP testing would be impractical, and no laboratories perform this testing at this time.

5.3.3 When autosomal markers are **reported** ~~used~~, multiple loci shall be the basis for the laboratory's findings.

The committee elected to replace the term "used" for "reported" for clarity. The intent of the standard has not changed.

~~**5.3.4** When the genetic profile of the untested party can be reconstructed, the laboratory shall use autosomal markers. Nonautosomal markers may additionally be used. Standard 6.4.2 applies.~~

This standard was deleted as it was in conflict with standards cited above. The removal was done for clarity.

5.3.6 This group of tests shall, with rare exceptions, provide a nonexcluded alleged parent with a **likelihood ratio** ~~relationship index~~ of at least 100 **to 1**. **Likelihood ratios of 100 to 1 or greater shall be considered genetic evidence supporting the alleged parental relationship.**

The committee edited standard 5.3.6 for clarity. The committee replaced the term "relationship index" with "likelihood ratios." A relationship index is a form of a likelihood ratio as a part of a hypothesized relationship. The additional sentence in bold provides additional clarity to the standard.

5.3.7 ~~The laboratory shall have policies, processes and procedures~~ **For laboratories performing** two-party tests **to determine** full sibling, half sibling, avuncular, or single grandparentage **relationships, the following standards apply**:

The committee edited this standard for clarity and to ensure the style and tone of the standards mirror the way the updated quality template is written.

5.3.7.1 Likelihood ratios greater than 10 **to 1** shall be considered genetic evidence supporting the **alleged** ~~tested~~ relationship.

The committee edited this standard for clarity. The edits mirror the changes made to standard 5.3.6 above, including the likelihood relationship component.

5.3.7.2 Likelihood ratios **from** 0.1 to **1** through **10 to 1** shall be considered inconclusive for the **alleged** ~~tested~~ relationship. **When reporting inconclusive results, the laboratory shall have attempted a minimum of 20 autosomal short tandem repeat (STR) loci.**

The content of this standard previously appeared as standard 5.3.8.1 and was moved to appear in a list format for flow purposes. This standard also encapsulated parts of standard 5.3.8.2 (which is now 5.3.7.2). The elements in the second sentence in bold previously appeared as 5.3.8.1.

~~**5.3.8.1** Before reporting an inconclusive result, the laboratory shall use a minimum test battery of at least 20 autosomal short tandem repeat (STR) loci when testing.~~

The committee deleted standard 5.3.8.1 as it will become a part of standard 5.3.7.2 highlighted below.

5.3.7.3 Likelihood ratios less than 0.1 **to 1** shall be considered genetic evidence **against** ~~not supporting~~ the **alleged** ~~tested~~ relationship **and supporting the alternative**.

The committee edited standard 5.3.7.3 to mirror changes made to standards listed below, all building off of the content of standard 5.3.6.

5.3.7.4 The laboratory shall report an estimate of the percentage of individuals of known relationship that may have a combined likelihood ratio that is inconclusive, supportive **of the tested relationship**, or ~~not~~ supportive of the alternative ~~tested relationship~~ for the laboratory's test protocol at the combined likelihood ratio **threshold or the** reported **value** ~~for the case work~~.

Reference Standard 6.4A, #3, (5, and 8) applies.

The committed edited this standard for clarity, again to mirror the changes to the standards above and to match the content of standard 5.3.6.

5.3.9 When using **non-traditional relationship testing statistics** ~~a computer algorithm(s) to evaluate a large number of loci (see Standard 5.3.11.3) that does not produce a standard combined relationship index~~, the laboratory shall provide an explanation of the evaluation, the equivalency to the combined relationship index of 100, and the ~~version of the algorithm~~ **statistical method(s)** used. **Standard 5.3.11.3 applies.**

Standard 5.3.9 has been edited to include the new concept of "non-traditional relationship testing statistics" and "traditional relationship testing statistics" which have been added to the proposed edition. This includes new definitions for the terms as well. This better reflects the current landscape of the field. The terms are defined below:

Non-Traditional Relationship Testing Statistics: Methods where the likelihood ratio, or other measure of statistical support, is calculated using formulas that do not include the frequencies of specific alleles, genotypes, or haplotypes of the tested parties. Instead, statistical support is calculated using formulas that include other parameters (e.g., shared centimorgans). These statistics are typically used for very large SNP or other nucleotide data sets.

Traditional Relationship Testing Statistics: Methods where the likelihood ratio is calculated using formulas that include the frequencies of specific alleles, genotypes, or haplotypes of the tested parties, as opposed to other parameters (e.g., shared centimorgans). These statistics are required for standard STR loci, but may also be applied to other types of loci.

5.3.10.1 The phenotype of an excluded alleged parent(s) shall be confirmed with an independent isolation (DNA extraction), and in cases without a known parent, the child's phenotype shall also be confirmed with an independent isolation. **Laboratories shall validate and define confirmation parameters for single nucleotide polymorphism (SNP) testing.** For closed systems, Standard 5.4.2 applies.

The committee added the sentence in bold for clarity and completeness. This addition leads into standards that appear below related to SNP testing.

5.4.1 DNA Polymorphism Testing

The laboratory shall use validated ~~processes and procedures for~~ DNA testing. The laboratory shall ~~have a process that~~ demonstrate reproducibility of test results.

The committee, in line with the updated quality template, has removed clauses, "processes and procedures" and "have a process that" for consistency and" for the standard to read appropriately.

5.4.1.1 ~~Nucleic Acid Testing (NAT) for~~ Short Tandem Repeat (STR) and Other Fragment Analysis

When ~~NAT is used for STR~~ **fragment** analysis **is performed**, the process shall include the following requirements:

3) The conditions for amplification, ~~hybridization~~ and detection shall be defined and controlled to ensure accurate allele determination.

6) Negative control(s) shall be processed with samples from extraction through analysis to monitor for sample contamination ~~and NAT product contamination~~. For closed systems, this shall be part of the acceptance process. Standard 4.5 applies.

The committee edited standard 5.4.1.1 for clarity. STR encapsulates DNA testing as a part of the fragment analysis. This edit ensures the standard matches the current practice in our labs.

5.4.1.2 ~~NAT for~~ Nucleotide Sequence Determination or SNP Analysis

When ~~NAT is performed for~~ sequence or SNP analysis **is performed**, ~~the process shall include the following~~ requirements **shall include**:

1) When an expert system is used to interpret the SNPs, results containing quality flags shall be interpreted by at least one human reviewer. If the reviewer makes a change, the change shall be confirmed by a second human reviewer.

2) When an expert system is used to interpret **the** SNPs, ~~allele determination,~~ all phenotypes that pass the established and validated criteria may be interpreted solely by the expert system. Allele determinations that do not pass criteria shall not be used in the final relationship calculations.

4) The conditions for amplification, hybridization, **control probes, control primers**, and detection **as applicable**, shall be defined and controlled to ensure accurate allele or sequence determination.

~~5) When a sequence-specific oligonucleotide probe (SSOP) method is used for allele determination, a control probe shall be used to ensure adequate target nucleic acid is available for analysis.~~

~~6) When a sequence-specific primer (SSP) method is used for allele determination, a positive internal control primer shall be included to verify that amplification has occurred for each reaction.~~

6) Negative control(s) shall be **extracted** ~~processed~~ with samples ~~from extraction through analysis~~ and used to monitor for sample contamination and product contamination.

~~9) The laboratory shall have policies and procedures to evaluate contamination, artifacts, and preferential amplification for each sample.~~

The title of standard 5.4.1.2 has been updated to mirror changes to standard 5.4.1.1 for similar reasons concerning testing. This addition also allows for genetic genealogy testing laboratories to meet the standard, this expands the footprint of the Standards. The first sentence was also edited in line with the updated quality template, by removing the clause, "the process" which also ensures that the standard is written in the active voice.

Subnumber 1 was added to this standard for completeness. This ensures that when SNPs are interpreted by the software in use, a human will review the result when a quality flag is found.

Subnumber 4 has been expanded for completeness to ensure that the Standards reflect current practice.

Former subnumbers 5 and 6 have been deleted as this type of testing is no longer required and is no longer included as a part of any CAP surveys to indicate that this testing is occurring. This testing was previously included to allow for HLA testing, which is no longer performed for relationship determinations as well.

Subnumber 6 has been edited for clarity and to mirror changes made throughout the testing methods section.

Former subnumber 9 has been deleted from this edition as the changes made to subnumber 4 now covers the content that previously appeared in this space.

5.4.2 Closed Systems

A ~~The~~ laboratory ~~shall have policies, processes, and procedures for~~ performing DNA testing using a closed system, **shall** ~~including profile anomalies that may affect the result.~~:

5.4.2.1 Identify profile anomalies that may affect the result.

The committee edited standard 5.4.2 to mirror the style, tone and language of the updated quality template. The elements in strike through that appeared at the end of standard 5.4.2 have been pulled from the standard to form the basis the of new standard 5.4.2.1.

5.4.2.2 ~~Laboratories using closed systems shall~~ **C**onfirm the placement of the sample in the specified location on the instrument through a visual check with a witness or electronic equivalent.

Based on the change to standard 5.4.2 (allowing for the creation of a list), standard 5.4.2.2 has been edited. The intent of the standard has not changed.

5.4.2.3 **Test a confirmatory sample(s)** in cases where there is a finding of no relationship if ~~, the laboratory shall test a confirmatory sample~~:

1) The sample is flagged for review by the closed system, **and a human review was not conducted or a human review confirms the flagged loci are found to affect the results of the relationship findings** or
2) The closed system fails and the sample is manually manipulated.
3) ~~Unless a human review is conducted and the flagged loci are found not to affect the results of the relationship findings.~~

Stadnard 5.4.2.3 has been edited to allow the standard to read as a part of the list that begins with standard 5.4.2. The content that previously appeared as subnumber 3 has been moved into subnumber 1 as they are extensions of the same concept. The intent of the requirement has not changed.

5.5 Calculations

The laboratory shall ~~have policies, processes and procedures for the~~ use ~~of~~ validated calculation methods ~~used in relationship testing~~.

The committee edited standard 5.5 to mirror the style, tone and language of the updated quality template by removing the clause surrounding p, p, ps. The clause "used in relationship testing" was removed as it was deemed redundant to the content of this set of RT Standards.

5.5.1 The results from loci exhibiting significant linkage disequilibrium shall not be used independently in **calculating traditional relationship testing statistics**~~ons~~.

In vein with the change to standard *5.3.9 the committee has been edited standard 5.5.1 to include the new concept of "traditional relationship testing statistics". This includes new definitions for the terms as well. This better reflects the current landscape of the field. The terms are defined below:*

Non-Traditional Relationship Testing Statistics: Methods where the likelihood ratio, or other measure of statistical support, is calculated using formulas that do not include the frequencies of specific alleles, genotypes, or haplotypes of the tested parties. Instead, statistical support is calculated using formulas that include other parameters (e.g., shared centimorgans). These statistics are typically used for very large SNP or other nucleotide data sets.

Traditional Relationship Testing Statistics: Methods where the likelihood ratio is calculated using formulas that include the frequencies of specific alleles, genotypes, or haplotypes of the tested parties, as opposed to other parameters (e.g., shared centimorgans). These statistics are required for standard STR loci, but may also be applied to other types of loci.

5.5.2 When linked loci are used **for calculating traditional relationship testing statistics**, the laboratory shall ~~have policies, processes and procedures for~~ estimate~~ing~~ and minimize~~ing~~ the effects of linkage on non-parentage cases.

The committee edited standard 5.5.2 to mirror the style, tone and language of the updated quality template by removing the clause surrounding p, p, ps. This includes the inclusion of "traditional relationship testing statistics."

5.5.5 Validation of Tables and Calculations

5.5.5.1 **All** formulae **and algorithms (including software)** used for statistical calculations **to generate test reports** shall be specified and ~~shall be~~ validated. ~~The weight of the genetic evidence for the hypothesized relationship shall be based calculated and on likelihood ratio (paternity index or other indices) or upon probabilities in the case of algorithms utilized to evaluate data from extensive SNP Standard 3.7.6 applies.~~

These include but are not limited to:

1) All parentage formulae found in Appendix 2 of the Guidance to the Standards for Relationship Testing Laboratories, and

2) The two party non parentage calculations (see standard 5.3.7).

The committee edited standard 5.5.5.1 for clarity. The additions and edits were made in line with changes made throughout the edition. The phrase "and algorithms (including software)" was added to expand the standards to include calculations done for genetic genealogy. The committee also added new subnumbers1 noting that the content of Appendix 2 Formulas for Paternity Index and RMNE Values for Simple Codominant Systems is the formulae all relationship testing facilities must use to ensure accuracy. The committee also included subnumbers 2 ensures that the laboratory is also noting the use of two party non parentage calculations and any other testing algorithms in use in the laboratory.

~~**5.5.5.2.3** Published tables shall be used only for systems/methods with discrete alleles.~~

~~**5.5.5.2.5** The laboratory using a serology-based frequency table for HLA molecular typing results shall validate the conversion of nucleic acid allele designations to equivalent serologic types.~~

The committee elected to delete former standards 5.5.5.2.3 and 5.5.5.2.5 as both related to testing that is no longer in use in laboratories accredited by AABB. This removal is in line with other deletions through the edition.

6.4.1 Findings of No Relationship

The facility shall ~~have policies, processes and procedures~~ indicate~~ing~~ the basis on which findings of no relationship are determined. These **determinations** ~~policies, processes and procedures~~ shall identify genetic inconsistencies that may lead to a false opinion of no relationship.

The committee edited standard 6.4.1 to mirror the style, tone and language of the updated quality template by removing the clause surrounding p, p, ps.

6.4.2 Nonautosomal Findings

Nonautosomal results, when tested for parentage, ~~avuncular,~~ full siblings, half siblings, **avuncular** and/or grandparentage **relationships**, shall be incorporated with autosomal results into the combined relationship index. In addition to the combined relationship index, the laboratory shall **be permitted** ~~have the opportunity~~ to discuss autosomal and nonautosomal findings separately.

The committee edited standard 6.4.2 for clarity. The intent of the standard has not changed.

6.4.3 The laboratory shall ~~have a process to~~ ensure that relationship testing services and test

reports meet these RT Standards before distribution or delivery. Reference Standard 6.4A, Requirements for Test Reports, applies.

The committee edited standard 6.4.3 to mirror the style, tone and language of the updated quality template by removing the clause surrounding "have a process to".

6.4.4 When the facility determines the final conclusion:

1) **For large nucleotide datasets the results of the algorithm analysis shall be presented.**

2) For all others, the individual relationship index shall be reported for each **independently calculated locus or linked loci**.

The committee edited standard to ensure that the Standards are able to be expanded to allow for forensic genetic genealogy testing activities to be accredited. These additions are in line with other additions and edits made to other standards within the edition.

6.5 Promotional Materials

The laboratory shall ~~have a process to~~ ensure that its promotional materials conform to all AABB requirements. Standards 5.2.3.5 and 6.5.2 apply.

The committee edited standard 6.5 to mirror the style, tone and language of the updated quality template by removing the clause surrounding "have a process to".

Reference Standard 6.4A. Requirements for Test Reports

II. Findings	
1	**A statement as to whether the alleged relationship can be excluded.** ~~Report the phenotypes of tested individuals for all genetic systems that meet the laboratory's minimum performance thresholds, as applicable with the exception of Amelogenin, other markers used for gender determination, and linked loci, as defined in standard 5.5 (Standards 5.3.12 and 5.3.13 apply).~~

The committee edited this entry to mirror other changes made to this edition of Standards.

II. Findings	
2 If ~~there is~~ a statement of nonrelationship is rendered	**Then the report shall include the following information:** 1) **For traditional relationship testing statistics:** ~~Then~~ the **STR** loci providing the basis for the finding shall be indicated in the statement of non-relationship. ~~For large array SNP assays the number of loci tested, the number of informative loci, and the number of loci that successfully yielded a result.~~
	2) For ~~large~~ **non-traditional relationship testing statistics** the number of loci tested, the number of informative loci, if applicable, and the minimum percentage of loci that successfully yielded a result.

The committee edited this entry to mirror other changes made to this edition of Standards concerning "traditional" and "non-traditional" relationship testing statistics.

II. Findings		
3	If there is a failure to exclude and the combined relationship index meets the established reporting policies for the indices obtained for the tested relationship (Standard 5.3.9 applies).	Then the report shall include the following information **for traditional relationship testing statistics**:
		1) The phenotypes of tested individuals for all loci that meet the laboratory's minimum performance thresholds, as applicable with the exception of amelogenin, other loci used for gender determination, and linked loci, as defined in standard 5.5 (Standards 5.3.11 and 5.3.12 apply).

Subnumber 1 previously appeared as the header for number 1 of II, Findings, based on the adjustment to the table. The content and intent of the entry has not changed.

II. Findings		
3	If there is a failure to exclude and the combined relationship index meets the established reporting policies for the indices obtained for the tested relationship (Standard 5.3.9 applies).	Then the report shall include the following information **for traditional relationship testing statistics**:
		~~1)~~ **2)** The individual relationship index for each **locus or group of loci** ~~genetic system~~ used in the conclusion.

The committee edited this entry to mirror other changes made to this edition of Standards.

II. Findings		
3	If there is a failure to exclude and the combined relationship index meets the established	**Then the report shall include the following information for non-traditional relationship statistics:**

	reporting policies for the indices obtained for the tested relationship (Standard 5.3.9 applies).	

In line with the changes to differentiate between "traditional" and "non-traditional" relationship testing statics, through the division of the reference standard.

II. Findings		
3	If there is a failure to exclude and the combined relationship index meets the established reporting policies for the indices obtained for the tested relationship (Standard 5.3.9 applies).	**Then the report shall include the following information for non-traditional relationship statistics:** **1) The number of loci tested, the number of informative loci, if applicable, and the minimum percentage of loci that successfully yielded a result.** **2)** An explanation of the evaluation, the equivalency to the combined relationship index, and the statistical method(s) used. Standard 5.3.11.3 applies. **Percentage DNA match or shared centimorgans, and the statistical support for the stated match, including the probability of relationship expressed as a percentage. The prior probabilities used to calculate the probability of relationship shall be stated.** **3) When autosomal loci are not tested, the conclusion shall not overstate the relationship. An explanation on non-recombining haplotypes inheritance and limitations to these markers shall be provided.** **4) When autosomal likelihood ratios are not in agreement with non-recombining haplotypes (leading to a different conclusion) an explanation on non-autosomal inheritance and limitations to these markers shall be provided.** **5) A statement that the calculations compare the tested individual(s) to a defined population, if applicable.** **6) As appropriate, a statement that the calculations compare the tested individual to either an unrelated or related individual.**

The committee added new elements 1 – 6 to the new section on "non-traditional relationship testing statistics" of the reference standard. These additions mirror the content of entries in the "traditional relationship testing statistics" section above. The content was included for completeness.

✎ **7.2.4.2** Materials, samples, and services that are determined **to be nonconforming** after release or issue ~~to be nonconforming~~ shall be reported to the customer.

The committee edited this standard for clarity, however the intent of the standard has not changed.

8.4.1.1 Quality indicator data shall include preanalytic, analytic, and postanalytic

activities ~~captured~~.

The committee edited this standard for clarity. As previously written the standard was not clear.

~~**10.1.1** The laboratory shall define the environmental conditions that have the potential to affect the quality of critical materials, tests, products, or services provided by the facility.~~

~~**10.1.1.1**Conditions shall be monitored andcontrolled.~~

The committee deleted these standards as they were deemed redundant to standard 10.0 and 10.1.

10.1.1 The laboratory shall define, monitor, control, and record environmental conditions, as required by relevant specifications or where they may influence the quality of the results. **Standard 5.2 applies.**

10.2.1 The laboratory shall define the environmental conditions that have the potential to cause harm to staff, clients, and visitors to the facility. **Standard 5.2 applies.**

The committee added cross references to standard 5.2 for completeness. Standard 5.2 focuses on sample collection and the consent issues surrounding chain of custody cases.

Glossary

Confirmatory Testing: Repeat testing to confirm an initial test result. Confirming a test result includes an answer to an exclusion/nonexclusion question and/or the phenotype of the tested individual in particular **locus or group of loci** ~~genetic system or systems~~.

As noted above, the committee elected to replace the term "genetic system" with "locus or group of loci" for accuracy and matching the terms used in industry by AABB member laboratories. Where the term "genetic system" exists throughout the RT Standards, it has been replaced by either locus, loci or group of loci where appropriate.

Database: In the context of ~~standard 5.5.3 of~~ these RT Standards, database means the ~~frequency table that is the~~ source of the frequencies used to provide ~~calculate~~ a **statistical support** ~~likelihood ratio~~.

The committee edited the term for clarity. The edits broaden the definition to better meet the expanded reach of the proposed edition.

~~**Genetic System:** Each locus or DNA site analyzed and reported by a laboratory.~~

Independent ~~Genetic Systems~~ Locus or Group of Loci: When the inheritance of the alleles **of any loci** ~~a genetic system~~ used for testing is demonstrated, by the laboratory or by published literature, to be statistically independent from the inheritance of the alleles of any other loci used for testing.

~~**Multiple Genetic Systems:** For the purposes of these RT Standards, three or more independent genetic systems.~~

The committee deleted the term "genetic system", "multiple genetic systems" and edited the term "independent locus or group of loci" to reflect the changes made throughout this edition.

Initiate: Direct contact between the petitioner (or other involved parties) and the accredited

facility before commencing relationship testing activities.

The committee elected to provide a definition of the term initiate based on feedback from our accredited laboratories and the Department of State. This ensures that it is understood what is meant by the opening of the process to start the activities of collection and identification.

New Test Method: As opposed to a novel method, a new test method is a change to or addition of a peer-reviewed existing technology already applied in relationship testing. For example, changing from ~~RFLP-based testing to STR-based testing or~~ STR-based testing to SNP-based testing is a new test method. Changing from ~~gel-based PCR testing to capillary based PCR testing~~ **one STR kit to another STR kit** is not an example of a new test method, but an example of a new procedure.

The committee edited this definition to reflect changes made throughout the edition with regard to the removal of tests and test kits that are no longer in use in the field.

Non-Traditional Relationship Testing Statistics: Methods where the likelihood ratio, or other measure of statistical support, is calculated using formulas that do not include the frequencies of specific alleles, genotypes, or haplotypes of the tested parties. Instead, statistical support is calculated using formulas that include other parameters (e.g., shared centimorgans). These statistics are typically used for very large SNP or other nucleotide data sets.

Traditional Relationship Testing Statistics: Methods where the likelihood ratio is calculated using formulas that include the frequencies of specific alleles, genotypes, or haplotypes of the tested parties, as opposed to other parameters (e.g., shared centimorgans). These statistics are required for standard STR loci, but may also be applied to other types of loci.

The committee created new definitions for non-traditional and traditional relationship testing statistics with the expansion of the testing methods section in chapter 5 and most specifically reference standard 6.4A. The edits to the Standards are noted above.

Nucleotide Datasets: Datasets generated by nucleotide sequence determination.

Nucleotide Sequence Determination: For the purposes of these RT Standards, any method able to determine DNA sequence. Including but not limited to, whole genome sequencing, indel determination, next generation sequencing, SNPs, capillary array, CHiP, microarray analysis, and Sanger sequencing.

The committee created new definitions for nucleotide datasets and nucleotide sequence determination with the expansion of the testing methods section in standard 6.4.4. The edits to the Standards are noted above.

Promotional Materials: Marketing, education, website, and advertising materials (both printed and electronic) related to activities covered by these Standards.

The committee created a new definition of promotional materials for clarity. This was done based on requests from members who wanted to ensure that users were clear on what these are and how they can appear.

Quarantine (verb): To isolate nonconforming materials, results, or unissued reports in a clearly designated

manner or marked area so that they cannot accidentally be used in ~~a downstream process~~ **subsequent steps**.

The committee edited this definition for clarity. The new wording is simpler and more clear.

Reagent: A substance used to perform an analytical procedure. ~~A substance used (as in detecting or measuring a component or preparing a product) because of its biological or chemical activity.~~

The committee edited this definition for clarity. The committee noted that the initial sentence was sufficient a definition and the second did not provide value beyond what was stated.

Relationship Index: See "Likelihood Ratio". ~~that compares the probability of the observed types given the hypothesized biological relationship between individuals and the probability of the observed types given the alternative hypothesized relationship.~~

The committee edited this definition for clarity. The committee felt that the definition of likelihood ratio better reflected the understanding of this term.

Sample Exchange Program: A process among two or more independent organizations to **compare concordance** ~~exchange samples~~ **in the absence of a formal graded** ~~to monitor~~ proficiency.

The committee edited this definition for clarity. This new definition better represents what the term and standards require.

Sequencing: See "Nucleotide Sequence Determination".

The committee elected to add a new definition of sequencing for clarity. Pushing users to the new definition of nucleotide sequence determination will provide a full circle view of the requirement.

Technical Leader: An individual identified in a forensic laboratory **who** ~~that~~ is responsible for the technical operations of the laboratory may be qualified to serve as a laboratory director under these RT Standards. This individual must ~~meet and have been audited to all FBI quality assurance standards for forensic DNA testing laboratory technical leaders in addition to being the~~ **be the current** technical leader in a DNA testing laboratory audited to FBI Quality Assurance Standards. See Standard 1.2.4.

The committee edited this definition with input from members that have a focus in the technical leader domain.

QSE 1 – Organization

Key Concepts:
This 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 receiver 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 part thereof, that has its own functions and executive management.*

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 System: *The documented organizational structure, responsibilities, policies, processes, procedures, and resources established by leadership to achieve quality.*

Examples of Objective Evidence:

- Policies, processes and procedures related to this chapter
- Organogram 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 and copies of any required certificates
- Defined quality system
- Process for approving exceptions to policies, processes and procedures and documented examples, if applicable
- Risk assessments and mitigation strategies
- Emergency operation and disaster continuity plan(s)
- Executive management review of customer feedback

1.0 Organization

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

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 *Standards* and applicable laws and regulations, including all applicable current Good Manufacturing Practices (cGMP).
3) Authority to establish or make changes to the quality system.
4) Responsibility for compliance with these Relationship Testing (RT) Standards
5) Responsibility to conduct scheduled management reviews to assess the effectiveness of the quality system.
6) Responsibility to obtain official transcripts for laboratory directors, laboratory director designees, and laboratory supervisors.

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 (or equivalent) accredited 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.

1.1.1.1.1 In cases where the director candidate's experience is not in a laboratory accredited by AABB (or equivalent), exceptions shall be considered on a case-by-case basis by the Relationship Testing Accreditation Committee. Standard 1.1.6 applies.

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.

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.

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 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/ experience in relationship testing in an AABB (or equivalent) accredited 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.

1.1.4.1 In cases where the director candidate's experience is not in a laboratory accredited by AABB (or equivalent), exceptions shall be considered on a case-by-case basis by the Relationship Testing Accreditation Committee. Standard 1.1.6 applies.

1.1.5 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.

1.1.6 Staffing Changes

The laboratory shall communicate to 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.

1.2 Quality System

The organization shall have a quality system. The organization's executive management shall ensure that this quality system is implemented and followed at all levels of the organization.

1.2.1 Quality Representative

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

1.2.1.1 The quality representative shall have relevant training and experience.

1.2.2 Management Reviews

Management shall assess the effectiveness of the quality system at defined intervals.

1.3 Policies, Processes, and Procedures

Policies, processes, and procedures shall be implemented and maintained to satisfy the applicable requirements of these *Standards*.

1.3.1 The medical director and/or laboratory director (as applicable to these *Standards*) shall approve all medical and technical policies, processes, and procedures.

1.3.2 Any exceptions to medical and technical policies, processes, and procedures shall require justification and preapproval by the medical director and/or laboratory director, as applicable.

1.4 Assessment of Risk

The facility shall have a process in place to perform risk assessments for activities at defined intervals. Standards 5.1.1 and 6.1.5 apply.

1.4.1 Mitigation strategies shall identify, assess, and address the level of risk associated with quality and safety.

1.5 Operational Continuity

The organization shall address continuity in the event that operations are at risk.

1.6 Emergency Preparedness

The organization shall have emergency operation plan(s) to respond to the effects of internal and external disasters.

1.6.1 The emergency management plan, including emergency communication systems, shall be tested at defined intervals.

1.7 Communication of Concerns

The organization shall have a process for personnel to anonymously communicate concerns about quality or safety. Personnel shall be given the option to communicate such concerns either to their organization's executive management, AABB, or both. AABB's contact information shall be readily available to all personnel.

1.8 Customer Focus

Executive management shall identify the organization's customers and their needs and expectations for products or services.

Standard	Record to be Maintained	Minimum Retention Time (Years)[1]
1.1.1, 1.1.1.1	Official transcripts for laboratory director, laboratory director designee, and laboratory supervisor.	5
1.1.2.1	Laboratory director responsibility for policies, processes, and procedures.	5
1.1.4	Technical leader qualifications and experience.	5
1.1.5	Supervisor qualifications and experience.	5
1.1.6	Laboratory director, laboratory director designee(s), laboratory supervisor(s), and/or quality representative change notification within 30 days.	5
1.2.1.1	Quality representative training and experience.	5
1.2.2	Management review of effectiveness of the quality system	5
1.3	Policies, processes, and procedures	10
1.3.2	Exceptions to policies, processes, and procedures	10
1.4	Risk Assessment	5
1.6.1	Emergency operation plan tested at defined intervals	2 years, or two organizational testing intervals (whichever is longer)

[1]Applicable state or local law may exceed this period.

QSE 2 – Resources

Key Concepts: This QSE describes the need for resources – human, financial and otherwise – to support the work performed. It also describes personnel issues such as the qualification of staff, assessments of competence (including those performed under CLIA), and continuing education requirements.

Key Terms:
Competence: *An individual's demonstrated ability to apply knowledge and skills needed to perform their job tasks and responsibilities at defined intervals.*

Qualification (individuals): *The aspects of an individual's education, training, and experience that are necessary for the individual to successfully meet the requirements of a position.*

Examples of Objective Evidence:

- Policies, processes and procedures related to this chapter
- Current job descriptions
- Evaluation of staffing levels and workload, if performed
- Process for recruiting and hiring
- Personnel records (e.g., certifications, qualifications, competence assessments, diplomas, transcripts)
- Training records
- Evaluations of competence records
- Evidence that job qualifications are met
- Continuing education records

2.0 Resources

The organization shall have adequate resources to perform, verify, and manage all the activities described in these *Standards*.

2.1 Human Resources

The organization shall employ an adequate number of individuals qualified by education, training, and/or experience.

2.1.1 Job Descriptions

The organization shall establish and maintain job descriptions defining the roles and responsibilities for each job position related to the requirements of these *Standards*.

2.1.2 Qualification

Personnel performing critical tasks shall be qualified to perform assigned activities on the basis of appropriate education, training, and/or experience in compliance with applicable laws and regulations.

2.1.3 Training

The organization shall provide training for personnel performing critical tasks.

2.1.3.1 All personnel shall be trained in the application of the quality system.

2.1.4 Competence

Evaluations of competence shall be performed before independent performance of assigned activities and at specified intervals.

2.1.4.1 Action shall be taken when competence has not been demonstrated.

2.1.4.2 Assessment of a specific task shall include the following when applicable:

1) Task outcomes using blinded testing materials.
2) Task execution for all applicable methods using direct observation.
3) Performance of calculations, or review of specific testing outcomes.

2.1.4.2.1 Evaluations of competence shall be performed annually for personnel performing specific critical tasks.

2.1.5 Personnel Records

Personnel records for each employee shall be maintained.

2.1.5.1 For those authorized to perform or review critical tasks, records of names, signatures, initials or identification codes, and inclusive dates of employment shall be maintained.

2.1.6 Continuing Education

The organization shall ensure that continuing education requirements applicable to these *Standards* are met when applicable.

2.1.6.1 Employees performing and/or reviewing specific testing methods or

calculations as defined by Standards 5.3, 5.4 and 5.5 shall participate in a minimum of 12 hours of relevant continuing education on an annual basis. The laboratory director shall define the continuing education needs of these personnel.

2.2 Laboratory Director Oversight

The laboratory director shall oversee a maximum of 10 accredited facilities. No more than 5 of these facilities shall be testing laboratories and the remaining may be collection/verification facilities.

2.2.1 The DNA technical leader acting as the laboratory director under these RT Standards shall oversee only those facilities that are a part of the forensic laboratory's system.

Standard	Record to be Maintained	Minimum Retention Time (Years)[1]
2.1.1	Job descriptions	5
2.1.2	Qualification of personnel performing critical tasks	5
2.1.3	Training records of personnel	5
2.1.4	Evaluations of competence	5
2.1.5	Personnel records of each employee	5 years following conclusion of employment period
2.1.5.1	Records of names, signatures, initials or identification codes, and inclusive dates of employment for personnel who perform or review critical tasks	10
2.1.6	Continuing education requirements	5

[1]Applicable state or local law may exceed this period.

QSE 3 – Equipment

Key Concepts: This QSE describes the selection, use, maintenance, and monitoring of equipment, including IT systems. It also describes the use and testing of alternative systems when primary systems fail.

Key Terms:

Backup: *Digital data and/or physical storage containing copies of relevant data.*

Calibrate: *To set or align measurement equipment against a known standard.*

Corrective Action: *Actions taken to address the root cause(s) of an existing nonconformance or other undesirable situation in order to reduce or eliminate recurrence.*

Critical Equipment/Materials: *A piece of equipment or material that can affect the quality of the organization's products.*

Data Integrity: *The accuracy, completeness and consistency of information resources*

Equipment: *A durable item, instrument, or device used in a process or procedure.*

Installation Qualification: *Verification that the correct equipment is received and that it is installed according to specifications and manufacturer's recommendations in an environment suitable for its operation and use.*

Operational Qualification*: Verification that equipment will function according to the operational specifications provided by the manufacturer.*

Performance Qualification: *Verification that equipment performs consistently as expected for its intended use in the organization's environment, using the organization's procedures and supplies.*

Validation: *Establishing evidence that a process, executed by users in their environment, will consistently meet predetermined specifications.*

Verification: *Confirmation by examination and provision of objective evidence that specified requirements have been met.*

Examples of Objective Evidence:

- Policies, processes and procedures related to this chapter
- Processes for equipment selection, qualification, and maintenance
- List or tool used for critical equipment identification
- Equipment calibration and maintenance records, if applicable
- Equipment qualification records
- Manufacturer's written instructions
- Records of investigation of equipment, malfunction, failure, repair and requalification, if applicable
- Alarm system testing and records of alarm management, if appropriate
- Evidence of information system backup and records of testing

3.0 Equipment

The organization shall define and control critical equipment.

3.1 Equipment Specifications

Equipment specifications shall be defined before purchase.

✎3.2 Qualification of Equipment

All critical equipment shall be qualified for its intended use. Equipment shall be requalified, as needed, after repairs and upgrades.

3.2.1 Installation Qualification

Equipment shall be installed per manufacturer's specifications.

3.2.2 Operational Qualification

Each piece of equipment and component of an information system shall be verified before actual use.

3.2.3 Performance Qualification

Equipment shall perform as expected for its intended use.

3.2.3.1 Performance specifications established by the manufacturer shall be met.

3.3 Use of Equipment

Equipment shall be used in accordance with the manufacturer's written instructions.

✎3.4 Unique Identification of Equipment

Equipment shall have unique identification.

3.5 Equipment Monitoring and Maintenance

Equipment shall be monitored and maintained in accordance with manufacturer's written instructions.

✎ 3.5.1 Calibration and Accuracy of Equipment

Calibrations and/or adjustments shall be performed using equipment and materials that have adequate accuracy and precision. At a minimum, calibrations and/or adjustments shall be confirmed as described below unless otherwise indicated by the manufacturer:

1) Before use.
2) After activities that may affect the calibration.
3) At prescribed intervals.

3.5.1.1 Calibration of equipment shall include details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria, and specified limitations.

3.5.1.2 Equipment used for calibration, inspection, measuring, and testing shall be certified to meet nationally recognized measurement standards. Certification shall occur before initial use, after repair, and at prescribed intervals. Where no such measurement standards exist, the basis for calibration shall be described and recorded.

3.5.1.3 Equipment shall be safeguarded from adjustments that would invalidate the calibration setting.

3.5.1.4 If the manufacturer's written instructions are not followed, the equipment shall be calibrated using the laboratory's validated procedures for the intended use.

✎ **3.5.2** When equipment is found to be out of calibration or specification, the validity of previous inspection and test results and the conformance of potential affected products or services, including those that have already been released or delivered shall be verified.

✎ **3.5.3** The organization shall:

1) Define cleaning and sanitization methods and intervals for equipment.
2) Ensure that environmental conditions are suitable for the operations, calibrations, inspections, measurements, and tests carried out.
3) Remove equipment from service that is malfunctioning/out of service and communicate to appropriate personnel.
4) Monitor equipment to ensure that defined parameters are maintained.
5) Ensure that the handling, maintenance, and storage of equipment are such that the equipment remains fit for use.
6) Ensure that all equipment maintenance and repairs are performed by qualified individuals and in accordance with manufacturer's recommendations.

3.5.4 Investigation and Follow-up

Investigation and follow-up of equipment malfunctions, failures, or adverse events shall include:

1) Assessment of products or services provided since the equipment was last known to be functioning per manufacturer's written instructions, or organization defined specifications.
2) Assessment of the effect on the safety of individuals affected.
3) Removal of equipment from service, if indicated.
4) Investigation of the malfunction, failure, or adverse event, and a determination if other equipment is similarly impacted, as applicable.
5) Requalification of the equipment.
6) Reporting the nature of the malfunction, failure, or adverse event to the manufacturer, when indicated.

✎ **3.6 Equipment Traceability**

The organization shall maintain records of equipment use in a manner that permits:

1) Equipment to be uniquely identified and traceable.

2) Tracing of any given product or service to all equipment associated with the procurement, processing, storage, distribution, and administration of the product or service.

3.7 Information Systems

The organization shall have controls in place for the implementation, use, ongoing support and modifications of information system software, hardware, and databases. Elements of planning and ongoing control shall include:

1) Numerical designation of system versions with inclusive dates of use.
2) Validation/verification/qualification of system software, hardware, databases, and user-defined tables prior to implementation.
3) Fulfillment of life-cycle requirements for internally developed software.
4) Defined processes for system operation and maintenance.
5) Defined process for authorizing and documenting modifications to the system.
6) System security to prevent unauthorized access.
7) Policies, processes, and procedures and other instructional documents developed using terminology that is understandable to the user.
8) Functionality that allows for display and verification of data before final acceptance of the additions or alterations.
9) Defined process for monitoring of data integrity for critical data elements.
10) System design that establishes and maintains unique identity of donor, product or service, and recipient (as applicable).
11) Training and competency of personnel who use information systems.
12) Procedures to ensure confidentiality of protected information.

3.7.1 Alternative Systems

An alternate system shall be maintained to ensure continuous operation in the event that computerized data and computer-assisted functions are unavailable. The alternate system shall be tested at defined intervals. Processes and procedures shall address mitigation of the effects of disasters and include recovery plans.

3.7.2 Personnel responsible for management of information systems shall be responsible for compliance with the regulations that affect their use.

3.7.3 The organization shall support the management of information systems.

3.7.4 A system designed to prevent unauthorized access to information systems and electronic records shall be in place.

3.7.5 The organization shall have measures in place to minimize the risk of an internal and external data breach.

Standard	Record to be Maintained	Minimum Retention Time (Years)[1]
3.2	Equipment qualification	10 years after retirement of the equipment
3.4	Unique identification of equipment	5
3.5.1	Equipment calibration activities	5
3.5.2	Equipment found to be out of calibration	5
3.5.3	Equipment monitoring, maintenance, calibration, and repair	5
3.6	Equipment traceability	5
3.7	Implementation and modification of software, hardware, or databases	2 years after retirement of system

[1]Applicable state or local law may exceed this period.

QSE 4 – Suppliers and Customers

Key Concepts: This QSE describes the need for agreements between the organization and its customers and suppliers. The agreements define expectations between both parties and measures taken when one entity fails to meet the expectations of an agreement.

Key Terms:

Agreement: *A contract, order, or understanding between two or more parties, such as between an organization and one of its customers.*

Agreement Review: *Systematic activities carried out before finalizing the agreement to ensure that requirements are adequately defined, free from ambiguity, documented, and achievable.*

Customer: *The receiver 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.*

Initiate: *Direct contact between the petitioner (or other involved parties) and the accredited facility before commencing relationship testing activities.*

Promotional Materials*: Marketing, education, website, and advertising materials (both printed and electronic) related to activities covered by these Standards.*

Qualification (materials): *For materials that come into contact with the product, verification that the materials are sterile, the appropriate grade and suitability for the intended use and, whenever possible, approved for human use by the United States Food and Drug Administration (FDA) or relevant Competent Authority.*

Quality: *Characteristics of a product or service that bear on its ability to fulfill customer expectations. The measurable or verifiable aspects of a product or service that can be used to determine if requirements have been met.*

Quality Control: *Testing routinely performed on materials and equipment to ensure their proper function.*

Supplier: *An entity that provides a material, product, or service.*

Supplier Qualification: *Evaluation of a supplier to assess its ability to consistently deliver products or services that meet specified requirements.*

Examples of Objective Evidence:

- Policies, processes and procedures related to this chapter
- Processes for defining and updating or changing agreements
- Process for recording verbal agreements, if practiced
- Agreement records
- Agreement review records
- Supplier qualification records
- Supplier evaluation records
- Supplier selection process

- Evidence of action taken when supplier fails to meet expectations, if applicable
- Evidence of receipt of product(s) as stipulated in agreements
- Records of inspection and testing

4.0 Suppliers and Customers

The organization shall ensure that agreements to provide or receive products or services are reviewed and approved and meet supplier and customer expectations.

4.1 Supplier Qualification

The organization shall evaluate the ability of suppliers of critical materials, equipment, and services to meet specified requirements.

4.1.1 The organization shall evaluate and participate in the selection of suppliers. If executive management is not included in the selection process, there shall be a mechanism to provide feedback to management with contracting authority.

4.1.2 When a supplier fails to meet specified requirements, it shall be reported to the management with contracting authority.

4.1.3 The laboratory director or a designated representative shall participate in the ongoing evaluation of suppliers.

4.1.5 Laboratory testing and other services required by these RT Standards shall be performed in a laboratory accredited by the AABB or equivalent accrediting body.

4.1.4.1 When another laboratory provides genetic test results, that laboratory shall be accredited by the AABB or equivalent, accrediting body for that activity. Reference Standard 6.4A, Requirements for Test Reports, I.7 applies.

4.2 Agreements

Agreements and any incorporated changes shall be reviewed and communicated.

4.2.1 Agreements shall be reviewed at defined intervals to ensure that the terms of agreement continue to meet requirements.

4.2.2 Changes to agreements shall be communicated to affected parties.

4.2.3 The responsibilities for activities covered by these *Standards* when more than one organization is involved shall be specified by agreement.

4.2.3.1 There shall be written agreements between laboratories and third-party administrators that define the following:

1) Collection requirements.
2) Responsibility for the testing process.
3) Reporting of test results.
4) Appropriate marketing materials and claims.
5) Use of the laboratory's name and accreditation status.
6) Unless accredited for collection or verification activities by AABB, third-party administrators are prohibited from initiating cases for United States of America immigration, visa, passport, and citizenship testing.

Standards 5.2.3.5, 6.5.4, and 6.5.5 apply.

✎4.3 Incoming Receipt, Inspection, and Testing

Incoming products or services, equipment and materials shall be received, inspected, and tested, as necessary, before approval for use.

4.3.1 Results shall not be released before quality approval of new lots and shipments.

4.3.1.1 The laboratory shall ensure that:

1) Each lot shall be tested.
2) Each shipment, regardless of lot, shall be tested.
3) Each lot within a shipment shall be tested.

4.3.1.2 Criteria for acceptance and rejection of the inspection and testing shall be established.

4.4 Supplier Evaluation

The laboratory director or a designated representative shall evaluate at defined intervals whether suppliers have met agreed-upon requirements and take appropriate follow-up action.

4.4.1 Review of Supplier Promotional Material

The laboratory shall review promotional materials of contracted third party administrators at defined intervals to ensure that the information complies with these RT Standards.

4.4.1.1 When a supplier fails to meet specified requirements, the laboratory director or a designated representative shall take appropriate action and report it to the facility's purchasing authority. Standard 7.0 applies.

✎4.5 Management of Supplies and Materials

The laboratory director or a designated representative shall ensure that laboratory processes address the availability, control, storage, handling, and transportation of critical supplies and reagents.

4.6 Traceability

Critical supplies and samples shall be traceable to the finished product and/or service.

4.6.1 The facility shall evaluate and respond to possible altered or fabricated documents.

Standard	Record to be Maintained	Minimum Retention Time (Years)[1]
4.1	Evaluation and participation in selection of suppliers	5
4.2	Agreements	5
4.2.1	Agreement review	5
4.2.3	Agreements concerning activities involving more than one organization	5
4.3	Inspection of incoming critical materials	10
4.5	Quality control of critical supplies and reagents	5

[1]Applicable state or local law may exceed this period.

QSE 5 – Process Control

Key Concepts: This QSE covers the organization's operations and production functions. It describes the need to ensure that this work is controlled, that processes function as expected, and that expected outcomes are met. This QSE encapsulates what occurs in each organization and forms the basis of their accreditation.

Key Terms:

Change Control: *A structured method of revising a policy, process, or procedure, including hardware or software design, transition planning, and revisions to all related documents.*

Critical Equipment/Materials/Tasks: *A piece of equipment, material, service, or task that can affect the quality of the organization's products.*

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.*

Process Control: *Activities designed to ensure that processes are stable and consistently operate within acceptable limits of variation in order to produce predictable output that meets specifications.*

Product: *A tangible output from a process.*

Reference Standard: *Specified requirements defined by the AABB. Reference standards define how or within what parameters an activity shall be performed and are more detailed than quality system requirements.*

Service: *An intangible output of a process.*

Standard: *A set of specified requirements upon which an organization may base its criteria for the products, components, and/or services provided.*

Validation: *Establishing evidence that a process, executed by users in their environment, will consistently meet predetermined specifications.*

Verification: *Confirmation by examination and provision of objective evidence that specified requirements have been met.*

Examples of Objective Evidence:

- Policies, processes and procedures related to this chapter
- Implementation records
- Records enabling traceability
- Storage records
- Quality control records
- Process planning, process validation and change control records
- Records of material storage, handling and use
- Records of inspection of materials
- Product inspection records
- Testing records

5.0 Process Control

The organization shall ensure the quality of products or services.

5.1 General Elements

The organization shall ensure that processes are carried out under controlled conditions.

5.1.1 Change Control

When the organization develops new processes or procedures or changes existing ones, they shall be validated before implementation.

5.1.1.1 The laboratory shall ensure that the implementation of new or changed processes is controlled. Laboratory employees shall be trained in the new or changed process(es) or procedure(s). Standard 2.1.3 applies.

5.1.2 Quality Control

A program of quality control shall be established that is sufficiently comprehensive to ensure that products, equipment, materials, and analytical functions perform as intended.

5.1.2.1 Quality control results shall be reviewed and evaluated against acceptance criteria.

5.1.2.2 Quality control failures shall be investigated before release of test results, products or services.

5.1.2.3 The validity of test results and methods and the acceptability of products or services provided shall be evaluated when quality control failures occur.

5.1.2.3.1 Results shall be reviewed and corrective and preventive action taken, where appropriate.

5.1.3 Process Planning

Quality requirements shall be incorporated into new or changed processes, products or services, and novel methods. Planning and implementation activities shall include the following:

1) Evaluation of accreditation, regulatory, and legal requirements related to the new or changed process, product or service.
2) Review of current available knowledge (e.g., review of medical practice and/or literature).
3) Evaluation of risk.
4) Identification of affected internal and external parties and mechanism to communicate relevant information.
5) Identification of performance measures applicable to the new or changed process, product or service.
6) Evaluation of resource requirements.
7) Evaluation of the impact of the new or changed process, product or service on other organization (or program) processes.

8) Evaluation of the need to create or revise documents for the new or changed process, product or service.
9) Review and approval of the output of process development and design activities (eg, pilot or scale-up study results, process flow charts, procedures, data forms).
10) Evaluation of the extent and scope of process validation or re-validation depending on the level of risk and impact of the new or changed products or services.

5.1.4 Process Validation

Before implementation, the new or changed processes and procedures shall be validated.

5.1.4.1 Validation activities shall include the following:

1) Identification of objectives, individual(s) responsible, expected outcomes, and/or performance measures.
2) Criteria for review of outcomes.
3) Approval of validation plan.
4) Review and approval of actual results.
5) Actions to be taken if objectives are not met.

5.1.5 Process Implementation

The implementation of new or changed processes and procedures shall be planned and controlled.

5.1.5.1 Postimplementation evaluations of new or changed processes and procedures shall be performed.

5.1.6 Use of Materials

All materials shall be stored and used in accordance with the manufacturer's written instructions and shall meet specified requirements.

5.1.7 Inspection

The **organization** shall ensure that products or services are inspected at organization-defined stages.

5.1.8 Identification and Traceability

The organization shall ensure that all products or services are identified and traceable.

5.1.9 Handling, Storage, and Transportation

The organization shall ensure that products or services are handled, stored, and transported in a manner that prevents damage, limits deterioration, and provides traceability.

5.1.10 Proficiency Testing Program

The laboratory shall participate in a proficiency testing program for each locus or group of loci used for reporting test results. Standard 7.2.5 applies.

5.1.10.1 A laboratory seeking initial accreditation shall participate in either one of the following:

1) A proficiency testing program for 2 years with successful results.
2) An exchange of at least 12 blinded cases representative of the casework the laboratory proposes to perform with an accredited relationship testing laboratory and demonstrate concordant results.

5.1.10.2 The laboratory shall participate in graded proficiency testing for the assignment of phenotypes and the assessment of relationships.

5.1.10.3 When a formal graded external proficiency testing program is available for one or more of the loci used to report test results, the laboratory shall participate three times a year for each locus analyzed in the laboratory.

5.1.10.4 When no formal graded external proficiency testing program is available for any of the loci used to report test results, the laboratory shall use one of the following methods:

1) Test on a monthly basis known samples that were originally tested when graded proficiency testing was available.
2) Test on a monthly basis a standard trio of samples developed from persons of an undisputed relationship.
3) Participate three times a year in a sample exchange program.

Standard 5.1.11.1 applies

5.1.10.5 When formal graded proficiency testing programs are available for some but not all loci, the laboratory shall test the loci not evaluated by a formal proficiency testing program using one of the following methods:

1) Test on a monthly basis known samples that were originally tested when graded proficiency testing was available.
2) Test on a monthly basis a standard trio of samples developed from persons of an undisputed relationship.
3) Participate three times a year in a sample exchange program.

5.1.10.6 Proficiency testing, whether graded or not graded, shall be representative of the cases the laboratory performs, including standard trios, single parent, and family studies (reconstruction cases).

5.1.11 Sample Retention

If available, an adequate sample of remaining biological materials obtained from a tested individual shall be stored for a minimum of 6 months after the completion of testing for the purpose of additional testing, if required.

5.1.11.1 If proficiency testing is not available for all of the loci relied upon to report test results, the samples tested, if available, shall be stored for as long as records are maintained. Standards 5.1.10.4 and 6.2.1 apply.

5.1.12 Privacy and Confidentiality

The laboratory shall have a policy to ensure that the relationship testing process is private and confidential.

5.1.12.1 The laboratory shall release test results, samples, or profiles only for purposes relevant to the relationship testing for a specific case. Otherwise, a court order or the written authorization of the individual(s) tested or the individual(s) with legal authority to provide consent is required. Standard 3.7.4 applies.

5.2 Sample Collection for Chain-of-Custody Cases

The laboratory shall ensure:

5.2.1 Consent

Before sample collection, consent shall be obtained according to applicable law from each tested person, or, in the case of a minor child or legally incompetent adult, from either an individual with legal authority to provide consent or a tribunal with legal authority to order testing.

5.2.2 Collection

All collections of samples shall be performed or witnessed by a competent person with no interest in the test outcome.

5.2.2.1 Collection materials shall only be sent directly to collectors and/or witnesses. Collection materials shall not be in the possession of any of the tested parties either before or after collection.

5.2.2.2 Collection methods shall protect the safety of the person from whom the sample is taken, preclude contamination, and maintain integrity of the sample.

5.2.2.3 The laboratory shall ensure that the individuals who perform collections are trained. Standard 2.1.3 applies.

5.2.2.4 Samples intended for immigration, visa, passport, and citizenship testing cases for the United States of America shall be transported directly from the place of collection to the testing laboratory.

5.2.3 Verification of Sample Collection and Documentation

The person collecting the sample and/or verifying the process shall confirm that the following conditions exist:

1) The identification of the tested person is accurate and the stated relationship is recorded.
2) Consent was obtained as stated in Standard 5.2.1.
3) The sample was collected from the intended person.
4) The label is accurate.
5) The sample is packaged in a tamper-evident manner.

5.2.3.1 Each sample shall bear an affixed label which includes the following information:

1) A unique identification for each sample collected.
2) Date of collection.
3) Initials or signature of the person collecting the sample.
4) The label shall not be obscured or removed.

5.2.3.2 The accuracy of the affixed label shall be verified in writing by the person whose sample is collected or by the individual with legal authority accompanying a minor or legally incompetent adult.

5.2.3.3 Test participants shall not package or transfer samples. Standard 5.2.2 applies.

5.2.3.4 Upon receipt of a sample, the laboratory shall verify package integrity.

5.2.3.5 Samples intended for immigration, visa, passport, and citizenship testing cases for the United States of America shall be accepted only if the case is initiated directly between the petitioner and a facility accredited by AABB for relationship testing activities. Records of the initiation of this service by the petitioner shall be maintained in the facility's records. Standard 4.6 applies.

5.2.3.6 The laboratory shall identify and clearly indicate on the final report whether it is a chain-of-custody or non-chain-of-custody case. Standard 4.6 applies.

5.2.4 Identification Records

The following records relating to each sample collected shall be acquired and maintained, including but not limited to:

5.2.4.1 Printed name, alleged relationship, and date of birth of each individual tested.

5.2.4.1.1 Printed name and relationship of an untested person(s) signing consent for a minor child or legally incompetent adult.

5.2.4.2 Race/ethnic background of all the tested parties, with the exception of a child in parentage cases.

5.2.4.3 Place, date, and type of sample collected.

5.2.4.4 Printed name, signature, and contact information of the person collecting the sample and/or witnessing the sample collection.

5.2.4.5 Printed name, signature, and contact information of the person verifying the collection process, if different from the person collecting the sample.

5.2.4.6 A history of transfusion in the preceding 3 months, or any history of allogeneic hematopoietic progenitor cell transplantation.

5.2.4.7 Original or legible photocopies of at least one of the following items for each individual tested and untested person(s) signing consent for a minor child or legally incompetent adult:
1) Valid government-issued photo identification (ID).
2) Photograph that is suitable for positive identification.

5.2.4.7.1 For cases intended for immigration, visa, passport, and citizenship for the United States of America, the following shall be submitted:

1) For an adult being tested, a legible copy of the government-issued photo ID and a photo suitable for positive ID.
2) For a child being tested, a copy of the government-issued photo ID or the birth certificate and a photo suitable for positive ID.

If these are not available, the collector shall record the reason for the absence of documentation.

5.2.4.8 Name of the person receiving the sample in the laboratory, date of receipt, and documentation of shipment receipt.

5.2.5 Special Circumstances
In circumstances (e.g., prenatal sample, coroner's sample, or samples provided by law enforcement agencies) where the sample cannot be obtained according to Standards 5.2 through 5.2.4.7, documentation of chain of custody shall be obtained.

5.3 Testing and Results

5.3.1 Autosomal loci shall be used to evaluate a relationship unless one of the following conditions exists:

1) Results for autosomal loci are not obtained.
2) Results for nonautosomal markers exclude the relationship.
3) Autosomal markers are not expected to be informative because the hypothesized relationship is beyond second order.

5.3.2 When autosomal markers are tested, a minimum of 8 independent loci shall be attempted.

5.3.3 When autosomal markers are reported, multiple loci shall be the basis for the laboratory's findings.

5.3.4 The laboratory shall use validated loci.

5.3.5 The laboratory shall use loci with chromosomal locations that are recorded in the scientific literature.

5.3.6 This group of tests shall, with rare exceptions, provide a nonexcluded alleged parent with a likelihood ratio of at least 100 to 1. Likelihood ratios of 100 to 1 or greater shall be considered genetic evidence supporting the alleged parental relationship.

5.3.7 For laboratories performing two-party tests to determine full sibling, half sibling, avuncular, or single grandparentage relationships, the following standards apply:

5.3.7.1 Likelihood ratios greater than 10 to 1 shall be considered genetic evidence supporting the alleged relationship.

5.3.7.2 Likelihood ratios from 0.1 to 1 through 10 to 1 shall be considered inconclusive for the alleged relationship. When reporting inconclusive results, the laboratory shall have attempted a minimum of 20 autosomal short tandem repeat (STR) loci.

5.3.7.3 Likelihood ratios less than 0.1 to 1 shall be considered genetic evidence against the alleged relationship and supporting the alternative.

5.3.7.4 The laboratory shall report an estimate of the percentage of individuals of known relationship that may have a combined likelihood ratio that is inconclusive, supportive of the tested relationship, or supportive of the alternative for the laboratory's test protocol at the combined likelihood ratio threshold or the reported value.

Reference Standard 6.4A, II, #3, (5, and 8) applies.

5.3.8 With relationship testing other than parentage and relationships described in Standard 5.3.7, the laboratory shall establish reporting policies for the indices obtained.

5.3.9 When using non traditional relationship testing statistics, the laboratory shall provide an explanation of the evaluation, the equivalency to the combined relationship index of 100, and the statistical method(s) used. Standard 5.3.11.3 applies.

5.3.10 Before releasing any report excluding a biological relationship:

5.3.10.1 The phenotype of an excluded alleged parent(s) shall be confirmed with an independent isolation (DNA extraction), and in cases without a known parent, the child's phenotype shall also be confirmed with an independent isolation. Laboratories shall validate and define confirmation parameters for single nucleotide polymorphism (SNP) testing. For closed systems, Standard 5.4.2 applies.

5.3.10.2 For nonparentage cases where the genetic evidence does not support the alleged relationship, either by exclusions or a low likelihood ratio, phenotypes for parties in question shall be confirmed with an independent isolation. For closed systems, Standard 5.4.2 applies.

5.3.11 A standard method of nomenclature for describing phenotypes in each locus shall be used.

5.3.11.1 For any apparent homozygote, only the observed phenotype shall be listed.

5.3.11.2 For mitochondrial DNA, the laboratory shall report the position of all nucleotide differences in comparison to the revised Cambridge Reference Sequence and the portion of the mitochondrial genome evaluated (eg, HVI, HVII, or HVIII).

5.3.11.3 When SNP assays use more than 100 loci, the laboratory shall report the number of SNPs used in each specific report. The laboratory shall keep records of all SNP loci and data utilized in the calculation of the relationship probability and provide them to the client upon request.

5.3.12 Minimum performance thresholds shall be defined and monitored for reliability, acceptability, and accuracy on a scheduled basis.

5.3.13 The laboratory director shall ensure that:

5.3.13.1 Before the laboratory changes a process or procedure for an existing test method or adds a new process or procedure, it shall be validated.

5.3.13.2 For new or novel test methods, part of the validation process shall require the analysis of at least 20 biological test samples, with accuracy and reproducibility of test results within the laboratory and between the laboratory and other laboratories. The complete validation process shall identify thresholds and acceptability criteria (eg, measurements, metrics) and include the evaluations of persons whose phenotypes are unknown, but whose relationships are well established. Standard 5.3.13.3 applies. Validation studies shall be reviewed and accepted by the Relationship Testing Standards Committee (RT SC) of the AABB before implementation.

5.3.13.3 For new multiplex kits or loci (or locus) added to existing test methods, the validation process shall require the analysis of at least 20 biological test samples, with accuracy and reproducibility of test results within the laboratory. If the laboratory establishes its own frequency database for the loci (or locus), the power of exclusion shall be determined and compared with published values, if available, as part of the validation process.

5.3.14 All test results shall be reviewed by two people, one of whom shall be the laboratory director or director designee. At a minimum, this review shall include critical test results, critical calculations, and worksheets that record interpretations and conclusions.

5.3.15 If the test battery in a case employs only methods or loci that are not used by other laboratories, the laboratory shall store samples for a minimum of 5 years in such a manner as to allow for confirmatory testing.

5.4 Specific Testing Methods

Specific testing methods shall ensure that accurate results are produced. Appropriate test controls shall be incorporated into the testing processes to ensure accurate results.

5.4.1 DNA Polymorphism Testing

The laboratory shall use validated DNA testing. The laboratory shall demonstrate reproducibility of test results.

1) For systems dependent on accurate measurement of allele sizes, a human DNA control of known phenotype shall be tested with each analysis.
2) Appropriate stringency conditions shall be used to ensure accurate allele determination.
3) For closed systems, the reproducibility studies shall be a part of the acceptance process. Standard 4.3 applies.

5.4.1.1 Short Tandem Repeat (STR) and Other Fragment Analysis

When fragment analysis is performed, the process shall include the following requirements:

1) Unless an expert system is used, all electropherogram or gel results shall be interpreted twice, independently. Phenotypes that are manually determined shall be read twice independently. Standard 5.3.14 applies.

2) When an expert system is used to interpret allele determinations, results that contain no artifacts that require human review may be interpreted solely by the expert system. Results containing artifacts that are flagged by the system should be interpreted by at least one human reviewer. If the reviewer makes a change to an allele determination, that change shall be confirmed by a second human reviewer.

3) The conditions for amplification, and detection shall be defined and controlled to ensure accurate allele determination.

4) When electrophoresis is used, ladders composed of discrete fragments of known size or tandem repeat number shall encompass the range of allele sizes routinely detected at the locus in question. Flanking size markers shall be used with sufficient frequency to accurately determine allele size.

5) STR alleles shall be identified by repeat number as adopted by the International Society of Forensic Genetics.

6) Negative control(s) shall be processed with samples from extraction through analysis to monitor for sample contamination. For closed systems, this shall be part of the acceptance process. Standard 4.5 applies.

7) The laboratory shall have policies and procedures to evaluate contamination, artifacts, and preferential amplification for each sample.

8) Post-amplification products shall be prevented from contaminating pre-amplification materials.

5.4.1.2 Nucleotide Sequence Determination or SNP Analysis

When sequence or SNP analysis is performed, the requirements shall include:

1) When an expert system is used to interpret the SNPs, results containing quality flags shall be interpreted by at least one human reviewer. If the reviewer makes a change, the change shall be confirmed by a second human reviewer.

2) When an expert system is used to interpret the SNPs, all phenotypes that pass the established and validated criteria may be interpreted solely by the expert system. Allele determinations that do not pass criteria shall not be used in the final relationship calculations.

3) When using a computer algorithm(s) to evaluate a large number of loci (see Standard 5.3.11.3 a single interpretation is acceptable

4) The conditions for amplification, hybridization, control probes, control primers, and detection as applicable, shall be defined and controlled to ensure accurate allele or sequence determination.

5) DNA sequence data shall be confirmed by sequence analysis of both strands of nucleic acid.

6) Negative control(s) shall be extracted with samples and used to monitor for sample contamination and product contamination.

8) Post-amplification products shall be prevented from contaminating pre-amplification materials.

5.4.2 Closed Systems

A laboratory performing DNA testing using a closed system, shall:

5.4.2.1 Identify profile anomalies that may affect the result.

5.4.2.2 Confirm the placement of the sample in the specified location on the instrument through a visual check with a witness or electronic equivalent.

5.4.2.3 Test a confirmatory sample(s) in cases where there is a finding of no relationship if:

1) The sample is flagged for review by the closed system, and a human review was not conducted or a human review confirms the flagged loci are found to affect the results of the relationship findings or
2) The closed system fails and the sample is manually manipulated.

5.5 Calculations

The laboratory shall use validated calculation methods.

5.5.1 The results from loci exhibiting significant linkage disequilibrium shall not be used independently in calculating traditional relationship testing statistics.

5.5.2 When linked loci are used for calculating traditional relationship testing statistics, the laboratory shall estimate and minimize the effects of linkage on non-parentage cases.

5.5.3 Manual calculations and computer-assisted calculations shall be reviewed by the laboratory director or a director designee before serving as the basis for a final report.

5.5.4 If only manual calculations are performed, they shall be performed by two individuals, one of whom shall be the laboratory director or a director designee.

5.5.5 Validation of Tables and Calculations

5.5.5.1 All formulae and algorithms (including software) used for statistical calculations to generate test reports shall be specified and validated. These include but are not limited to:

1) All parentage formulae found in Appendix 2 of the Guidance to the Standards for Relationship Testing Laboratories, and
2) Two party non parentage calculations (see standard 5.3.7).

5.5.5.2 Tables including, but not limited to, allele or haplotype frequencies and mutation rates shall be validated. Tables shall be developed in-house, published, or imported with a sample exchange.

5.5.5.2.1 Tables developed in-house shall be compared with other published data (when available) from similar populations.

5.5.5.2.2 The size of the population from which tables are developed shall be scientifically adequate.

5.5.5.2.3 The laboratory validating an imported table by sample exchange shall share a minimum of 20 samples from unrelated individuals with the laboratory that originally validated the table. The table shall be validated to ensure accuracy in identifying alleles by size,

repeat number, or sequence.

5.5.6 Validation of Expert Systems

A laboratory using an expert system to make allele determinations from electropherogram data of STR loci, instead of a laboratory director or laboratory director designee review, shall validate the expert system.

5.5.6.1 Validation shall include:

1) Evidence that the system correctly determines alleles and identifies artifacts that require human review by comparing at least 200 determinations made by the expert system with allele determinations made by a laboratory director or laboratory director designee.
2) Evidence that the system makes accurate allele determinations and identifies artifacts that require human review by comparing results from at least 200 electropherograms.
3) Demonstration that the expert system produces complete concordant results for at least 100 electropherograms that contain artifactual peaks or other anomalies requiring human review (eg, spikes, off-ladder alleles, contamination, size standard shifting).

5.5.6.1.1 For closed systems, the laboratory shall establish thresholds for allelic drop-in and drop-out and establish procedures to ensure those thresholds are consistent with the validation studies. Standard 5.5.5.1 applies.

5.5.6.1.2 Validation studies shall be reviewed and accepted by the RT SC of the AABB before implementation.

Standard	Record to be Maintained	Minimum Retention Time (Years)[1]
5.1.1	Validation of new or changed processes and procedures	5
5.1.8	Identification and traceability of products	5
5.1.10	Participation in proficiency testing program	5
5.1.10.1	For laboratories seeking initial accreditation, either results of successful participation in proficiency testing program for previous two years or concordant results with a relationship testing laboratory accredited by the AABB or other, equivalent accrediting body for sample exchange of at least 12 blinded cases	5
5.1.10.4	Monthly testing of samples	5
5.1.10.5	Monthly testing of samples	5
5.1.10.6	Proficiency testing, whether graded or not graded, shall be representative of the cases the laboratory performs, including standard trios, single parent, and family studies (reconstruction cases).	5

5.2.1	Chain of custody consent from each tested person, legal guardian, or conservator; include record in case file.	5
5.2.2	Individual performing collection; include record in case file.	5
5.2.2.3	Training of collectors.	5
5.2.3	Individual verifying sample collection; include record in case file.	5
5.2.3.2	Verification by person providing legal consent of accuracy of label.	5
5.2.3.4	Verification of package integrity upon receipt	5
5.2.3.5	Verification that chain of custody samples received are from an AABB-accredited relationship testing facility that initiated the case.	5
5.2.4	Identification records, including: 1) Name, relationship, date of birth, and the race/ethnic background of each parent/alleged parent. 2) Name, relationship, and date of birth of the child. Printed name and relationship of an untested person(s)signing consent for a minor child or legally incompetent adult. 3) Place, date, and type of sample collected. 4) Printed name, signature, and contact information of the person collecting or witnessing the sample, if applicable. 5) Printed name, signature, and contact information of the person verifying collection process, if different from the person collecting the sample. 6) A history of transfusion in the preceding 3 months or any history of allogeneic hematopoietic progenitor cell transplantation. 7) Original or legible photocopies of one or both of the following items for each individual tested and untested person(s) signing consent for a minor child or legally incompetent adult: a) Government-issued photo identification. b) Photograph that is suitable for positive identification. 8) Name of person receiving sample, date of receipt, and documentation of the shipment.	5
5.2.4.7.1	Explanation for a lack of government-issued photo identification for immigration, visa, passport, and citizenship.	5
5.2.5	Chain of custody where sample cannot be obtained according to these RT Standards.	5
5.3.1	Use of autosomal markers for genetic profile determination of the untested party	5

5.3.4	Use of validated loci.	5
5.3.13.1	Validation of test methods (10 years after retirement of the system).	5
5.3.13.2	Validation studies for new test methods.	5
5.3.14	Review of case by two people, including the laboratory director or designee; review of critical test results, work-sheets that record interpretations, conclusions, critical calculations, and case reports.	5
5.4.1	Validated processes and procedures for DNA polymorphism testing	5
5.4.1.1, #1	Unless an expert system is used, all electropherogram or gel results shall be interpreted twice, independently. Phenotypes that are manually determined shall be read twice.	5
5.4.1.1, #3	Defined conditions of amplification, hybridization, and detection of NAT for STR.	5
5.4.1.2, #4	Defined conditions of amplification, hybridization, and detection for SNP.	5
5.4.2	DNA testing using a closed system.	5
5.5.3	Laboratory supervisor and/or laboratory director-designated representative review of calculations before issue of report.	5
5.5.4	Duplicate manual calculations.	5
5.5.5.2.1	Validation of in-house-developed tables compared with published data.	5
5.5.6	Validation of expert systems.	5

[1]Applicable state or local law may exceed this period.

QSE 6 – Documents and Records

Key Concepts: This QSE focuses on the need to maintain all documents and records in a manner that ensures their confidentiality, traceability, completeness, uniformity, and ability to retrieve and locate in a time deemed adequate. This QSE also includes the need to ensure data integrity and that all data can be backed up and retrieved.

Key Terms:

Backup: *Digital data and/or physical storage containing copies of relevant data.*

Confidentiality: *The protection of private, sensitive, or trusted information resources from unauthorized access or disclosure*

Data Integrity: *The accuracy, completeness and consistency of information resources.*

Document (noun): *Written or electronically generated information and work instructions. Examples of documents include quality manuals, procedures, or forms.*

Document (verb): *To capture information through writing or electronic media.*

Label: *An inscription affixed or attached to a product for identification.*

Labeling: *Information that is required or selected to accompany product, which may include content, identification, description of processes, storage requirements, expiration date, cautionary statements, or indications for use.*

Master List of Documents: *A reference list, record, or repository of an organization's policies, processes, procedures, forms, and labels related to the Standards which includes information for document control.*

Record (noun): *Information captured in writing or through electronically generated media that provides objective evidence of activities that have been performed or results that have been achieved, such as test records or audit results. Records do not exist until the activity has been performed and documented.*

Record (verb): *To capture information for use in records through writing or electronic media.*

Examples of Objective Evidence:

- Policies, processes and procedures related to this chapter
- Records of activities performed
- Record system
- Master list of documents
- An electronic record system, if applicable
- Uniform storage media and ability to track newer technologies to older ones as needed
- Evidence of document and record review
- Evidence of standardized formats for all documents and records
- Record retention periods
- Record traceability
- Data back up plans
- Record change process
- Obsolescence of records and disposition

- Record destruction

6.0 Documents and Records

The organization shall ensure that documents and records are created, stored, and archived in accordance with record retention policies.

6.1 Document Control

The organization shall control all documents that relate to the requirements of these *Standards*. Documents shall be protected from unauthorized access and accidental or unauthorized modification, deletion, or destruction.

6.1.1 Format

Documents shall be in standardized formats. Additional policies, processes, and procedures (such as those in an operator's manual or published in the AABB *Technical Manual*) may be incorporated by reference.

6.1.2 Document Review, Approval, and Distribution

The document control process shall ensure that documents:

1) Are reviewed by personnel trained and/or qualified in the subject area.
2) Are approved by an authorized individual.
3) Are identified with the current version and effective date.
4) Are available at all locations where operations covered by these *Standards* are performed.
5) Invalid or obsolete documents are not used.
6) Any archived or obsolete documents are identified as such.

6.1.3 Document Changes

Changes to documents shall be reviewed and approved by an authorized individual.

6.1.3.1 The organization shall track changes to documents.

6.1.4 Master List of Documents

The organization shall maintain complete lists of all active policies, processes, procedures, labels, forms, and other documents that relate to the requirements of these *Standards*.

6.1.5 Review of Policies, Processes, and Procedures

Review of each policy, process, and procedure shall be performed by an authorized individual at a minimum every 2 years.

6.1.5.1 Review and approval by the laboratory director of new and revised technical documents before use.

6.1.6 Document Retention

The organization shall determine which documents shall be archived, destroyed, or made obsolete.

6.1.7 Document Storage

Documents shall be stored in a manner that preserves integrity and legibility; protects from accidental or unauthorized access, loss, destruction, or modification; and is accessible and retrievable.

6.1.8 Document Retrieval

The organization shall ensure that documents are retrievable in a timely manner.

6.1.9 The organization shall use only current and valid documents. Applicable documents shall be available at all locations where activities essential to meeting the requirements of these *Standards* are performed.

6.2 Record Control

The organization shall maintain a system for identification, collection, indexing, accessing, filing, storage, maintenance, and disposition of original records.

6.2.1 Records

Records shall be complete, retrievable in a period of time appropriate to the circumstances and protected from accidental or unauthorized destruction or modification.

6.2.1.1 The record system shall make it possible to trace any relationship test report or relationship testing service from its source to final disposition and to review the records applying to the specific relationship test report or relationship testing service.

6.2.2 Record Traceability

The records system shall ensure traceability of:

1) Critical activities performed.
2) The individual who performed the activity.
3) Date the activity was performed.
4) Time the activity was performed, if applicable.
5) Results obtained.
6) Method(s) used.
7) Equipment used.
8) Critical materials used.
9) The organization where the activity was performed.

6.2.3 Information to Be Retained

Records shall demonstrate that a material, product or service conforms to specified requirements and that the quality system is operating effectively.

6.2.4 Legibility

All records shall be legible and indelible.

6.2.5 Record Change

The organization shall establish processes for changing records. The date and identity of the person making the change shall be recorded. Record changes shall not obscure previously recorded information.

6.2.5.1 Changes to records (including electronic records) shall be verified for accuracy and completeness.

6.2.5.2 If an amended report is issued, the original report shall be maintained. Standard 6.2.1 applies.

6.2.6 Records shall be created concurrently with performance of each critical activity.

6.2.7 Copies

Before destruction of original records, copies of records shall be verified as containing the original content and shall be legible, complete, and accessible.

6.2.8 Confidentiality

The organization shall ensure the confidentiality of records.

6.2.8.1 Relationship testing reports shall be released only to authorized individuals. Standard 5.1.12 applies.

6.2.9 Retention

Records required by these *Standards* shall be retained for a period of time indicated in the record retention table at the end of each chapter.

6.2.10 Record Review

Records shall be reviewed for accuracy, completeness, and compliance with applicable standards, laws, and regulations.

6.2.11 Storage of Records

Records shall be stored to:

1) Preserve record legibility and integrity for the entire retention period.
2) Protect from accidental or unauthorized access, loss, deterioration, damage, destruction, mix-up, or modification.
3) Permit ready identification
4) Allow retrieval in a defined timeframe.

6.2.12 Destruction of Records

Destruction of records shall be conducted in a manner that protects the confidential content of the records.

6.3 Electronic Records

The organization shall support the management of information systems.

6.3.1 Access to Data and Information

Access to data and information shall be controlled.

6.3.1.1 The authorization to access and release data and information shall be defined, and individuals authorized to enter, change, and release results shall be identified.

6.3.1.1.1 Electronic records shall include the date and identity of the person making a change.

6.3.2 Data Integrity

Data integrity shall ensure that data are retrievable and usable.

6.3.2.1 Data shall be accurately, reliably, and securely sent from the point of entry to final destination.

6.3.2.2 Data shall be retrievable for the entire retention period.

6.3.2.2.1 The organization shall archive records or data from media and platforms no longer in use.

6.3.2.3 There shall be a process in place for routine backup of all critical data.

6.3.3 Storage Media

Data storage media shall be protected from damage or unintended access and destruction.

6.3.4 Back-Up Data

The organization shall back up all critical data.

6.3.4.1 Back-up data shall be stored in a secure off-site location.

6.3.4.2 Back-up data shall be protected from unauthorized access, loss, or modification.

6.3.4.3 The ability to retrieve data from the back-up system shall be tested at defined intervals.

6.4 Relationship Test Reports

When the relationship tests have been completed, a relationship test report shall be generated that includes the information required by Reference Standard 6.4A, Requirements for Test Reports.

6.4.1 Findings of No Relationship

The facility shall indicate the basis on which findings of no relationship are determined. These determinations shall identify genetic inconsistencies that may lead to a false

opinion of no relationship.

6.4.1.1 A finding of no relationship shall not be rendered on the basis of a single inconsistency without supporting evidence.

6.4.1.2 Genetic inconsistencies shall be reported and incorporated appropriately into the calculations as applicable.

6.4.1.3 If the laboratory renders an opinion of no relationship in family study cases solely on the basis of a low likelihood ratio, that likelihood ratio and a statement indicating that the finding of no relationship is based on the low likelihood ratio shall be included on the report.

6.4.2 Nonautosomal Findings

Nonautosomal results, when tested for parentage, full siblings, half siblings, avuncular and/or grandparentage relationships, shall be incorporated with autosomal results into the combined relationship index. In addition to the combined relationship index, the laboratory shall be permitted to discuss autosomal and nonautosomal findings separately.

6.4.2.1 A single haplotype frequency for all loci shall be incorporated into calculations for paternal Y chromosomal transmissions, and mitochondrial DNA results.

6.4.2.2 A single haplotype frequency for loci in linkage disequilibrium shall be incorporated into calculations for X chromosome transmission results.

6.4.3 The laboratory shall ensure that relationship testing services and test reports meet these RT Standards before distribution or delivery. Reference Standard 6.4A, Requirements for Test Reports, applies.

6.4.3.1 The AABB-accredited facility shall manage all processes in the generation and delivery of a relationship report including but not limited to collection, testing, data analysis, and report creation.

6.4.3.1.1 If a process is outsourced to another accredited facility, the accredited facility outsourcing the process shall perform its own review of the case and confirm that it meets both AABB and customer requirements before release to the client.

6.4.4 When the facility determines the final conclusion:

1) For large nucleotide datasets the results of the algorithm analysis shall be presented.
2) For all others, the individual relationship index shall be reported for each independently calculated locus or linked loci.

6.4.4.1 If the laboratory evaluates more than one possible relationship (eg, full sibling vs unrelated and half sibling vs unrelated) and presents one of the relationships as the final conclusion, the other relationships considered may also be reported without presenting the alternative individual likelihood ratios. A record of the alternative likelihood ratios shall be maintained.

6.5 Promotional Materials

The laboratory shall ensure that its promotional materials conform to all AABB requirements. Standards 5.2.3.5 and 6.5.2 apply.

6.5.1 An AABB-accredited laboratory shall use AABB trademarks, including logos, or make claims about AABB accreditation only in reference to activities for which it is accredited by AABB.

6.5.2 The facility shall distinguish between AABB-accredited and nonaccredited activities with respect to all claims in promotional, marketing, and educational materials in which the AABB trademarks are used.

6.5.3 The facility shall be truthful in advertising its accreditation status and its implications.

6.5.4 The facility shall ensure that "AABB" or AABB.org (or any derivation thereof, eg, AABB.edu, AABB.fr, etc) will not be used in any domain name or email address that is owned or used in any way by an accredited facility or through cooperative agreement with a third party.

6.5.5 The facility shall ensure that "AABB" or AABB.org (or any derivation thereof, eg, AABB.edu, AABB.fr, etc) will not be used in search engine advertisements or the web page title tags displayed on search engine results pages that are owned or used in any way by an accredited facility or through cooperative agreement with a third party. Usage shall be restricted to the accredited facility's official website.

6.6 The laboratory shall participate in data collection and submission for the AABB Relationship Testing Technical Report through the provision of requested data.

Standard	Record to be Maintained	Minimum Retention Time (Years)[1]
6.1.2	Document control, including review and approval of all documents before use	5
6.1.3	Review and approval of changes to documents	5
6.1.4	List of all active policies, processes, procedures, labels, and forms	5
6.1.5	Biennial review of each policy, process, or procedure	5
6.1.6	Documents that are archived, destroyed, or made obsolete	5
6.2.5	Record change	5
6.2.7	Verification that copies of records contain the original content and are legible, complete, and accessible before the original records are destroyed	5
6.2.10	Review of records for accuracy, completeness, and compliance with applicable standards, laws, and regulations	5
6.3	Electronic records	5
6.3.1.1.1	Date and identity of person making change(s) to electronic records	5
6.4.4.1	Alternative likelihood ratios.	5

6.5	Review of promotional materials.	5
6.6	Data collection and submission for the AABB Relationship Testing Technical Report.	5

[1]Applicable state or local law may exceed this period

Reference Standard 6.2.9A

Standard	Record to be Maintained	Minimum Retention Time (Years)[1]
1.1.1, 1.1.1.1	Official transcripts for laboratory director, laboratory director designee, and laboratory supervisor.	5
1.1.2.1	Laboratory director responsibility for policies, processes, and procedures.	5
1.1.4	Technical leader qualifications and experience.	5
1.1.5	Supervisor qualifications and experience.	5
1.1.6	Laboratory director, laboratory director designee(s), laboratory supervisor(s), and/or quality representative change notification within 30 days.	5
1.2.1.1	Quality representative training and experience.	5
1.2.2	Management review of effectiveness of the quality system	5
1.3	Policies, processes, and procedures	10
1.3.2	Exceptions to policies, processes, and procedures	10
1.4	Risk Assessment	5
1.6.1	Emergency operation plan tested at defined intervals	2 years, or two organizational testing intervals (whichever is longer)
2.1.1	Job descriptions	5
2.1.2	Training records of personnel	5
2.1.3	Evaluations of competence	5
2.1.4	Personnel records of each employee	5 years following conclusion of employment period
2.1.4.1	Records of names, signatures, initials or identification codes, and inclusive dates of employment for personnel who perform or review critical tasks	10
2.1.5	Continuing education requirements	5
3.2	Equipment qualification	10 years after retirement of the equipment
3.4	Unique identification of equipment	5
3.5.1	Equipment calibration activities	5
3.5.2	Equipment found to be out of calibration	5
3.5.3	Equipment monitoring, maintenance, calibration, and repair	5
3.6	Equipment traceability	5
3.7	Implementation and modification of software, hardware, or databases	2 years after retirement of system
4.1	Evaluation and participation in selection of suppliers	5
4.2	Agreements	5
4.2.1	Agreement review	5
4.2.3	Agreements concerning activities involving more than one organization	5
4.3	Inspection of incoming critical materials	10
4.5	Quality control of critical supplies and reagents	5

5.1.1	Validation of new or changed processes and procedures	5
5.1.8	Identification and traceability of products	5
5.1.10	Participation in proficiency testing program	5
5.1.10.1	For laboratories seeking initial accreditation, either results of successful participation in proficiency testing program for previous two years or concordant results with a relationship testing laboratory accredited by the AABB or other, equivalent accrediting body for sample exchange of at least 12 blinded cases	5
5.1.10.4	Monthly testing of samples	5
5.1.10.5	Monthly testing of samples	5
5.1.10.6	Proficiency testing, whether graded or not graded, shall be representative of the cases the laboratory performs, including standard trios, single parent, and family studies (reconstruction cases).	5
5.2.1	Chain of custody consent from each tested person, legal guardian, or conservator; include record in case file.	5
5.2.2	Individual performing collection; include record in case file.	5
5.2.2.3	Training of collectors.	5
5.2.3	Individual verifying sample collection; include record in case file.	5
5.2.3.2	Verification by person providing legal consent of accuracy of label.	5
5.2.3.4	Verification of package integrity upon receipt	5
5.2.3.5	Verification that chain of custody samples received are from an AABB-accredited relationship testing facility that initiated the case.	5
5.2.4	Identification records, including: 1) Name, relationship, date of birth, and the race/ethnic background of each parent/alleged parent. 2) Name, relationship, and date of birth of the child. Printed name and relationship of an untested person(s)signing consent for a minor child or legally incompetent adult. 3) Place, date, and type of sample collected. 4) Printed name, signature, and contact information of the person collecting or witnessing the sample, if applicable. 5) Printed name, signature, and contact information of the person verifying collection process, if different from the person collecting the sample. 6) A history of transfusion in the preceding 3 months or any history of allogeneic hematopoietic progenitor cell transplantation.	5

	7) Original or legible photocopies of one or both of the following items for each individual tested and untested person(s) signing consent for a minor child or legally incompetent adult: a) Government-issued photo identification. b) Photograph that is suitable for positive identification. 8) Name of person receiving sample, date of receipt, and documentation of the shipment.	
5.2.4.7.1	Explanation for a lack of government-issued photo identification for immigration, visa, passport, and citizenship.	5
5.2.5	Chain of custody where sample cannot be obtained according to these RT Standards.	5
5.3.1	Use of autosomal markers for genetic profile determination of the untested party	5
5.3.4	Use of validated loci.	5
5.3.13.1	Validation of test methods (10 years after retirement of the system).	5
5.3.13.2	Validation studies for new test methods.	5
5.3.14	Review of case by two people, including the laboratory director or designee; review of critical test results, worksheets that record interpretations, conclusions, critical calculations, and case reports.	5
5.4.1	Validated processes and procedures for DNA polymorphism testing	5
5.4.1.1, #1	Unless an expert system is used, all electropherogram or gel results shall be interpreted twice, independently. Phenotypes that are manually determined shall be read twice.	5
5.4.1.1, #3	Defined conditions of amplification, hybridization, and detection of NAT for STR.	5
5.4.1.2, #4	Defined conditions of amplification, hybridization, and detection for SNP.	5
5.4.2	DNA testing using a closed system.	5
5.5.3	Laboratory supervisor and/or laboratory director-designated representative review of calculations before issue of report.	5
5.5.4	Duplicate manual calculations.	5
5.5.5.2.1	Validation of in-house-developed tables compared with published data.	5
5.5.6	Validation of expert systems.	5
6.1.2	Document control, including review and approval of all documents before use	5
6.1.3	Review and approval of changes to documents	5
6.1.4	List of all active policies, processes, procedures, labels, and forms	5
6.1.5	Biennial review of each policy, process, or procedure	5

6.1.6	Documents that are archived, destroyed, or made obsolete	5
6.2.5	Record change	5
6.2.7	Verification that copies of records contain the original content and are legible, complete, and accessible before the original records are destroyed	5
6.2.10	Review of records for accuracy, completeness, and compliance with applicable standards, laws, and regulations	5
6.3	Electronic records	5
6.3.1.1.1	Date and identity of person making change(s) to electronic records	5
6.4.4.1	Alternative likelihood ratios.	5
6.5	Review of promotional materials.	5
6.5.6	Data collection and submission for the AABB Relationship Testing Technical Report.	5
7.1	Deviations	10 years after any impacted product is used or discarded
7.2	Nonconforming products or services	10 years after any impacted product is used or discarded
7.2.4	Nature of nonconformances discovered after release and subsequent actions taken, including acceptance for use	10
7.2.4.1	Disposition of the nonconforming product or service	10
7.2.4.2	Description and resolution of nonconformances that have been identified after release.	10
7.2.5	Investigation and resolution of discrepant test results, among laboratories participating in a sample exchange program.	10
7.4	Retraining and reevaluation of laboratory personnel who fail to meet expected performance criteria for competency testing for performance of those procedures before they are permitted to test client samples.	10
8.1	Internal assessments	5
8.2	External assessments	5
8.3	Management of assessment results	5
9.0	Implementation of changes to policies, processes, and procedures resulting from corrective and preventive action	5
9.1	Corrective action	5
9.2	Preventive action	5
10.1.1.1	Environmental condition monitoring.	5
10.1.2	Environmental conditions	5
10.2	Monitoring of biological, chemical, and radiation safety	5
10.3	Appropriate discard of products	10

Reference Standard 6.4A. Requirements for Test Reports

Chain of Custody Reports		
I. Identifiers		
1	Date of collection for each sample.	
2	Name, address, and contact information of the laboratory or, if the laboratory is a subcontractor, the agreed-upon contact information.	
3	The laboratory's accession or case number, if assigned.	
4	Name or other unique identifier of each person tested and his/her relationship or alleged relationship to the other individual(s) in the case.	
5	Racial/ethnic background(s) used by the laboratory for calculations as designated by the participants or closest available frequency database. Standard 5.2.4.2 applies.	
6	The original signature of the laboratory director or director designee.	
7	The identity of any other laboratory that provided genetic test results used in the report and any portion(s) of the report for which that laboratory was responsible.	
II. Findings		
1	A statement as to whether the alleged relationship can be excluded.	
2	If a statement of nonrelationship is rendered	Then the report shall include the following information: 1) For traditional relationship testing statistics: the STR loci providing the basis for the finding shall be indicated in the statement of non-relationship.
		2) For non traditional relationship testing statistics: the number of loci tested, the number of informative loci, if applicable, and the minimum percentage of loci that successfully yielded a result.
3	If there is a failure to exclude and the combined relationship index meets the established reporting policies for the indices obtained for the tested relationship	Then the report shall include the following information for traditional relationship testing statistics:
		1) The phenotypes of tested individuals for all loci that meet the laboratory's minimum performance thresholds, as applicable with the exception of amelogenin, other loci used for gender determination, and linked loci, as defined in standard 5.5 (Standards 5.3.11 and 5.3.12 apply).
		2) The individual relationship index for each locus or group of loci used in the conclusion.
		3) The combined relationship index.
		4) The probability of relationship expressed as a percentage. The prior probabilities used to calculate the probability of relationship shall be stated.

	(Standard 5.3.8 applies).	5) When autosomal loci are not tested, the conclusion shall not overstate the relationship. An explanation on non-recombining haplotypes inheritance and limitations to these markers shall be provided.
		6) When autosomal likelihood ratios are not in agreement with non-recombining haplotypes (leading to a different conclusion) an explanation on non-autosomal inheritance and limitations to these markers shall be provided.
		7) A statement that the calculations compare the tested individual(s) to a defined population.
		8) As appropriate, a statement that the calculations compare the tested individual to either an unrelated or related individual.
		Then the report shall include the following information for non- traditional relationship statistics:
		7) The number of loci tested, the number of informative loci, if applicable, and the minimum percentage of loci that successfully yielded a result.
		8) An explanation of the evaluation, the equivalency to the combined relationship index, and the statistical method(s) used. Standard 5.3.11.3 applies. Percentage DNA match or shared centimorgans, and the statistical support for the stated match, including the probability of relationship expressed as a percentage. The prior probabilities used to calculate the probability of relationship shall be stated.
		9) When autosomal loci are not tested, the conclusion shall not overstate the relationship. An explanation on non-recombining haplotypes inheritance and limitations to these markers shall be provided.
		10) When autosomal likelihood ratios are not in agreement with non-recombining haplotypes (leading to a different conclusion) an explanation on non-autosomal inheritance and limitations to these markers shall be provided.
		11) A statement that the calculations compare the tested individual(s) to a defined population, if applicable.
		12) As appropriate, a statement that the calculations compare the tested individual to either an unrelated or related individual.
4	If there is a failure to exclude and results are unusual, inconclusive, or involve relationship testing other than parentage and do not meet Standard 5.3.8.	Then report according to the laboratory's policies, which shall include an explanation of the reported results. The explanation shall include one of the following:
		1) A statement supporting the alleged relationship.
		2) A statement supporting no relationship.
		3) An inconclusive finding.
5	Identification of any test methods not covered by these *RT Standards.*	

QSE 7 – Deviations, Nonconformances and Adverse Events

Key Concepts: This QSE focuses on the need to ensure capture, management, and response of deviations, nonconformances or adverse events. This also includes the need to maintain records of resolution.

Key Terms:

Adverse Event: *A complication in an individual or product. Adverse events may occur in relation to organization-defined activities.*

Conformance: *Fulfillment of requirements. Requirements may be defined by customers, practice standards, regulatory agencies, or law.*

Deviation: *A departure from policies, processes, procedures, applicable regulations, standards, or specifications.*

Disaster: *An event (internal, local, or national) that can affect the safety and availability of the product or of individuals.*

Near-Miss Event: *An unexpected occurrence that did not adversely affect the outcome but could have resulted in a serious adverse event.*

Nonconformance: *Failure to meet requirements.*

Root Causes: *The underlying cause(s) of an event or nonconformance that, if eliminated, would prevent recurrence.*

Traceability: *The ability to follow the history of a product or service from source to final distribution or disposition using records.*

Examples of Objective Evidence:

- Policies, processes and procedures related to this chapter
- Records and evaluation of deviations, nonconformances and adverse events
- Notification to customer(s) following investigation, if appropriate
- Records of evidence that measures were taken to ensure deviations, nonconformances and adverse events do not recur.
- Planned deviation records, if any
- Records of deviation reporting to appropriate parties (e.g FDA)

7.0 Deviations, Nonconformances, and Adverse Events

The organization shall capture, assess, investigate, and monitor failures to meet specified requirements. The responsibility for review and authority for the disposition of nonconformances shall be defined. These events shall be reported in accordance with specified requirements and to outside agencies as required.

7.1 Deviations

The organization shall capture, assess, investigate, and report events that deviate from accepted policies, processes, or procedures. The assessment shall ensure timely and appropriate clinical management of the recipient, if applicable.

7.2 Nonconformances

Upon discovery, nonconforming products or services shall be evaluated and their disposition determined.

7.2.1 Nonconforming products shall be quarantined and/or destroyed.

7.2.2 The unintended distribution or use of products or services that do not conform to specified requirements shall be prevented.

7.2.3 The organization shall:

1) Identify, quarantine, retrieve, recall and determine the disposition of nonconforming products or services.
2) Identify and manage nonconforming products or services.

7.2.4 Released Nonconforming Products or Services

Products or services that are determined after release not to conform to specified requirements shall be evaluated to determine the effect of the nonconformance on the quality and/or safety of the product or service.

7.2.4.1 Records shall include the disposition of the nonconforming product or service, the rationale, and the name(s) of the individual(s) responsible for the decision.

7.2.4.2 Materials, samples, and services that are determined to be nonconforming after release or issue shall be reported to the customer.

7.2.4.3 Circumstances that warrant the issuing of an amended report shall be defined.

7.2.4.3.1 The laboratory shall identify an amended report. The new report shall indicate that it is an amended report and that it supersedes the previous report. Changes shall be identified in the amended report.

7.2.4.3.2 If a laboratory issues an amended report, the laboratory shall distribute amended reports to all recipients of the original report.

7.2.5 Nonconforming Proficiency Test Results

When nonconforming proficiency test results are obtained, the laboratory shall evaluate and

take appropriate action in response to results with unacceptable grades or deviation from nongraded challenges with known answers or that have reached 80% consensus.

7.2.5.1 Nonconforming results in a graded proficiency testing program shall be investigated in accordance with Standard 9.1 and a corrective action plan shall be developed and implemented.

7.2.5.1.1 If the laboratory fails an overall conclusion regarding alleged genetic relationship, the corrective action plan shall include communicating to AABB's Accreditation and Quality Department within 30 days the following items:

1) The nonconformance(s).
2) The corrective actions taken.
3) The plan to monitor the effectiveness of the corrective actions.

7.2.5.2 Discordant test results among laboratories participating in a sample exchange program shall be investigated in accordance with Standard 9.1. A corrective action plan shall be developed and implemented.

7.3 Adverse Events

The organization shall detect, monitor, evaluate, manage and report adverse events related to safety and quality.

7.3.1 Records of adverse events and the related investigations, evaluations, and notifications shall be maintained.

7.3.2 Investigation results and analysis shall be communicated among all facilities involved if applicable.

7.4 Nonconforming Competency Assessments

Laboratory personnel who fail to meet expected performance criteria for competency testing shall be retrained and reevaluated for performance of those procedures before they are permitted to test client samples.

Standard	Record to be Maintained	Minimum Retention Time (Years)[1]
7.1	Deviations	10 years after any impacted product is used or discarded
7.2	Nonconforming products or services	10 years after any impacted product is used or discarded
7.2.4	Nature of nonconformances discovered after release and subsequent actions taken, including acceptance for use	10
7.2.4.1	Disposition of the nonconforming product or service	10
7.2.4.2	Description and resolution of nonconformances that have been identified after release.	10
7.2.5	Investigation and resolution of discrepant test results,	10

	among laboratories participating in a sample exchange program.	
7.4	Retraining and reevaluation of laboratory personnel who fail to meet expected performance criteria for competency testing for performance of those procedures before they are permitted to test client samples.	10

[1]Applicable state or local law may exceed this period.

QSE 8 – Assessments: Internal and External

Key Concepts: This QSE addresses the organization's internal quality assessment functions as well as processes to support external assessments by accreditors, health authorities and regulators This chapter also describes the need for the organization to engage in ongoing quality monitoring and utilization review.

Key Terms:

Adverse Event: *A complication in an individual. Adverse events may occur in relation to organization defined activities.*

Assessment: *A systematic examination to determine whether actual activities comply with planned activities, are implemented effectively, and achieve objectives. Types of assessments include external assessments, internal assessments, peer review, and self-assessments.*

Competent Authority: *The agency responsible under its national law for regulations applicable to organization.*

Conformance*: Fulfillment of requirements. Requirements may be defined by customers, practice standards, regulatory agencies, or law.*

Corrective Action: *Actions taken to address the root cause(s) of an existing nonconformance or other undesirable situation in order to reduce or eliminate recurrence.*

Deviation: *A departure from policies, processes, procedures, applicable regulations, standards, or specifications.*

Nonconformance: *Failure to meet requirements.*

Preventive Action: *An action taken to reduce or eliminate the potential for unexpected deviations, nonconformances or other undesirable situations.*

Quality Indicator Data: *Information that may be collected and used to determine whether an organization is meeting its quality objectives as defined by top management in its quality policy. Indicators are measured by data for movement or regression with regard to those quality intentions. The data used for monitoring a quality indicator may consist of single-source data or multiple-source data, as long as it is clear how the data will come together to define the indicator.*

Root Causes: *The underlying cause(s) of an event or nonconformance that, if eliminated, would prevent recurrence.*

Examples of Objective Evidence:

- Policies, processes and procedures related to this chapter
- Records of internal assessments scheduled and conducted
- Records of evidence that deficiencies discovered during assessments and inspections have been addressed, including changes to quality or operational functions.
- Records of external assessments being conducted
- Quality indicator data collection and review

8.0 Internal and External Assessments

The organization shall conduct assessments of operations and quality systems.

✎8.1 Internal Assessments

The organization shall conduct internal assessments. Internal assessments shall be performed by personnel independent of those having direct responsibility for the activity being assessed.

✎8.2 External Assessments

The organization shall participate in an external assessment program applicable to the activities performed in the organization.

✎8.3 Management of Assessment Results

The results of assessments shall be:

1) Reviewed by the personnel having responsibility for the area assessed.
2) Evaluated to determine the need for corrective and preventive action.
3) Communicated to the appropriate staff.
4) Reported to executive management.

8.3.1 Follow-up action shall verify the implementation and effectiveness of corrective and preventive action. Standards 9.1 and 9.2 apply.

8.4 Quality Monitoring

The organization shall collect and evaluate quality indicator data on a scheduled basis, including adverse events.

8.4.1 The organization shall provide data generated to the personnel who have responsibility for the quality indicator data collected.

8.4.1.1 Quality indicator data shall include preanalytic, analytic, and postanalytic activities.

Standard	Record to be Maintained	Minimum Retention Time (Years)[1]
8.1	Internal assessments	5
8.2	External assessments	5
8.3	Management of assessment results	5

[1]Applicable state or local law may exceed this period.

QSE 9 – Process Improvement

Key Concepts: This QSE focuses on the use of corrective and preventive actions to drive process improvement. It describes measures to ensure that the root causes of nonconformances are effectively addressed.

Key Terms:
Adverse Event: *A complication in an individual. Adverse events may occur in relation to organization defined activities.*

Assessment: *A systematic examination to determine whether actual activities comply with planned activities, are implemented effectively, and achieve objectives. Types of assessments include external assessments, internal assessments, peer review, and self-assessments.*

Corrective Action: *Actions taken to address the root cause(s) of an existing nonconformance or other undesirable situation in order to reduce or eliminate recurrence.*

Deviation: *A departure from policies, processes, procedures, applicable regulations, standards, or specifications.*

Near-Miss Event: *An unexpected occurrence that did not adversely affect the outcome but could have resulted in a serious adverse event.*

Nonconformance: *Failure to meet requirements.*

Preventive Action: *An action taken to reduce or eliminate the potential for unexpected deviations, nonconformances or other undesirable situations.*

Root Causes: *The underlying cause(s) of an event or nonconformance that, if eliminated, would prevent recurrence.*

Examples of Objective Evidence:

- Policies, processes and procedures related to this chapter
- Records of collected data, analysis and corrective action taken when near misses, deviations, or adverse events are discovered
- Tracking of relevant data that impacts the organization's current and future operations
- Records that corrective and preventive action is taken
- Records that corrective and preventive action taken was effective and is monitored
- Documentation that process improvement data is included in executive management review

9.0 Process Improvement

The organization shall collect data, perform analysis, and follow-up on issues requiring corrective and preventive action, including near-miss events.

9.1 Corrective Action

The organization shall have a process for corrective action that includes:

1) Description of the event.
2) Investigation of the root causes of nonconformances relating to the product or service, the process, and the quality system.
3) Determination of the corrective action needed to eliminate the cause of nonconformances, as applicable.
4) Ensuring that corrective action is reviewed and found to be effective.

9.2 Preventive Action

The organization shall have a process for preventive action that includes:

1) Analysis of appropriate sources of information to detect, analyze, and eliminate potential causes of nonconformances.
2) Determination of steps needed to address any problems requiring preventive action.
3) Initiation of preventive action and application of controls to ensure that it is effective.

9.3 Performance Improvement

The organization shall track and identify trends in information related to its operational and quality system performance to identify opportunities for improvement.

Standard	Record to be Maintained	Minimum Retention Time (Years)[1]
9.0	Implementation of changes to policies, processes, and procedures resulting from corrective and preventive action	5
9.1	Corrective action	5
9.2	Preventive action	5

[1]Applicable state or local law may exceed this period.

QSE 10 – Facilities and Safety

Key Concepts: This QSE addresses the safety and adequacy of areas where the work required by these Standards is performed. This includes occupational safety, biohazardous materials disposal, environmental monitoring and compliance with applicable local and national regulations.

Key Terms:

Environmental Monitoring: *Policies, processes, and procedures used for monitoring any or all of the following: temperature, humidity, particulates, and microbial contamination in a specific area. Where appropriate, the program shall include sampling sites, frequency of sampling, and investigative and corrective actions that should be followed when specified limits are exceeded.*

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 part thereof, that has its own functions and executive management.*

Examples of Objective Evidence:

- Policies, processes and procedures related to this chapter
- Safe environmental conditions for all individuals in the organization
- Local, state, and national regulations being followed
- Proper discard of hazardous and potentially hazardous materials
- Personal Protective Equipment (PPE) is available and in use

10.0 Facilities and Safety

The organization shall ensure safe environmental conditions. The work area shall be suitable for the activities performed. Safety programs shall meet local, state, and national regulations.

10.1 Safe Environment

The organization shall minimize and respond to environmentally related risks to the health and safety of all individuals and products or services. Suitable quarters, environment, and equipment shall be available to maintain safe operations.

✎ **10.1.1** The laboratory shall define, monitor, control, and record environmental conditions, as required by relevant specifications or where they may influence the quality of the results. Standard 5.2 applies.

10.1.2 Storage space for critical materials, products, samples, and records shall be adequate to meet specified requirements and to prevent mix-ups.

10.1.3 The infrastructure for communication and information management shall be adequate to support the needs of the facility and its customers.

✎10.2 Biological, Chemical, and Radiation Safety

The organization shall monitor adherence to biological, chemical, and radiation safety standards and regulations.

10.2.1 The laboratory shall define the environmental conditions that have the potential to cause harm to staff, clients, and visitors to the facility. Standard 5.2 applies.

✎10.3 Handling and Discarding of Products

Products shall be handled and discarded in a manner that minimizes the potential for human exposure to infectious agents.

Standard	Record to be Maintained	Minimum Retention Time[1]
10.1.1	Environmental conditions	5
10.2	Monitoring of biological, chemical, and radiation safety	5
10.3	Appropriate discard of products	10

[1]Applicable state or local law may exceed this period.

Glossary

Adverse Event: A complication. Adverse events may occur in relation to organization defined activities.

Agreement: A contract, order, or understanding between two or more parties, such as between an organization and one of its customers.

Agreement Review: Systematic activities carried out before finalizing the agreement to ensure that requirements are adequately defined, free from ambiguity, documented, and achievable.

Allele: An alternative form of a gene or an alternate sequence of DNA at a specific locus.

Allelic Drop-in: Detection of additional alleles whose source cannot be identified.

Allelic Drop-out: Missing information in STR analyses in which one or both allelic copies at a locus fall below the detection threshold.

Amended Report: A subsequent report that corrects and/or supersedes a previous report.

Anonymous Testing: Cases where the identity of the persons tested is not known to the laboratory. The identity is maintained by another responsible person, such as an attorney or physician. For this type of testing, exceptions to the requirements for identification of the tested parties are acceptable, although requirements not relating to the identification of the tested parties will still apply

Assessment: A systematic examination to determine whether actual activities comply with planned activities, are implemented effectively, and achieve objectives. Types of assessments include external assessments, internal assessments, peer review, and self assessments.

Backup: Digital data and/or physical storage containing copies of relevant data.

Blinded Testing: The analysis of samples for which the results are unknown to the analyst.

Calibrate: To set or align measurement equipment against a known standard.

Change Control: A structured method of revising a policy, process, or procedure, including hardware or software design, transition planning, and revisions to all related documents.

Claims: With respect to these RT Standards, the direct or indirect implication that a facility or a service offered by that facility is accredited. Claims may appear in any information made available by the facility to potential clients or others, such as websites, educational or promotional materials, final reports, or other communication vehicles, including information given verbally to prospective clients.

Closed System: An instrument and pre-assembled set of reagents that consist of cartridges, chips, or biochips whose purpose is to perform DNA extraction, or purification, amplification, and separation in a single unit without human intervention.

Collection: The controlled process for obtaining a sample for relationship testing, including but not limited to: client scheduling and instruction, consent, identification, sampling, chain-of-custody documentation, and secure transport to the testing laboratory.

Collection/Verification Facility: An organization or location that is assessed and accredited by the AABB for the specific activities of collection and verification.

Competence: An individual's demonstrated ability to apply knowledge and skills needed to perform their job tasks and responsibilities.

Competency Testing: Evaluation of the ability to perform a specific task according to procedures and to obtain expected results.

Competent Authority: The agency responsible under its national law for regulations applicable to the **organization**.

Compliance: See "Conformance."

Confidentiality: The protection of private, sensitive, or trusted information resources from unauthorized access or disclosure

Confirmatory Testing: Repeat testing to confirm an initial test result. Confirming a test result includes an answer to an exclusion/nonexclusion question and/or the phenotype of the tested individual in particular locus or group of loci.

Conformance: Fulfillment of requirements. Requirements may be defined by customers, practice standards, regulatory agencies, or law.

Contract: See "Agreement."

Corrective Action: Actions taken to address the root cause(s) of an existing nonconformance or other undesirable situation in order to reduce or eliminate recurrence.

Critical Equipment/Materials/Tasks: A piece of equipment, material, service, or task that can affect the quality of the organization's products or services.

Customer: The receiver 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.

Data Integrity: The accuracy, completeness and consistency of information.

Database: In the context of these RT Standards, database means the source of the frequencies used to provide a statistical support.

Deviation: A departure from policies, processes, procedures, applicable regulations, standards, or specifications.

Disaster: An event (internal, local, or national) that can affect the safety and availability of the organization's products or the safety of individuals.

Document (noun): Written or electronically generated information and work instructions. Examples of documents include quality manuals, procedures, or forms.

Document (verb): To capture information through writing or electronic media.

Equipment: A durable item, instrument, or device used in a process or procedure.

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.

Environmental Monitoring: Policies, processes, and procedures used for monitoring any or all of the following: temperature, humidity, particulates, and microbial contamination in a specific area. Where appropriate, the program shall include sampling sites, frequency of sampling, and investigative and corrective actions that should be followed when specified limits are exceeded.

Establish: To perform all of the activities required to plan, validate, and implement a system or process.

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.

Expert System: Software that has been validated as an alternative to the decision-making process of a human expert.

Facility: A location or operational area within an organization. The part of the organization that is assessed by the AABB and receives AABB accreditation for its specific activities.

Final Inspection: To measure, examine, or test one or more characteristics of a product or service, and compare results with specified requirements in order to establish whether conformance is achieved for each characteristic.

Genetic Inconsistencies: Findings that appear to exclude a relationship. These could include true exclusions, apparent mutations, or silent (null) alleles.

Graded Proficiency Testing Program: A proficiency testing program in which results submitted by a participant are evaluated by an organization independent of the laboratory and declared as conforming or nonconforming.

Hematopoietic Progenitor Cell: Primitive pluripotent hematopoietic cells capable of self-renewal and/or differentiation as well as maturation into any of the hematopoietic lineages (granulocytes, lymphocytes, monocytes, erythrocytes, and platelets) including committed and lineage-restricted progenitor cells, unless otherwise specified, regardless of tissue source (eg, marrow, mobilized peripheral blood, or umbilical cord blood).

Hypothesis: For the purpose of these RT Standards, a hypothesis is a mutually exclusive, limited statement regarding the biological relationship that exists among tested individuals.

Inconclusive Result: When determining relationship a result that does not provide evidence for or against the hypothesized result.

Independent Locus or Group of Loci: When the inheritance of the alleles of any lociused for testing is demonstrated, by the laboratory or by published literature, to be statistically independent from the inheritance of the alleles of any other loci used for testing.

Initiate: Direct contact between the petitioner (or other involved parties) and the accredited facility before commencing relationship testing activities.

Inspect: To measure, examine, or test one or more characteristics of a product or service and compare

results with specific requirements.

Installation Qualification: Verification that the correct equipment is received and that it is installed according to specifications and manufacturer's recommendations in an environment suitable for its operation and use.

Key Quality Functions: Essential job functions that affect the services provided by the organization.

Label: An inscription affixed or attached to a product for identification.

Labeling: Information that is required or selected to accompany the product, which may include content, identification, description of processes, storage requirements, expiration date, cautionary statements, or indications for use.

Laboratory: A location where testing is performed. Unless a standard specifically indicates otherwise, the terms facility and laboratory are used interchangeably in these RT Standards. See "Facility".

Likelihood Ratio: A ratio of two probabilities of the same event under different hypotheses. The relationship index is an example of a likelihood ratio, as well as related vs unrelated, full siblings vs half siblings, or a possible alleged father vs an uncle. See Appendix 3 in Guidance for Standards for Relationship Testing Laboratories.

Linkage Disequilibrium: When alleles at two or more loci are found together more or less often than expected as calculated by the product of their individual frequencies.

Linked Loci: Two or more loci that are on the same chromosome with a recombination rate between them of less than 50%.

Locus (loci): A specific region or address on a chromosome or on mitochondrial DNA.

Maintain: To keep in the current state; to preserve or retain; to keep in a state of validity.

Master List of Documents: A reference list, record, or repository of an organization's policies, processes, procedures, forms, and labels related to the Standards which includes information for document control.

Material: A supply item used in a process or procedure.

Mutation: Alteration or change at a locus or site resulting in an apparent inconsistency in a putative biological relationship. See "Genetic Inconsistencies".

Near-Miss Event: An unexpected occurrence that did not adversely affect the outcome but could have resulted in an adverse event.

New Test Method: As opposed to a novel method, a new test method is a change to or addition of a peer-reviewed existing technology already applied in relationship testing. For example, changing from STR-based testing to SNP-based testing is a new test method. Changing from one STR kit to another STR kit is not an example of a new test method, but is an example of a new procedure.

Non-Chain-of-Custody Testing: Sample collections that do not have a record showing where a sample was collected, who collected the sample, date of collection, and other information found in Standard 5.2.

Non-Traditional Relationship Testing Statistics: Methods where the likelihood ratio, or other measure

of statistical support, is calculated using formulas that do not include the frequencies of specific alleles, genotypes, or haplotypes of the tested parties. Instead, statistical support is calculated using formulas that include other parameters (e.g., shared centimorgans). These statistics are typically used for very large SNP or other nucleotide data sets.

Nonrecombining Haplotypes: A set of genetic markers that are inherited as a group from one parent in its entirety, eg, commonly used Y chromosome markers.

Nonconformance: Failure to meet requirements.

Novel Method: A procedure that has not been peer-reviewed for the purposes of relationship testing. It may include a procedure that has been peer-reviewed for other purposes or a method that has not been peer-reviewed for other purposes.

Nucleotide Datasets: Datasets generated by nucleotide sequence determination.

Nucleotide Sequence Determination: For the purposes of these RT Standards, any method able to determine DNA sequence, including but not limited to, whole genome sequencing , indel determination, next generation sequencing, SNPs, capillary array, CHiP, microarray analysis, and Sanger sequencing.

Operational Qualification: Verification that equipment will function according to the operational specifications provided by the manufacturer.

Operational Systems: Processes, resources, and activities that work together to result in a product or service.

Organization: An institution, laboratory, or program that has its own functions and executive management.

Performance Qualification: Verification that equipment performs consistently as expected for its intended use in the organization's environment, using the organization's procedures and supplies.

Phenotype: The observed testing result.

Policy: A set of basic principles or guidelines that direct or restrict the organization's plans, actions, and decisions.

Power of Exclusion: The ability of a genetic test or test battery to detect an inconsistency between a nonparent and child. The average (mean) power of exclusion measures this ability over all relationship tests and is used by laboratories to assess the potential usefulness of genetic tests and test batteries. The individual power of exclusion expresses the ability of a genetic test or test battery to exclude a nonparent of a defined ethnic background as a parent of a particular child.

Preferential Amplification: The formation of more PCR products of one allele in comparison with another allele at the same locus, usually due to less efficient amplification of one allele.

Preventive Action: An action taken to reduce or eliminate the potential for unexpected deviations, nonconformances or other undesirable situations.

Prior Probability: The strength of the nongenetic evidence that the hypothesized relationship is correct.

Probability of Paternity: Requires the use of Bayes' Theorem. This incorporates the combined likelihood

ratio and a prior probability.

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.

Process Control: Activities designed to ensure that processes are stable and consistently operate within acceptable limits of variation in order to produce predictable output that meets specifications.

Product: A tangible output from a process.

Proficiency Testing: The structured evaluation of laboratory methods of testing that encompass the suitability of processes, procedures, equipment, materials, and personnel to produce expected results.

Promotional Materials: Marketing, education, website, and advertising materials (both printed and electronic) related to activities covered by these Standards.

Qualification (individuals): The aspects of an individual's education, training, and experience that are necessary for the individual to successfully meet the requirements of a position.

Qualification (materials): For materials that come into contact with the product verification that the materials are sterile, the appropriate grade and suitability for the intended use and, whenever possible, approved for human use by the United States Food and Drug Administration (FDA) or relevant Competent Authority.

Quality: Characteristics of a product or service that bear on its ability to fulfill customer expectations. The measurable or verifiable aspects of a product or service that can be used to determine if requirements have been met.

Quality Control: Testing routinely performed on materials and equipment to ensure their proper function.

Quality Function: Activities of persons designated by the organization to administer the approved quality system.

Quality Indicator Data: Information that may be collected and used to determine whether an organization is meeting its quality objectives as defined by executive management in its quality policy. Indicators are measured by data for movement or regression with regard to those quality intentions. The data used for monitoring a quality indicator may consist of single-source data or multiple-source data, as long as it is clear how the data will come together to define the indicator.

Quality Management System: The organizational structure, responsibilities, policies, processes, procedures, and resources established by executive management to achieve quality.

Quarantine (verb): To isolate nonconforming materials, results, or unissued reports in a clearly designated manner or marked area so that they cannot accidentally be used in subsequent steps.

Reagent: A substance used to perform an analytical procedure.

Record (noun): Information captured in writing or through electronically generated media that provides objective evidence of activities that have been performed or results that have been achieved, such as test records or audit results. Records do not exist until the activity has been performed and documented.

Record (verb): To capture information for use in records through writing or electronic media.

Reference Standard: Specified requirements defined by the AABB. Reference standards define how or within what parameters an activity shall be performed and are more detailed than quality system requirements.

Regulation: Rules promulgated by federal, national, state, or local authorities to implement laws enacted by legislative bodies.

Relationship Index: See "Likelihood Ratio".

Release: Removal of a product from quarantine or in-process status for the purpose of distribution.

Risk: The threat of quantifiable damage or any other negative occurrence that is caused by external or internal vulnerabilities and that may be avoided through preemptive action.

Risk Assessment: An analysis of risk includes predictable kinds of negative occurrences, severity, and the probability of their happening.

Root Causes: The underlying cause(s) of an event or nonconformance that, if eliminated, would prevent recurrence.

Sample Exchange Program: A process among two or more independent organizations to compare concordance in the absence of a formal graded proficiency.

Sensitivity: The percent of persons of a known relationship that have a likelihood ratio (LR) greater than a set threshold. For example, if a population of known half siblings are tested and a threshold is set at a LR of 10, and 60 out of 100 half siblings exceed 10, the sensitivity is 60%.
Sequencing: See "Nucleotide Sequence Determination".

Service (noun): An intangible output of a process.

Service (verb): An action that leads to the creation of a product or a result that can affect donors, patients, and/or recipients.

Shall: A term used to indicate a requirement.

Specified Requirements: Any requirements in these Standards, including, but not limited to, FDA requirements; requirements of a facility's internal policies, processes, and procedures; manufacturers' instructions; customer agreements; practice standards; and requirements of accrediting organizations such as the AABB.

Specificity: The percent of random pairs with likelihood ratios less than a set threshold. For example, if a population of known random individuals are tested as half siblings and a threshold is set at a LR of 10, and 98 out of 100 comparisons are less than 10, the specificity is 98%.

Standard: A set of specified requirements upon which an organization may base its criteria for the products, components, and/or services provided.

Standard Test Battery: A group of tests, each of which is covered by these RT Standards, that is performed routinely on each case evaluated by the laboratory.

Supplier: An entity that provides a material, product, or service.

Supplier Qualification: Evaluation of a potential supplier to assess its ability to consistently deliver products or services that meet specified requirements.

Task: See "Procedure".

Technical Leader: An individual identified in a forensic laboratory who is responsible for the technical operations of the laboratory may be qualified to serve as a laboratory director under these RT Standards. This individual must be the current technical leader in a DNA testing laboratory audited to FBI Quality Assurance Standards. See Standard 1.2.4.

Third-Party Administrators: Businesses that are not laboratories themselves, but market relationship tests and then send the client or client's samples to a laboratory for relationship testing. Also referred to as brokers, vendors, or resellers.

Traceability: The ability to follow the history of a product or service from source to final distribution or disposition using records.

Traditional Relationship Testing Statistics: Methods where the likelihood ratio is calculated using formulas that include the frequencies of specific alleles, genotypes, or haplotypes of the tested parties, as opposed to other parameters (e.g., shared centimorgans). These statistics are required for standard STR loci, but may also be applied to other types of loci.

Validation: Establishing evidence that a process, executed by users in their environment, will consistently meet predetermined specifications.

Verification: Confirmation by examination and provision of objective evidence that specified requirements have been met.