Proposed 17th edition of Standards for Relationship Testing Laboratories

Effective January 1, 2026

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 17th edition begins on page 2 and runs through page 15. The proposed 1st edition begins on page 16 and runs through page 90.

~~2.2~~ **1.1.5 Laboratory Director Oversight**

The laboratory director shall oversee a maximum of 10 accredited facilities. No more than five of these facilities shall be testing laboratories, with the remainder being accredited collection/verification facilities.

~~2.2.1~~ **1.1.5.1** The 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.

These standards have not been updated, however, they previously appeared in Chapter 2 as standards 2.2 and 2.2.1. The committee felt that the standards better fit under the Laboratory Director Qualifications and Responsibilities section.

1.4.2 The organization shall assess:

1) Potential threats for fraud and/or loss of sample integrity associated with the collection of a tested person's sample.

2) Potential threats to continuity of technology and communication infrastructure.

The committee added new standard 1.4.2 to the proposed edition for completeness of risk assessment and mitigation. This standard ensures that accredited organizations have plans in place to identify threats associated with sample integrity and the infrastructure of the technology and communication systems.

1.9 Organization Status Changes

The organization shall communicate to AABB within 30 days a change that directly or indirectly impacts an organization's accreditation status, including if a laboratory ceases operations.

1.9.1 If the organization is the subject of regulatory enforcement action by a relevant Competent Authority, they shall notify AABB within 7 days of receipt of notification.

The committee added new standards 1.9 and 1.9.1 for completeness. These standards require that accredited organizations contact AABB in the case where they are under enforcement regulatory action by their Competent Authority.

~~3.5.1.4~~ **3.3.1** If the manufacturer's written instructions are not followed, the equipment shall be validated for its intended use.

This standard is not new to the edition, however it previously appeared as standard 3.5.1.4.

3.8 Technology Infrastructure

The organization shall have an ongoing program to ensure that critical technology and communication infrastructures function as intended, including risk-based monitoring or testing at organization defined intervals. Standards 1.4, 1.5, and 1.6 apply.

The committee added new standard 3.8 to the edition for completeness. This ensures that facilities

monitor their critical technology infrastructure and that they function as expected. This standard requires that there are defined checks to monitor that technology is working as intended and expected.

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

4) ~~Appropriate~~ Marketing materials and claims **as defined by standard 6.5**.

6) Initiation of cases for immigration, visa, passport, and citizenship testing adjudicated by an agency of the United States of America.

Standards 5.2.3.5, 6.5.4, and 6.5.5 apply.

The committee edited subnumber 4 of the standard for clarity. The term "appropriate" is difficult to assess, and the addition referencing standard 6.5 ensures that users refer back to the standard on promotional materials.

Subnumber 6 is new to the proposed edition and was added for completeness. This ensures that accredited organizations define the requirements for initiation of immigration cases in their written agreements with third-party administrators.

4.2.3.1.1 Third party administrators are prohibited from initiating testing activities for immigration, visa, passport, and citizenship testing adjudicated by an agency of the United States of America unless accredited by AABB. Standard 5.2.3.5 applies.

This standard previously appeared as standard 4.2.3.1 #6, however the committee felt it should appear as its own standard and edited it for clarity. This request has come from accredited members and individuals from the Department of State on the committee.

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.~~

The committee removed the clause in strikethrough as it was deemed redundant to standard 4.4.1.

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 the failure and remediation to the organization's purchasing authority. Standard 7.0 applies.

This standard previously appeared as standard 4.4.1.1, however the committee felt it should appear as its own standard.

5.1.6.1 If the manufacturer's written instructions are not followed, the material shall be used in accordance with the laboratory's validated procedures for the intended use.

The committee created new standard 5.1.6.1 understanding that it is common practice to validate reduced volume amplification reactions, and that to do so a laboratory would need to not follow the instructions provided. The concept behind this standard previously appeared as a part of the guidance to standard 5.1.2.

~~4.6~~5.1.8.1 **Traceability**

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

✎ **~~4.6.1~~5.1.8.2** The organization shall have a policy that mitigates the potential risk for fraud or loss of sample integrity. Standard 1.4 applies.

Standards 5.1.8.1 and 5.1.8.2 are not new to this edition, having previously appeared as standards 4.6 and 4.6.1. The committee felt that standards focusing on traceability should appear under the identification and traceability standard.

5.1.8.3~~4.6.1~~ The organization shall evaluate and respond to suspected altered or fabricated documents misrepresenting identity, including but not limited to, borrowed or fraudulent identification documents presented at the time of collection, official United States of America government paperwork or fabricated relationship determination reports.

Standard 5.1.8.3 is not new to this standard, having previously appeared as standard 4.6.1. The committee expanded standard 5.1.8.3 for completeness. The inclusion of this standard mirrors requirements set forth by the Department of State and USCIS.

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

2) A **sample** exchange **with an accredited relationship testing laboratory demonstrating concordant** results of at least 12 **questioned relationships** ~~blinded cases~~ **that are** representative of the casework **performed by** the laboratory **seeking accreditation** ~~proposes to perform with an accredited relationship testing laboratory and demonstrate concordant results~~.

The committee edited subnumber 2 of the standard for clarity. The genesis of the change was based on a request for clarification received to the 16th edition. The main change is replacing "blinded cases" for "questioned relationships" which better reflects the current terminology.

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

The committee added the clause "or geneotypes" for completeness.

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

The committee edited the entries above for accuracy. The changes of the testing requirements from monthly to quarterly was done to mirror current practice, and also reflects that a monthly basis of testing was potentially difficult due to the quantity of samples available to test.

5.1.10.6 **For non-traditional relationship testing:**

1) When a formal graded proficiency testing program is available, a test that grades on consensus or conclusion is acceptable.
2) When a formal graded proficiency testing program is not available, the laboratory shall use one of the following methods:
a) On a quarterly basis, test known samples that were originally tested when graded proficiency testing was available.
b) On a quarterly basis, test a standard trio of samples developed from persons of an undisputed relationship.
c) Participate three times a year in a sample exchange program.

The committee created new standard 5.1.10.6 for completeness. With the creation of standards related to "non-traditional" relationship testing in the 16th edition, the committee felt it important to add a standard focused on non-traditional relationship testing as it relates to formal graded proficiency testing.

5.1.12.2 **The laboratory shall have a policy for the return and/or destruction of samples in accordance with applicable local laws, jurisdiction, regulations, and case type.**

5.1.12.2.1 **The laboratory shall define what is considered a sample versus work product.**

5.1.12.2.1.1 **This shall include determining requirements for traceability and final disposition of a sample and/or a work product.**

Work Product: The material that is produced as a result of DNA analysis, which may include extracts, amplified products and amplification tubes or plates as defined by the laboratory.

The committee added new standards 5.1.12.2 – 5.1.12.2.1.1 for completeness. The addition of the standards are based on elements from the FBI Quality Assurance Standards. Including these elements as a part of the privacy and confidentiality section ensures that accredited organizations return or dispose of samples and work products in a manner that ensures traceability of the chain of custody.

5.2.1.1 **The laboratory shall inform the tested person or their legal representative of the potential additional use of their sample and profile beyond the originally requested relationship testing and, where legally required, obtain consent.**

The committee added new standard 5.2.1.1 for completeness recognizing there are instances where an individual's provided sample can be used for something other than determination of relationship, such as research or other studies.

5.2.1.2 **If the laboratory maintains a profile database for the purpose of genetic genealogy or allows for the sharing of profiles for law enforcement purposes, a distinct consent acknowledging inclusion shall be made available to the tested person or their legal representative.**

The committee added new standard 5.2.1.2 to continue the expansion of the Standards into the genetic genealogy space. This standard ensures that accredited organizations that are collecting samples that could be used for law enforcement purposes must have a separate consent form for potentially tested parties to ensure that they are aware of that, and how this affects their personal data privacy.

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

The committee edited standard 5.2.2.4 to remain parallel with updated language in chapter 4.

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's ~~with~~ legal **representative** ~~authority accompanying a minor or legally incompetent adult~~.

The committee edited the standard for clarity and brevity, the intent of the standard has not changed.

5.2.3.3 **All packaging and transfer of samples shall be performed by a person with no interest in the test outcome** ~~Test participants shall not package or transfer samples~~. Standard 5.2.2 applies.

The committee edited standard 5.2.3.3 for clarity and to mirror current practice.

5.2.3.5 Samples intended for immigration, visa, passport, and citizenship testing cases **adjudicated by an agency of** ~~for~~ the United States of America shall be accepted only if the case is initiated directly between the petitioner and an organization accredited by AABB for relationship testing activities. Records of the initiation of this service by the petitioner shall be maintained in the organization's records. Standard 5.1.8.1 applies.

The committee edited standard 5.2.3.5 to remain parallel with updated language in chapter 4.

5.2.4.1.1 Printed name and relationship of an untested person(s) **legal representative** signing consent for the **tested person** ~~a minor or legally incompetent adult~~.

Tested Person: The individual from whom a sample is being collected.

The committee edited the standard for clarity and brevity, the intent of the standard has not changed. In conjunction, the committee created a new definition for "tested person."

5.2.4.2 **Self-declared r**~~R~~ace/ethnicity ~~background~~ of all the tested parties, with the exception of a child in parentage cases.

The committee edited standard 5.2.4.2 to reflect current practice. The intent of the standard has not changed.

5.2.4.7 Original or legible photocopies of at least one of the following items for each individual tested and untested **legal representative** ~~person(s)~~ signing consent for the ~~a minor or legally incompetent adult~~ **tested person**:

1) Valid government-issued photo identification (ID).
2) Photograph that is suitable for positive ID.

The committee edited the standard for clarity and brevity, the intent of the standard has not changed.

✎ **5.2.4.7.1** For cases intended for immigration, visa, passport, and citizenship **adjudicated by an agency of** the United States of America, the following shall be submitted:

The committee edited standard 5.2.4.7.1 to remain parallel with updated language in chapter 4.

5.2.5.1 **The laboratory shall have a policy for the receipt of samples that have not been obtained according to standards 5.2 through 5.2.4.7 which includes an evaluation of the provider and accreditation status, if applicable.**

The committee created new standard 5.2.5.1 under the "Special Circumstances" section to ensure that the Standards cover activities where samples are obtained in a manner different than what is required by standards 5.2 through 5.2.4.7.

5.2.5.2 **For genetic genealogy cases, the laboratory shall identify on the final report all profiles obtained from a publicly available database where identity has not been verified.**

The committee created new standard 5.2.5.2 to ensure that reports created for genetic genealogy cases that have profiles obtained from the publicly available space where identity is not verified are identified as such.

✎ **5.3.1** Autosomal **short tandem repeat (STR) markers** ~~loci~~ shall be used to evaluate a relationship unless one of the following conditions exists:

1) Results for autosomal STR markers are not obtained.
2) Results for nonautosomal STR markers exclude the relationship.

3) Autosomal STR markers are not expected to be informative because the hypothesized relationship is beyond second order.

4) Non-traditional testing methods are used for determination of relationship.

The committee replaced "loci" with "STR markers" for accuracy and parallel construction with the subnymbers included in the standard. STR analysis is used to compare alleles at specific loci in DNA, and hence more accurate in terms of what is being evaluated in the standard.

Subnumber 4 is new to the proposed edition and was included for completeness recognizing that the where appropriate "non-traditional testing methods" need to be included in the edition.

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

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

In conjunction with the addition of "STR" to standard 5.3.1, the term has been added to standards 5.3.2 and 5.3.3 for parallel construction purposes.

5.3.45 The laboratory shall use STR markers with chromosomal locations that are recorded in scientific literature.

This standard previously appeared as "5.3.5" however has been reordered for accuracy, the content of the standard has not changed.

✎ **5.3.5** The laboratory shall use **genetic markers characterized by validation studies** ~~valid loci~~.

The committee edited this standard for clarity and accuracy. This edit reflects changes made to this section and to mirror current industry practice.

5.3.10 Before releasing any report **supporting the alternate hypothesis** ~~excluding biological relationship~~:

The committee edited standard 5.3.10 for clarity. The change better reflects language used by accredited organizations.

5.3.10.2 For nonparentage cases where the genetic evidence ~~does not~~ support**s** the **alternate hypothesis** ~~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.

Based on the edit made to standard 5.3.10, the committee edited standard 5.3.10.2.

✎ **5.3.13.2** For new or novel **STR** ~~test~~ methods, **new STR multiplex kits, or loci (or locus) added to existing 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**/or** between ~~the laboratory and~~ **laboratories involved in sample exchange**. 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.~~

The committee edited standard 5.3.13.2 for clarity and to mirror the updates made to the standards in the 5.3 section detailed above.

5.3.13.3 For new or novel methods, including SNP or nucleotide sequencing, part of the validation process shall require the analysis of an organization defined number of biological samples to demonstrate that the method performs as expected with accuracy and reproducibility of test results within the laboratory and/or between laboratories involved in sample exchange. 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. Validation studies shall be reviewed and accepted by the RT SC of the AABB before implementation.

The committee added new standard 5.3.13.3 to the proposed edition. This standard was created to mirror standard 5.3.13.2 however, with a focus on SNP or nucleotide sequencing as a part of next gen sequencing.
The last sentence in the standard previously appeared in standard 5.3.13.2.

5.3.13.3.1 For nucleotide sequencing methods, a number of samples shall be determined in the validation plan to demonstrate:
1) Nucleic acid quality and quantity.
2) Library qualification and quantification.
3) Depth of coverage.
4) Uniformity of coverage.
5) Cluster density and alignment rate.
6) Mapping quality.

With the creation of new standard 5.3.13.3, the committee created new standard 5.3.13.3.1 to provide information on what should included as a part of an organization's validation plan. The committee has already created guidance for each entry to assist users in the implementation of the standard.

5.3.13.~~4~~3 For **addition of loci to novel methods, including SNP or nucleotide sequencing** ~~multiplex kits or loci (or locus) added~~ to existing test methods, the validation process shall require the analysis of an organization **defined number of biological samples** ~~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.~~

The committee edited standard 5.3.13.4 for clarity. For some novel or non-traditional testing methods that include next gen sequencing, 20 samples is not typically sufficient to provide accuracy and reproducibility. The onus will fall on the organization to define what that number is.

✎ **5.4.1 DNA Polymorphism Testing**

The laboratory shall use **methods that have been subjected to validation** ~~valid DNA testing~~ **studies**. The laboratory shall demonstrate reproducibility of test results.

1) ~~For systems dependent on accurate measurement of allele size~~ **A known** human DNA control ~~of known phenotype~~ shall be tested with each analysis.
2) ~~Appropriate~~ Stringency conditions **determined during validation** 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.

The committee edited the intro to standard 5.4.1 for clarity. The edit ensures that the standard mirrors current practice. Subnumbers 1 and 2 have been edited for clarity.

5.4.1.2 Nucleotide Sequence Determination or SNP Analysis

1) When an expert system is used to interpret the SNPs **or other nucleotide datasets**, 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 **or other nucleotide datasets**, 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.
6) Negative control(s) shall be extracted **and amplified** with samples and used to monitor for sample contamination and **work** product contamination. **A DNA quantification threshold shall be established by validation studies that demonstrate an acceptable negative control (eg, before sequencing, before library prep).**

Subnumbers 1 and 2 have been expanded to ensure that the standards reflect the use of expert system analysis of other data.

Subnumber 6 has been expanded to include the need for accredited organizations to define criteria for acceptable negative controls (a sample not expected to produce a result) through validation studies.

5.5 Calculations

The laboratory shall use ~~validated~~ calculation methods **established by validation studies**.

The committee edited standard 5.5to mirror the inclusion of "validation studies" throughout the edition.

5.5.5 ~~Validation of Tables and~~ Calculations and Datasets

As a part of a change throughout the edition, the committee has replaced the use of the term "table" with "datasets", which is more expansive.

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 for Standards for Relationship Testing Laboratories*, and
2) Two-party nonparentage calculations (see Standard 5.3.7).

Standard 3.7 applies.

The committee added a crossreference to standard 3.7 which is focused on information systems for completeness.

5.5.5.2 Datasets containing, ~~tables including~~ but not limited to, **macros,** allele or haplotype frequencies and mutation rates, shall be **verified for concordance and/or accuracy** ~~validated~~. **Datasets** ~~Tables~~ shall be developed in-house, published, or imported with a sample exchange.

The committee edited standard 5.5.5.2 to mirror other edits to the edition for parallel construction. The use of the term "verified" in place of "validated" is for accuracy reflecting how datasets are reviewed, in most cases which are not prepared in house.

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

5.5.5.2.2 The sample size from which **datasets** ~~tables~~ are developed shall be scientifically adequate.

5.5.5.2.3 The laboratory **verifying** ~~validating~~ an imported **dataset** ~~table~~ by sample exchange shall share a minimum of 20 samples from unrelated individuals with the laboratory that originally **verified** ~~validated~~ the **dataset** ~~table~~. The **dataset** ~~table~~ shall be **verified** ~~validated~~ to ensure accuracy in identifying alleles by size, repeat number, or sequence.

The committee edited these standards for parallel construction throughout the edition.

✎ **5.5.6 Validation of Expert Systems**

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

The committee edited standard 5.5.6 for completeness, and parallel construction.

5.5.6.1 Validation shall include:

1) Evidence that the system correctly **evaluates** ~~determine~~ alleles, **SNPs, or other nucleotide datasets** 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 **samples** ~~electropherograms~~.
3) Demonstration that the expert system produces complete concordant results for at least 100 **samples** ~~electropherograms~~ that contain artifacts ~~artifactual peaks~~ or other anomalies requiring human review ~~(eg, spikes, off-ladder alleles, contamination, size standard shifting)~~.

Artifact: A non-allelic product of the amplification process, an anomaly of the detection process, or a byproduct of primer synthesis that may be observed in data.

The committee edited standard 5.5.6.1 for completeness, and parallel construction and to reflect the use of expert systems by accredited organizations. The elements in subnumber 3 as an "eg" have been deleted and will be included in guidance.
The committee also added a definition of the term "artifact" to the glossary for completeness.

6.4.1.1 A finding of no relationship shall not be rendered ~~on the basis of a single inconsistency without supporting evidence.~~:.
1) For STR on the basis of a single inconsistency without supporting evidence.
2) For SNP or nucleotide datasets below the threshold determined by validation studies.

The committee edited standard 6.4.1.1 reflecting changes throughout chapter 5 to include requirements for STR testing and SNP/Sequencing testing.

6.4.2 Nonautosomal STR Findings
Nonautosomal **STR** results, when testing for parentage, full sibling, half sibling, avuncular and/or grandparentage relationships, shall be incorporated with autosomal results into the likelihood ratios. In addition to the likelihood ratios, the laboratory shall be permitted to ~~discuss~~ **present** autosomal and nonautosomal **STR** findings separately. Standard 5.3.1 applies.

The committee edited this standard to reflect changes made throughout the edition.

6.4.4 When the organization determines the final conclusion:
1) For large nucleotide datasets, the results of the algorithm analysis shall be presented.
2) For all others, the individual likelihood ratios shall be reported for each independently calculated locus or linked loci **as defined in Reference Standard 6.4 A, Requirements for Test Reports**.

The committee added the crossreference to reference standard 6.4A for completeness.

Reference Standard 6.4A. Requirements for Test Reports

Chain-of-Custody Reports	
I. Identifiers	
5	**Self-declared** race/ethnicity ~~ethnic background~~ used by the laboratory for calculations ~~as designated by the participants~~ or closest available frequency database. Standard 5.2.4.2 applies.

The committee edited entry #5 for parallel construction with edits made to standard 5.2.4.2.

Chain-of-Custody Reports
I. Identifiers

6	The ~~original~~ signature of the laboratory director or director designee.

The committee remove the term "original" as it was deemed redundant.

Chain-of-Custody Reports		
II. Findings		
2	If a statement of no relationship 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.

The committee elected to remove the term "statistics" from the edition as it was deemed too restrictive.

Chain-of-Custody Reports		
II. Findings		
3	**Traditional Relationship Testing** If there is a failure to exclude and the likelihood ratios meet the established reporting policies for the indices obtained for the tested relationship (Standard 5.3.8 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, and other loci **solely tested** for **quality control of biological sex** ~~gender~~ determination, as defined in Standard 5.5 (Standards 5.3.11 and 5.3.12 apply).
		4) The probability of relationship expressed as a percentage. **All probabilities are less than 100% as a statistical reality**. The prior probabilities used to calculate the probability of relationship shall be stated.
		6) When autosomal likelihood ratios are not in agreement with nonrecombining haplotypes, **(see Guidance for Standards for Relationship Testing Laboratories for examples)** ~~(leading to a different conclusion)~~ an explanation of nonautosomal inheritance and limitations of these markers shall be provided.

The committed edited #1 to provide clarity as gender in this case could cause confusion for individuals implementing the standard.

The committee edited #4 to provide clarity that this testing and probability cannot in any way achieve 100% certainty.

The committee edited #6 to ensure users referenced the guidance to the standard for clarity.

Chain-of-Custody Reports

II. Findings		
4	**Non-Traditional Relationship Testing ~~Statistics~~** If there is a failure to exclude and the likelihood ratio meets the established reporting policies for the indices obtained for the tested relationship (Standard 5.3.8 applies)	Then the report shall include the following information for non-traditional relationship **<u>testing</u>** ~~statistics~~:
		2) An explanation of the evaluation, the equivalency to the likelihood ratios, 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. **<u>All probabilities are less than 100% as a statistical reality.</u>** The prior probabilities used to calculate the probability of relationship shall be stated.
		3) ~~When autosomal loci are note tested~~ The conclusion shall not overstate the relationship. **<u>When autosomal loci are not tested</u>**, an explanation of nonrecombining haplotype inheritance and limitations of these markers shall be provided.
		4) When autosomal likelihood ratios are not in agreement with nonrecombining haplotypes **<u>(see Guidance for Standards for Relationship Testing Laboratories for examples)</u>** ~~(leading to a different conclusion)~~, an explanation of nonautosomal inheritance and limitations of these markers shall be provided.
		<u>7) A statement identifying all profiles obtained from a publicly available database where identity has not been verified.</u>

The committee elected to remove the term "statistics" from the edition as it was deemed too restrictive.

The committed edited #2 to provide clarity as gender in this case could cause confusion for individuals implementing the standard.

The committee edited #3 for clarity.

The committee edited #4 to ensure users referenced the guidance to the standard for clarity.

The committee added new #7 to the reference standard for completeness. This ensures that reports provided for non-traditional relationship testing using publicly available databases indicate where the identity has not been affirmed.

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.

The committee removed the term "appropriate" as it was deemed redundant.

10.1.2 ~~Storage space for~~ Critical materials, products, samples, and records shall be ~~adequate~~ **<u>stored in a manner to maintain integrity</u>** ~~to meet specified requirements~~ and to prevent mix-ups.

The committee edited standard 10.1.2 for clarity, the intent of the standards has not changed.

~~**10.1.3** The infrastructure for communication and information management shall be adequate to~~

~~support the needs of the organization and its customers.~~

Standard 10.1.3 was deleted with the inclusion of new standard 3.8.

QSE 1 – Organization

Key Concepts

This quality system essential (QSE) describes the responsibilities of executive management, the nature of the quality system, and the need for ongoing attention to operational and quality issues through demonstrated management commitment.

Key Terms

Customer: The recipient of a product or service. A customer may be internal (eg, another organizational unit within the same organization) or external (eg, a patient, client, donor, or another organization).

Emergency Management: Strategies and specific activities designed to manage situations in which there is a significant disruption to organization operations or a significantly increased demand for the organization's products or services.

Executive Management: The highest-level personnel within an organization, including employees, clinical leaders, and independent contractors, who have responsibility for the operations of the organization and who have the authority to establish or change the organization's quality policy. Executive management may be an individual or a group of individuals.

Organization: An institution, or a location or operational area within that organization; the entity assessed by the AABB and receiving AABB accreditation for specific activities.

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

Procedure: A defined series of tasks and instructions that specify how an activity is to be performed.

Process: A set of related activities that transform inputs into outputs.

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

Examples of Objective Evidence

- Policies, processes, and procedures related to this chapter.
- Organizational charts or documents describing roles, responsibilities, and decision-making authority.
- Evidence of executive management review of a quality system.
- Applicable federal, national, state, and local laws and regulations, as well as copies of any required certificates.
- Defined quality system.
- Process for approving exceptions to policies, processes, and procedures, as well as documented examples, if applicable.
- Risk assessments and mitigation strategies.
- Emergency operation and disaster continuity plan(s).
- Executive management review of customer feedback.

1.0 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 RT Standards and applicable laws and regulations, including all applicable current good manufacturing practice (cGMP) requirements.
3) Authority to establish or make changes to the quality system.
4) Responsibility to conduct scheduled management reviews to assess the effectiveness of the quality system.
5) 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-accredited (or equivalent) laboratory or under the guidance of a laboratory director currently or previously employed in an accredited laboratory. Participation in proficiency testing shall be part of the training/experience. Where indicated, the laboratory director may delegate responsibilities to another qualified individual; however, the laboratory director shall retain ultimate responsibility for laboratory director duties.

1.1.1.1.1 In cases where the director candidate's 2 or more years of experience is not in a laboratory accredited by AABB, exceptions shall be evaluated on a case-by-case basis by the Relationship Testing Accreditation Committee. Standard 1.1.7 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 purpose shall be further qualified by training or experience to serve in the role of laboratory director for the purposes

of these RT Standards. The technical leader shall have 3 years of training/experience in relationship testing in an AABB-accredited (or equivalent) relationship testing laboratory or under the guidance of a laboratory director
currently or previously employed in an accredited laboratory. Participation in proficiency testing shall be part of the training/experience.

1.1.4.1 In cases where the experience of the director candidate is not in a laboratory accredited by AABB (or equivalent), exceptions shall be evaluated on a case-by-case basis by the Relationship Testing Accreditation Committee. Standard 1.1.7 applies.

1.1.5 Laboratory Director Oversight

The laboratory director shall oversee a maximum of 10 accredited facilities. No more than five of these facilities shall be testing laboratories, with the remainder being accredited collection/verification facilities.

1.1.5.1 The 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.

1.1.6 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.

1.1.7 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. All such policies, processes, and procedures shall be in writing or captured electronically and shall be followed.

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 RT Standards. All such policies, processes, and procedures shall be in writing or captured electronically and shall be followed.

1.3.1 The medical director and/or laboratory director (as applicable) 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 Risk Assessment

The organization shall have a process in place to perform risk assessments for activities at defined intervals.

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

1.4.2 The organization shall assess:

1) Potential threats for fraud and/or loss of sample integrity associated with the collection of a tested person's sample.
2) Potential threats to continuity of technology and communication infrastructure.

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 an 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.

1.9 Organization Status Changes

The organization shall communicate to AABB within 30 days a change that directly or indirectly impacts an organization's accreditation status, including if a laboratory ceases operations.

1.9.1 If the organization is the subject of regulatory enforcement action by a relevant Competent Authority, they shall notify AABB within 7 days of receipt of notification.

Excerpt of Reference Standard 6.2.9A Relevant to Organization

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
1.1.6	Supervisor qualifications and experience	5
1.1.7	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)

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 Clinical Laboratory Improvement Amendment (CLIA) regulations], and continuing education requirements.

Key Terms

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

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 (eg, 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 RT 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 RT 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.

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 RT 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.

Excerpt of Reference Standard 6.2.9A Relevant to Resources

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 information 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 the 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.

3.3.1 If the manufacturer's written instructions are not followed, the equipment shall be validated for its intended use.

✎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.

3.5.2 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 the 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 affected, 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) Numeric designation of system versions with inclusive dates of use.
2) Validation/verification/qualification of system software, hardware, databases, and user-defined tables before 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 the donor, the product or service, and the 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 alternative 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 the use of the system.

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 internal and external data breaches.

✎3.8 Technology Infrastructure

The organization shall have an active program to ensure that critical technology and communication infrastructures function as intended, including risk-based monitoring or testing at organization defined intervals. Standards 1.4, 1.5, and 1.6 apply.

Excerpt of Reference Standard 6.2.9A Relevant to Equipment

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
3.8	Monitoring of organization technology infrastructure	5

[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 suppliers and customers. 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).

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 a 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, are 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.

4.1.4 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 any genetic profile(s), that laboratory shall be accredited by the AABB or an 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 RT 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) Marketing materials and claims as defined by standard 6.5.
5) Use of the laboratory's name and accreditation status.
6) Initiation of cases for immigration, visa, passport, and citizenship testing adjudicated by an agency of the United States of America.

Standards 5.2.3.5, 6.5.4, and 6.5.5 apply.

4.2.3.1.1 Third party administrators are prohibited from initiating testing activities for immigration, visa, passport, and citizenship testing adjudicated by an

agency of the United States of America unless accredited by AABB. Standard 5.2.3.5 applies.

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.

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

4.4.2 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*.

4.5 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.

Excerpt of Reference Standard 6.2.9A Relevant to Suppliers and Customers

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
4.4.1	Corrective action when specified requirements are not met	5
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 its 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 (eg, 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 revalidation 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.

5.1.6.1 If the manufacturer's written instructions are not followed, the material shall be used in accordance with the laboratory's validated procedures for the intended use.

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.

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

5.1.8.2 The organization shall have a policy that mitigates the potential risk for fraud

or loss of sample integrity. Standard 1.4 applies.

5.1.8.3 The organization shall evaluate and respond to suspected altered or fabricated documents misrepresenting identity, including but not limited to, borrowed or fraudulent identification documents presented at the time of collection, official United States of America government paperwork or fabricated relationship determination reports.

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) A sample exchange with an accredited relationship testing laboratory demonstrating concordant results of at least 12 questioned relationships that are representative of the casework performed by the laboratory seeking accreditation.

5.1.10.2 The laboratory shall participate in graded proficiency testing for the assignment of phenotypes or genotypes 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) On a quarterly basis, test known samples that were originally tested when graded proficiency testing was available.
2) On a quarterly basis, test 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) On a quarterly basis, test known samples that were originally tested when graded proficiency testing was available.
2) On a quarterly basis, test 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 For non-traditional relationship testing:

3) When a formal graded proficiency testing program is available, a test that grades on consensus or conclusion is acceptable.
4) When a formal graded proficiency testing program is not available, the laboratory shall use one of the following methods:
   a) On a quarterly basis, test known samples that were originally tested when graded proficiency testing was available.
   b) On a quarterly basis, test a standard trio of samples developed from persons of an undisputed relationship.
   c) Participate three times a year in a sample exchange program.

5.1.10.7 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, a 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.

5.1.12.2 The laboratory shall have a policy for the return and/or destruction of samples in accordance with applicable local laws, jurisdiction, regulations, and case type.

5.1.12.2.1 The laboratory shall define what is considered a sample versus work product.

5.1.12.2.1.1 This shall include determining requirements for traceability and final

disposition of a sample and/or a work product.

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.

5.2.1.1 The laboratory shall inform the tested person or their legal representative of the potential additional use of their sample and profile beyond the originally requested relationship testing and, where legally required, obtain consent.

5.2.1.2 If the laboratory maintains a profile database for the purpose of genetic genealogy or allows for the sharing of profiles for law enforcement purposes, a distinct consent acknowledging inclusion shall be made available to the tested person or their legal representative.

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 or other potentially interested individual(s) 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 individual(s) who performs collections is trained. Standard 2.1.3 applies.

5.2.2.4 Samples intended for immigration, visa, passport, and citizenship testing cases adjudicated by an agency of 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's legal representative.

5.2.3.3 All packaging and transfer of samples shall be performed by a person with no interest in the test outcome.
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 adjudicated by an agency of the United States of America shall be accepted only if the case is initiated directly between the petitioner and an organization accredited by AABB for relationship testing activities. Records of the initiation of this service by the petitioner shall be maintained in the organization's records. Standard 5.1.8.1 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 5.1.8.1 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 legal representative signing consent for the tested person.

5.2.4.2 Self-declared race/ethnicity 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 legal representative signing consent for the tested person:

1) Valid government-issued photo identification (ID).
2) Photograph that is suitable for positive ID.

5.2.4.7.1 For cases intended for immigration, visa, passport, and citizenship adjudicated by an agency of 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 where the sample cannot be obtained according to Standards 5.2 through 5.2.4.7 (eg, prenatal sample, coroner's sample, or samples provided by law enforcement agencies), documentation of chain-of-custody shall be obtained.

5.2.5.1 The laboratory shall have a policy for the receipt of samples that have not been obtained according to standards 5.2 through 5.2.4.7 which includes an evaluation of the provider and accreditation status, if applicable.

5.2.5.2 For genetic genealogy cases, the laboratory shall identify on the final report all profiles obtained from a publicly available database where identity has not been verified.

5.3 Testing and Results

5.3.1 Autosomal short tandem repeat (STR) markers shall be used to evaluate a relationship unless one of the following conditions exists:

1) Results for autosomal STR markers are not obtained.
2) Results for nonautosomal STR markers exclude the relationship.
3) Autosomal STR markers are not expected to be informative because the hypothesized relationship is beyond second order.
4) Non-traditional testing methods are used for determination of relationship.

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

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

5.3.4 The laboratory shall use STR markers with chromosomal locations that are recorded in

scientific literature.

5.3.5 The laboratory shall use genetic markers characterized by validation studies.

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 (and not supporting the alternative).

5.3.7.2 Likelihood ratios from 0.1 to 1 through 10 to 1 shall be considered inconclusive for any relationship. When reporting inconclusive results, the laboratory shall have attempted a minimum of 20 autosomal 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 report shall include 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 nontraditional relationship testing, the laboratory shall provide an explanation of the evaluation, the equivalency to the likelihood ratio of 100 to 1, and the statistical method(s) used. Standard 5.3.11.3 applies.

5.3.10 Before releasing any report supporting the alternate hypothesis:

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 to include an independent isolation. For closed systems, Standard 5.4.2 applies.

5.3.10.2 For nonparentage cases where the genetic evidence supports the alternate hypothesis, 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 STR methods, new STR multiplex kits, or loci (or locus) added to existing 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/or between laboratories involved in sample exchange. 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..

5.3.13.2.1 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.

5.3.13.3 For new or novel methods, including SNP or nucleotide sequencing, part of the validation process shall require the analysis of an organization defined number of biological samples to demonstrate that the method performs as expected with accuracy and reproducibility of test results within the laboratory and/or between laboratories involved in sample exchange. 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. Validation studies shall be reviewed and accepted by the RT SC of the AABB before implementation.

5.3.13.3.1 For nucleotide sequencing methods, a number of samples shall be determined in the validation plan to demonstrate:
1) Nucleic acid quality and quantity.
2) Library qualification and quantification.
3) Depth of coverage.
4) Uniformity of coverage.
5) Cluster density and alignment rate.

6) Mapping quality.

5.3.13.4 For addition of loci to novel methods, including SNP or nucleotide sequencing to existing test methods, the validation process shall require the analysis of an organization defined number of biological samples, with accuracy and reproducibility of test results within the laboratory.

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 in a case employs only methods 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 methods that have been subjected to validation studies. The laboratory shall demonstrate reproducibility of test results.

4) A known human DNA control shall be tested with each analysis.
5) Stringency conditions determined during validation shall be used to ensure accurate allele determination.
6) 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

1) Unless an expert system is used, all 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 shall 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 for 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 4.3 applies.
7) The laboratory shall have policies and procedures to evaluate contamination, artifacts, and preferential amplification for each sample.
8) Postamplification products shall be prevented from contaminating preamplification materials.

5.4.1.2 Nucleotide Sequence Determination or SNP Analysis

1) When an expert system is used to interpret the SNPs or other nucleotide datasets, 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 or other nucleotide datasets, 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 and amplified with samples and used to monitor for sample contamination and work product contamination. A DNA quantification threshold shall be established by validation studies that demonstrate an acceptable negative control (eg, before sequencing, before library prep).
7) Postamplification products shall be prevented from contaminating preamplification materials.
8) When STR alleles are determined by nucleotide sequencing, Standard 5.4.1.1 applies.

5.4.2 Closed Systems

A laboratory performing DNA testing using a closed system shall:

5.4.2.1 Identify and investigate 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.

3) No witness or electronic equivalent is documented, as required by Standard 5.4.2.2.

5.5 Calculations

The laboratory shall use calculation methods established by validation studies.

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

5.5.2 When linked loci are used for calculating traditional relationship testing, the laboratory shall estimate and minimize the effects of linkage on nonparentage 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 Calculations and Datasets

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 for Standards for Relationship Testing Laboratories*, and
2) Two-party nonparentage calculations (see Standard 5.3.7).

Standard 3.7 applies.

5.5.5.2 Datasets containing, but not limited to, macros, allele or haplotype frequencies and mutation rates shall be verified for concordance and/or accuracy. Datasets shall be developed in-house, published, or imported with a sample exchange.

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

5.5.5.2.2 The sample size from which datasets are developed shall be scientifically adequate.

5.5.5.2.3 The laboratory verifying an imported dataset by sample exchange shall share a minimum of 20 samples from unrelated individuals with the laboratory that originally verified the dataset. The dataset shall be verified 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 or to evaluate SNP or other nucleotide datasets, 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 evaluates alleles, SNPs, or other nucleotide datasets 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 samples.
3) Demonstration that the expert system produces complete concordant results for at least 100 samples that contain artifacts or other anomalies requiring human review.

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.

Excerpt of Reference Standard 6.2.9A Relevant to Process Control

Standard	Record to Be Maintained	Minimum Retention Time (Years)[1]
5.1.1	Validation of new or changed processes and procedures	5
5.1.2	Quality control records and review of quality control results	5
5.1.8	Identification and traceability of products	5
5.1.8.2	Mitigation policy of potential risks for fraud or loss of sample integrity.	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 2 years or concordant results with a relationship testing laboratory accredited by the AABB (or equivalent accrediting body) for sample exchange of at least 12 blinded cases	5
5.1.10.4	Quarterly testing of samples	5
5.1.10.5	Quarterly testing of samples	5
5.1.10.6	Quarterly testing of samples	5
5.1.10.7	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 are received from an AABB-accredited relationship testing organization 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 the tested person. 3) Place, date, and type of sample collected.	5

	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 the 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 the tested person: a) Government-issued photo ID. b) Photograph that is suitable for positive ID. 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 ID for immigration, visa, passport, and citizenship adjudicated by an agency of the United States of America	5
5.2.5	Chain-of-custody where sample cannot be obtained according to these *RT Standards*	5
5.3.1	Loci used to evaluate relationship	5
5.3.5	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 nucleic acid testing for STRs	5
5.4.1.2, #4	Defined conditions of amplification, hybridization, and detection for SNPs	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 be retrieved and located 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 a 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,* including 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 backup 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 RT 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 RT Standards are performed.
5) Are not used when deemed invalid or obsolete.
6) Are identified as archived or obsolete when appropriate.

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 RT 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 of 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 ensures accessibility and retrievability.

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 RT 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 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 the 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 RT Standards shall be retained for a period 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 time frame.

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 Backup Data
The organization shall back up all critical data.

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

6.3.4.2 Backup data shall be protected from unauthorized access, loss, or modification.

6.3.4.3 The ability to retrieve data from the backup 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 organization 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:

1) For STR on the basis of a single inconsistency without supporting evidence.
2) For SNP or nucleotide datasets below the threshold determined by validation studies.

6.4.1.2 Genetic inconsistencies shall be incorporated appropriately into the calculations and reported 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 STR Findings

Nonautosomal STR results, when testing for parentage, full sibling, half sibling, avuncular and/or grandparentage relationships, shall be incorporated with autosomal results into the likelihood ratios. In addition to the likelihood ratios, the laboratory shall be permitted to present autosomal and nonautosomal STR findings separately. Standard 5.3.1 applies.

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 organization 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 organization, the accredited organization 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 organization determines the final conclusion:

1) For large nucleotide datasets, the results of the algorithm analysis shall be presented.
2) For all others, the individual likelihood ratios shall be reported for each independently calculated locus or linked loci as defined in Reference Standard 6.4 A, Requirements for Test Reports.

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 4.2.3.1, 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 organization 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 organization shall be truthful in advertising its accreditation status and its implications.

6.5.4 The organization 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 organization or through cooperative agreement with a third party.

6.5.5 The organization 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 organization or through cooperative agreement with a third party. Usage shall be restricted to the accredited organization'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.

Excerpt of Reference Standard 6.2.9A Relevant to Documents and Records

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. Retention of Records

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
1.1.6	Supervisor qualifications and experience	5
1.1.7	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 description	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
2.1.5.1	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
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
3.8	Monitoring of organization technology infrastructure	5
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

4.4.1	Corrective action when specified requirements are not met	5
4.5	Quality control of critical supplies and reagents	5
5.1.1	Validation of new or changed processes and procedures	5
5.1.2	Quality control records and review of quality control results	5
5.1.8	Identification and traceability of products	5
5.1.8.2	Mitigation policy of potential risks for fraud or loss of sample integrity.	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 2 years or concordant results with a relationship testing laboratory accredited by the AABB (or equivalent accrediting body) for sample exchange of at least 12 blinded cases	5
5.1.10.4	Quarterly testing of samples	5
5.1.10.5	Quarterly testing of samples	5
5.1.10.6	Quarterly testing of samples	5
5.1.10.7	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 are received from an AABB-accredited relationship testing organization 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 the tested person. 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

	5) Printed name, signature, and contact information of the person verifying the 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 the tested person: 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 adjudicated by an agency of the United States of America	5
5.2.5	Chain-of-custody where sample cannot be obtained according to these *RT Standards*	5
5.3.1	Loci used to evaluate relationship	5
5.3.5	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 nucleic acid testing for STRs	5
5.4.1.2, #4	Defined conditions of amplification, hybridization, and detection for SNPs	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
6.6	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	Environmental condition monitoring	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.

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	Self-declared race/ethnicity used by the laboratory for calculations or closest available frequency database. Standard 5.2.4.2 applies.	
6	The 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 no relationship is rendered	Then the report shall include the following information:
		1) For traditional relationship testing: the STR loci providing the basis for the finding shall be indicated in the statement of non-relationship.
		2) For nontraditional relationship testing: the number of loci tested, the number of informative loci, if applicable, and the minimum percentage of loci that successfully yielded a result.
3	**Traditional Relationship Testing** If there is a failure to exclude and the likelihood ratios meet the established reporting policies for the indices obtained for the tested relationship (Standard 5.3.8 applies)	Then the report shall include the following information for traditional relationship testing:
		1) The phenotypes of tested individuals for all loci that meet the laboratory's minimum performance thresholds, as applicable, with the exception of amelogenin, and other loci solely tested for quality control of biological sex determination, as defined in Standard 5.5 (Standards 5.3.11 and 5.3.12 apply).
		2) The individual likelihood ratios for each locus or group of loci used in the conclusion.
		3) The combined likelihood ratio.
		4) The probability of relationship expressed as a percentage. All probabilities are less than 100% as a statistical reality. The prior probabilities used to calculate the probability of relationship shall be stated.

		5) When autosomal loci are not tested, the conclusion shall not overstate the relationship. An explanation of nonrecombining haplotype inheritance and limitations of these markers shall be provided.
		6) When autosomal likelihood ratios are not in agreement with nonrecombining haplotypes, (see Guidance for Standards for Relationship Testing Laboratories for examples) an explanation of nonautosomal inheritance and limitations of 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.
4	**Non-Traditional Relationship Testing** If there is a failure to exclude and the likelihood ratio meets the established reporting policies for the indices obtained for the tested relationship (Standard 5.3.8 applies)	Then the report shall include the following information for non-traditional relationship testing:
		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 likelihood ratios, 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. All probabilities are less than 100% as a statistical reality. The prior probabilities used to calculate the probability of relationship shall be stated.
		3) The conclusion shall not overstate the relationship. When autosomal loci are not tested, an explanation of nonrecombining haplotype inheritance and limitations of these markers shall be provided.
		4) When autosomal likelihood ratios are not in agreement with nonrecombining haplotypes (see Guidance for Standards for Relationship Testing Laboratories for examples), an explanation of nonautosomal inheritance and limitations of 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.
		7) A statement identifying all profiles obtained from a publicly available database where identity has not been verified.
5	If there is a failure to exclude and results are unusual, inconclusive, or involve relationship testing other	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.

	than parentage and do not meet Standard 5.3.8	2) A statement supporting no relationship.
		3) An inconclusive finding.
6	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 of, management of, and response to deviations, nonconformances, or adverse events. This also includes the need to maintain records of resolution.

Key Terms

Adverse Event: A complication. 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 organization's products or the safety 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 Cause(s): 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 (eg, 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 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.

Excerpt of Reference Standard 6.2.9A Relevant to Deviations, Nonconformances, and Adverse Events

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, 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

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

QSE 8 – Internal and External Assessments

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. 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 the 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 Cause(s): 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.

Excerpt of Reference Standard 6.2.9A Relevant to Internal and External Assessments

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. 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 Cause(s): 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 affect the organization's current and future operations.
- Records indicating that corrective and preventive action was taken.
- Records indicating that corrective and preventive action taken was effective and is being monitored.
- Documentation that process improvement data are 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 cause(s) 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.

9.1.1 Investigation and corrective action shall include consideration of deviations, nonconformances, and complaints.

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.

Excerpt of Reference Standard 6.2.9A Relevant to Process 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 *Out-of-Hospital and Prehospital Standards* is performed. This includes occupational safety, biohazardous material 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 Critical materials, products, samples, and records shall be stored in a manner to maintain integrity and to prevent mix-ups.

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 organization. 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.

Excerpt of Reference Standard 6.2.9A Relevant to Facilities and Safety

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: Where 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.

Artifact: A non-allelic product of the amplification process, an anomaly of the detection process, or a byproduct of primer synthesis that may be observed in data.

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.

Avuncular: Pertaining to an uncle or aunt.

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 an organization or a service offered by that organization is accredited. Claims may appear in any information made available by the organization 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 preassembled 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 Organization: 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.

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 recipient of a product or service. A customer may be internal (eg, another organizational unit within the same organization) or external (eg, a patient, client, donor, or another organization).

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

Database: In the context of these RT Standards, "database" means the source of the population data used to provide 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.

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.

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

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, including artificial intelligence software.

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 Genealogy: Determination of biological relationship through the combined application of DNA analysis, databases, historical records, and/or other data sources.

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 relationship.

Independent Locus or Group of Loci: When the inheritance of the alleles of any loci 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.

Initiate: Direct contact between the petitioner (or other parties permitted under current US immigration rules) and the accredited organization 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 the 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 organization and laboratory are used interchangeably in these RT Standards. See Organization.

Laboratory Director Designee: An individual with a doctoral degree in medicine, biology, chemistry, genetics, or clinical laboratory science authorized by the laboratory director to perform assigned tasks. A technical leader may act as a designee under a laboratory director in an accredited forensic laboratory. This can include individuals working to complete their training to serve as a laboratory director.

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 father vs 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, including 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 a serious 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: 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 (eg, shared centimorgans). These are typically used for very large SNP or other nucleotide datasets. See Traditional Relationship Testing.

Nonconformance: Failure to meet requirements.

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).

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, or a location or operational area within that organization; the entity assessed by the AABB and receiving AABB accreditation for specific activities.

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 RT 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 US 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.

Regulatory Enforcement Action: Measures taken by a Competent Authority that include but are not limited to progressive measures (eg, suspension or termination of operations, information notices requiring specific documentation or data, fines incurred) or critical triggers (eg, pattern of recurrent, unresolved issues, deficiencies in risk management systems.)

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 Cause(s): 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 percentage 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 an LR of 10 to 1, and 60 out of 100 half-siblings exceed 10 to 1, 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.

Specificity: The percentage of random pairs with likelihood ratios (LRs) 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 an LR of 10 to 1, and 98 out of 100 comparisons are less than 10 to 1, the specificity is 98%.

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

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 1.1.4.

Tested Person: The individual from whom a sample is being collected.

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: 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 (eg, shared centimorgans). These are required for standard STR loci, HLA types, and blood types, but may also be applied to other methods. See Non-Traditional Relationship Testing.

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.

Work Product: The material that is produced as a result of DNA analysis, which may include extracts, amplified products and amplification tubes or plates as defined by the laboratory.