Significant Changes and Response to Comments Received to the 16th edition of Standards for Relationship Testing Laboratories

Please note that public comments that were submitted address the proposed 16th edition of Standards for Relationship Testing Laboratories (*RT Standards*), and not the final version. The RT Standards Committee has elected to make the substance of public comments that were submitted a part of this document. Guidance that appears with the 16th edition of *RT Standards* in the Standards Portal provides a more in-depth look at the additions, deletions and changes and the rationales behind those decisions than what appears below.

Standard (15th edition)	Significant Change (SC)/Response to Comment (RtC)	Comment	Change made?	Outcome
General	SC	NA	NA	The 16th edition of Standards for Relationship Testing Laboratories incorporates AABB's updated Quality System Essentials (QSEs). The updated quality system essentials include the following updates: • All standards are written in the active voice. • Once a requirement has been stated, it is not repeated. • Each chapter begins with a description of what the standards therein cover. • Each chapter contains a list of key terms that relate to the content of the chapter, with their definitions. • Each chapter contains a list of examples of objective evidence that an assessor could look for during an on-site assessment; however, this list is not comprehensive, nor will it be assessed against by an assessor. It is merely for guidance purposes only. • Each chapter now concludes with the record retention table for that chapter. Note that a comprehensive record retention table still exists at the end of Chapter 6.

1.1.1.1.1 (New)	SC	NA	NA	The committee created new standard 1.1.1.1.1 in the 16th edition to allow for individuals that wish to serve as a laboratory director but do not work in an accredited laboratory, to have their candidacy reviewed by the RT Accreditation Committee and deemed equivalent or not. The new standard reads as follows: **1.1.1.1.1** In cases where the director candidate's 2 or more years of experience is not in a laboratory accredited by AABB, exceptions shall be evaluated on a case-by-case basis by the Relationship Testing Accreditation Committee. Standard 1.1.6 applies.
1.1.1.1.1 (New)	RtC	We suggest that in the Guidance to the Standards that a list be presented of accreditation bodies that would be considered "equivalent". This information is known. "Equivalent" without such list is not helpful.	NO	The committee noted this comment but did not make a change at this time. At this time, there are no equivalent accreditations available, but should one become available, they would be added to the guidance in the Standards Portal. This would require the organization claiming equivalence to provide evidence to that effect.
1.1.1.1.1 (New), 1.1.4.1 (New)	RtC	We suggest that standards 1.1.1.1.1 and 1.1.4.1 be deleted. These additions and modifications greatly diminishes the quality of AABB accreditation program, the quality of Laboratory Operations and the Public trust. Exceptional qualifications are necessary to be the AABB accredited RT Lab Director (see RT Stds 1.1.1.1 and 1.1.4). The ability to achieve this title requires a great deal of support and mentorship for he/she and their lab to be successful. I do not believe AABB has a path or written procedures to accommodate and support this type of candidate nor does the AABB Accreditation Committee have the qualifications to assess if an individual without documented training by a RT Lab Director, who is qualified to be RT Lab Director. If the RT Std Committee still believes that the 2-year experience is not necessary for certain individuals, then the nominee's qualifications should be presented to all RT Laboratories for unanimous vote. Otherwise, delete these proposed standards.	NO	The committee noted this comment but did not feel that a change would be appropriate at this time. The committee does not feel that allowing for equivalence to be demonstrated by petitioning individuals ensures that qualified candidates are not ignored due to circumstances beyond their control. The AABB does have procedures for determining equivalence for these types of roles for other sets of Standards and the expertise of the individuals that sit on the AABB's Relationship Testing Accreditation Committee is appropriate to the task.
1.1.1.1.1 (New), 1.1.4.1 (New)	RtC	A strong case could be made for Quality Managers/RT Lab Supervisors qualifications to allow these professionals to sign Legal DNA test reports. This recommendation has been previously submitted for the 14th, 15th and 16th Ed RT Stds. '	NO	The committee noted this comment but did not feel that a change was appropriate. The committee does not agree with the assertion that because an individual with equivalent credentials to that required to serve in the

		Quality Managers and RT Lab Supervisor with a Master's degree and relevant training and experience have full knowledge of the testing and reporting requirements and the lab's quality system and thresholds, and they certainly are capable of serving in Expert Witness Testimony. RT Lab Directors should be given the sole authority to train and determine if a Quality Manager and/or a RT Lab Supervisor are qualified to sign Legal DNA Test reports. A Quality Manager and a RT Lab Supervisor with specific credentials can be fully-qualified to certify the accuracy and validity of DNA test results for any Legal proceeding. As reference, the FBI QAS and CLIA allow non-PhD's/non-MD's with relevant experience to act as Certifying Scientists. Why not AABB? The proposal also models from practices by CLIA Forensic Toxicology Labs. For instance, the proposal included that (like CLIA Forensic Tox Labs) reports signed by a Certifying Scientist have the name and title of the RT Laboratory Director printed on a prominent location in addition to the Certifying Scientist's name and signature. Furthermore, in extension to the earlier proposals, the scope for the Quality Manager/RT Lab Supervisor role in the reporting process can also be modeled after federally regulated toxicology reports from SAMHSA/HHS certified labs that allows MRO Assistants to process 75% of the reports with normal test results with the MRO personally reviewing/signing 25% of the normal reports and 100% of eventful cases. Thus, for Legal DNA Testing the scope could be limited to uneventful, inclusionary Parentage Reports and RT Directors personally reviewing and signing 25% of the parentage reports and all the reports with adverse test results and special circumstances (e.g., single inconsistencies). Under this model, the RT Director(s) might also be required to review/sign ALL the reports if this is a requirement by an Officially Interested Third-Party (e.g. a federal agency or a court-order). Our proposal retains the RT Lab Director Qualifications and requirement as well as the requirement that qualified Staff may act as Interim/Successor RT Lab Director (namely the RT Director Designee position). Please explain the rationale for declining to make this change previously, while now proposing that inexperienced individuals could serve as RT Lab Director. For the latter, RT Lab Director of an AABB Accredited RT Laboratory is regarded as the most important component of that laboratory; lowering RT Lab Director Requirements undermines the value of the		capacity of a laboratory director that this diminishes the Standards or that the change is the equivalent to adjusting who can present evidence during testimony concerning testing results. As noted, in cases where testimony is called for, the complexity of the cases presented require a PhD level of education when discussing and presenting on genetic testing reports. Maintaining this level of education as a minimum for signing off on an RT Report is an imperative based on the requirements surrounding genetic and relationship testing appearing throughout the Standards. If an individual feels that their credentials would meet the level of equivalence for performing this sign off and potential eventual testimony, AABB's Relationship Testing Accreditation Committee would welcome the opportunity to review this individual's qualifications based on education, training and experience.

		accreditation program generally and weakens the trust of both requesting agencies and the public.		
1.1.3 (1.2.3)	RtC	Is this standard meant for a different purpose than what is written with in the 1.1.1? If not, it is repetitive. If it is, clarification would help to know what is meant by a designee.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that standard 1.1.3 is not redundant per standard 1.1.1, specifically because a laboratory can have multiple individuals with the credentials to serve as a laboratory director or designee is appropriate, especially in terms of coverage. It should be noted that these individuals can serve in the capacity of RT laboratory director trainees as well. Having a designee available when the laboratory director is not present ensures that coverage is always available. To provide as much clarity as possible, the RT Standards Committee provided a new definition in the Glossary of the term "Laboratory Director Designee" which is included below: **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.
1.1.4 (1.2.4)	SC	NA	NA	The committee elected to edit the wording of standard for clarity. The committee added the term "further" to the standard for clarification noting, that the FBI QAS Standards provide information, that are then later expanded upon in the continuation of the standard. The term "education" was removed from the standard as well, as this term is included in the FBI QAS Standards, and to maintain it in the standard could cause confusion for laboratories thinking they would need to determine additional educational requirements.

1.1.4 (1.2.4)	RtC	The Forensic Technical Leaders of a forensic DNA Lab Accredited by FBI QAS Standards are professionals with exceptional qualifications (both by education and relevant training/experience). The 3 years training/experience requirement may be justified to be reduced to 2 years.	NO	The committee noted this comment but did not feel that a change was needed at this time. Of note, in the three years that a forensic technical leader will see the same amount of tests that a laboratory director will see in two years. As a part of ensuring that the standard is as clear as possible, the committee has adjusted this standard to focus the educational requirements on the requirements contained in the FBI QAS and not something determined by the laboratory themselves.
1.1.4.1 (New)	SC	NA	NA	The committee created new standard 1.1.4.1 to allow for individuals that wish to serve as a laboratory director but do not work in an accredited laboratory, to have their candidacy and equivalence reviewed by the Relationship Testing Accreditation Committee. The language of the new standard reads as follows: **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 1.1.6 applies.
1.3.2 (New)	SC	NA	NA	The committee added standard 1.3.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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.
1.4.1 (1.6.1)	SC	NA	NA	The committee revised standard 1.4.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **1.4.1** Mitigation strategies shall identify, assess, and address the level of risk associated with quality and safety.

2.1.4 (2.1.3)	SC	NA	NA	The committee revised standard 2.1.4 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**2.1.4 Competence** Evaluations of competence shall be performed before independent performance of assigned activities and at specified intervals.
2.2	SC	NA	NA	The committee elected to edit standard 2.2 for clarity. The intent of the standard has not changed. The standard now reads as follows: **2.2 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	RtC	Suggest replacing "remaining may be" with "remainder being accredited".	YES	The committee reviewed this comment and agreed with the request and the change was made.
2.2	RtC	Please address the potential conflicts associated with a relationship testing laboratory director involvement in the proficiency testing program of the facilities they oversee. Partial facilities are likely to be on the same proficiency program as the laboratory performing the testing. If the laboratory director oversees the proficiency testing program of several testing laboratories (up to 5), how can each laboratory perform and report independently the testing when the same RT Lab Director is reviewing their data? RT Standards do not address this situation.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee does not believe that there appear to be an ethical issue in the description provided. However, in the case where a laboratory director finds a proficiency test that is incorrect that they should review all other tests. This occurrence should be covered by the laboratory's policies, processes and procedures. The laboratory director in this case should follow the standards focused on proficiency testing (5.1.10 – 5.1.10.6) and respect the independence of the laboratories in question.
3.1 (New)	SC	NA	NA	The committee added standard 3.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.1 Equipment Specifications** Equipment specifications shall be defined before purchase.

3.5.3 (New)	SC	NA	NA	The committee added standard 3.5.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.5.3** The organization shall: 1) Define cleaning and sanitation 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, #2 (New)	SC	NA	NA	The committee added standard 3.5.4, #2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.5.4 Investigation and Follow-up** Investigation and follow-up of equipment malfunctions, failures, or adverse events shall include: 2) Assessment of the effect on the safety of individuals affected. This appears as a part of the investigation and follow up requirements concerning equipment malfunction.
3.5.4, #3 (3.4.3, #2)	SC	NA	NA	The committee revised standard 3.5.4, #3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.5.4 Investigation and Follow-up**

				Investigation and follow-up of equipment malfunctions, failures, or adverse events shall include: 3) Removal of equipment from service, if indicated.
3.5.4, #4 (3.4.3, #3)	SC	NA	NA	The committee revised standard 3.5.4, #4 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.5.4 Investigation and Follow-up** Investigation and follow-up of equipment malfunctions, failures, or adverse events shall include: 4) Investigation of the malfunction, failure, or adverse event, and a determination if other equipment is similarly affected, as applicable.
3.6 (New)	SC	NA	NA	The committee added standard 3.6 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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, #1 (3.5.1, #3)	SC	NA	NA	The committee revised standard 3.7, #1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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.

3.7, #2 (3.5.1, #1)	SC	NA	NA	The committee revised standard 3.7, #2 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**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: 2) Validation/verification/qualification of system software, hardware, databases, and user-defined tables before implementation.
3.7, #4 (3.5, #2)	SC	NA	NA	The committee revised standard 3.7, #4 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**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: 4) Defined processes for system operation and maintenance.
3.7, #5 (3.5, #5)	SC	NA	NA	The committee revised standard 3.7, #5 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**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: 5) Defined process for authorizing and documenting modifications to the system.
3.7, #6 (New)	SC	NA	NA	The committee added standard 3.7, #6 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**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: 6) System security to prevent unauthorized access.
3.7, #7 (3.5, #3)	SC	NA	NA	The committee revised standard 3.7, #7 based on updates to the AABB Quality System Essentials. The standard reads as follows: **✎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: 7) Policies, processes, and procedures and other instructional documents developed using terminology that is understandable to the user.
3.7, #7 (3.5, #3)	RtC	Have removed references to policies, processes, and procedures elsewhere in the document, for consistency purposes, should this be removed here as well?	NO	The committee reviewed this comment but did not feel that a change was needed at this time. In this instance, the committee felt it appropriate to maintain the requirements for having policies, processes and procedures and included in the standard in this way.
3.7, #8 (3.5, #5)	SC	NA	NA	The committee revised standard 3.7, #8 based on updates to the AABB Quality System Essentials. The standard reads as follows: **✎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: 8) Functionality that allows for display and verification of data before final acceptance of the additions or alterations.
3.7, #10 (New)	SC	NA	NA	The committee added standard 3.7, #10 based on updates to the AABB Quality System Essentials. The standard reads as follows:

				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: 10) System design that establishes and maintains unique identity of the donor, the product, or service, and the recipient (as applicable).
3.7, #11 (New)	SC	NA	NA	The committee added standard 3.7, #11 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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: 11) Training and competency of personnel who use information systems.
3.7, #12 (New)	SC	NA	NA	The committee added standard 3.7, #12 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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: 12) Procedures to ensure confidentiality of protected information.
3.7.1 (3.5.2)	SC	NA	NA	The committee revised standard 3.7.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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.
4.1 (4.1)	SC	NA	NA	The committee revised standard 4.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**4.1 Supplier Qualification** The organization shall evaluate the ability of suppliers of critical materials, equipment, and services to meet specified requirements.
4.1.2 (New)	SC	NA	NA	The committee added standard 4.1.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **4.1.2** When a supplier fails to meet specified requirements, it shall be reported to the management with contracting authority.
4.1.4 (4.2.3)	RtC	We feel that this standard is not clear and request that AABB provide a list of equivalent accrediting bodies.	NO	The committee noted this comment but did not feel that a change was needed at this time. The committee feels that the standard as written does read clearly, ensuring that all laboratory testing be performed in an AABB accredited laboratory. Concerning the question of equivalence, there currently is not an equivalent accrediting body, however should one come to exist, they will be listed in the Guidance to the RT Standards.
4.1.4 (4.2.3),	RtC	Without reading the guidance, these standards imply that testing from non-AABB accredited facilities is acceptable on Legal DNA Test reports covered by the AABB Accreditation. The correct wording for RT Std 4.1.4 should be: "Under extenuating circumstances (e.g. an evidence sample at a forensic lab or a biopsy sample at a clinical lab that cannot be transferred to the AABB lab; or a sample collected in a country whose laws do not permit specimen export to the AABB lab), laboratory testing and other services required by these RT Standards shall be performed in a laboratory accredited by either the AABB (or equivalent accrediting body)."	NO	The committee noted this comment but did not feel that the commenter's interpretation of the standards was accurate. The committee notes that at this time there is no equivalent accreditation to AABB accreditation, and therefore any testing from a non accredited AABB laboratory would not be deemed equivalent. However, it is important to note that at a future point there could be an accrediting body that deemed equivalent and that the Standards should reflect that possibility.
4.1.4.1 (4.2.3.1)	SC	NA	NA	The committee edited standard 4.1.4.1 for clarity. The committee elected to replace the clause "test results" with "genetic profiles" as this term provides a more complete picture of what is provided from one laboratory to another.

				It should be noted that genetic profiles include genetic test results among other things. The committee also removed the clause "or other equivalent" before "accrediting body" understanding that there are some tests that are performed by laboratories that are not accredited by AABB but do provide some testing for AABB accredited laboratories.
4.1.4.1 (4.2.3.1)	RtC	This standard is ok as written as long as RT Std 4.1.4 is re-written to clarify its intent. (see above, recommended wording for RT Std 4.1.4)	NO	The committee noted this comment but did not feel that a change was needed at this time. The committee noted this request but did not feel it was appropriate to make this change to standard 4.1.4.1 as it would not be appropriate to make the change suggested to standard 4.1.4.
4.1.4.1 (4.2.3.1)	RtC	Will AABB accept RT results from Labs accredited by other bodies?	NO	The committee reviewed this comment but did not feel that a change was needed at this time. As noted in other rows, if an accrediting body is deemed equivalent to AABB accreditation for these activities, those tests and test results would be acceptable.
4.2.1 (4.3.2)	SC	NA	NA	The committee revised standard 4.2.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **4.2.1** Agreements shall be reviewed at defined intervals to ensure that the terms of agreement continue to meet requirements.
4.2.2 (New)	SC	NA	NA	The committee added standard 4.2.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **4.2.2** Changes to agreements shall be communicated to affected parties.
4.2.3 (New)	SC	NA	NA	The committee added standard 4.2.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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, #6 (4.3.3, #6)	RtC	Please insert the element in quotes below into the existing standard while also adding a crossreference to standard 1.2.2.1 as well. This standard should read: Unless accredited for collection or verification activities by AABB, third-party administrators are prohibited from initiating cases or being involved in the process of selecting a lab and scheduling the appointment cases for United States of America immigration, visa, passport, and citizenship testing. Standards 1.1.2.1, 5.2.3.5 and 6.5 and sub-sections 6.5.1-6.5.5 apply. Comment(s): Part of the above-noted Suggestion was submitted to RT Standards Committee (RTSC) during the initial comment window for the Draft 16th Edition of Standards for Relationship Testing Laboratories. The Draft of 16th Edition (currently in the Public Comment window) has a definition for "Initiate" instead. I am resubmitting the suggestion I made earlier, supplemented with additional information, including an Article for consideration as an Appendix in the 16th Edition Guidance for Relationship Testing Laboratories (for the later, see more details below). In response to my inquiry on standard clarification (as currently written), the AABB Standards Department responded the following: "Nothing in this standard, or the guidance to this standard, prohibits the payment of commissions for referrals from third parties. This standard only prohibits the third party from involvement in the testing process." Actually, this is incorrect and requires remediation as this is an alternative interpretation that is not consistent with the true intent of this standard and the US Department of State policies (DOS) for US Immigration DNA Testing. The Draft of the 16th RT Std Committee also added a definition for the word "Initiate" on the Glossary Section; however, such definition widens the deviation from both the true intent of this standard and the federal government policies. To remediate the deficiencies noted in this standard: i) The element "or being involved in the process of selecting a lab and scheduling the appointment cases" was inserted to realign the interpretation to its true intent. This element was extracted directly from USDOS policy for US Immigration DNA Testing. References: https://travel.state.gov/content/travel/en/us-visas/immigrate/family-immigration/dna-relationship-testing-procedures.html (scroll down to "Step 1:	NO	The committee reviewed this comment but did not feel that a change would be appropriate at this time. The committee notes that the suggested edit would be very difficult to assess or to hold a laboratory to the requirement. In this case, AABB will put the onus on the laboratories to follow the requirements set forth by AABB and the Department of State. For more information please follow this link. As noted in the comment, the committee added the term "initiate" to the standard and to the glossary. Also, when AABB's lead assessor for relationship testing laboratories does in fact review who initiates the testing. Finally, AABB does not review financial information of its institutional members.

		Locating and Accredited Facility"; then click the expand/collapse functionality to expose the content) https://travel.state.gov/content/travel/en/legal/travel-legal-considerations/us-citizenship/US-Citizenship-DNA-Testing.html (scroll down to "DNA Testing Process") ii) Since the word "Initiate" has been identified as the word stirring controversy, I am also proving the correct definition of "Initiate" (see my submission for the Glossary and QSE 4 Term). iii) Since the definition of the word "Initiate" also has an impact on RT Std 5.2.3.5 interpretation, an appropriate element was inserted to refocus back to its true intent (see below, Suggestion for RT Std 5.2.3.5). iv) RT Std 1.1.2.1 is also referenced (see above) to delegate the enforcement to the RT Lab Director of the AABB Accredited Facility (ies) with contractual agreements with non-accredited entities to ensure that his/her lab provides correct guidance to them. v) To assist the proper interpretation of RT 4.2.3.1(6) and 5.2.3.5, I am submitting the "Immigration DNA Testing" article for the Appendix section of the 16th Edition Guidance for Standards for Relationship Testing Laboratories (see below, a detailed description).		
4.3 (4.5), 4.3.1 (New)	RtC	States material should be tested before approval for use and then in 4.3.1, state that the reports can't go out until it is approved. The two statements seem contradictory. 4.3.1 is allowing the use of unchecked reagents to be used on samples before they are approved – at least how it currently reads.	NO	The committee reviewed this comment but does not agree with the statement that the standards are in conflict. The writing of these standards allows for concurrent testing of samples to occur and to ensure that samples are always tested and no reports are issued with untested samples. The committee notes that guidance to these standards are clear on this.
4.3.1 (New)	SC	NA	NA	The committee added standard 4.3.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **4.3.1** Results shall not be released before quality approval of new lots and shipments.
4.4.1	SC	NA	NA	The committee elected to add a title to standard 4.4.1 which reads as follows, "Review of Supplier Promotional Material". This addition of a title was created for the sake of clarity.

4.4.1.1	SC	NA	NA	The committee added a record retention requirement to standard 4.4.1.1 for completeness. This ensures that laboratories maintain documentation of any corrective action put in place when a supplier fails to meet specified requirements covered in the suppliers and customers agreements.
Proposed new standard 4.4.1.2	RtC	I suggest that a new standard be created that reads as follows, "When a Third-Party Administrator fails to meet specified requirements, the laboratory director or his/her designated representative shall take appropriate documented action e.g., provide warning with consequence of termination of the service agreement for repeat offenders. Standards 4.2.3.1 (1-6) and 6.5 and 6.5.1-6.5.5 apply."	NO	The committee reviewed this comment but did not feel the addition would be appropriate. The committee feels that this requirement should be determined by each laboratory and how they conduct their business. The action they take should be defined in the laboratory's policies, processes and procedures. As noted in the description of the change to standard 4.4.1.1, there must be documentation when there is a failure by a supplier to meet the needs of those that they supply.
5.1.3 (New)	SC	NA	NA	The committee added standard 5.1.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1.3 Process Planning** Quality requirements shall be incorporated into new or changed processes, products, 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. The committee noted that laboratories have processes to meet these requirements already.
5.1.4.1 (New)	SC	NA	NA	The committee added standard 5.1.4.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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. The committee noted that laboratories have processes to meet these requirements already.
5.1.5.1 (New)	SC	NA	NA	The committee added standard 5.1.5.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1.5.1** Postimplementation evaluations of new or changed processes and procedures shall be performed.

				The committee noted that laboratories have processes to meet these requirements already.
5.1.6 (New)	SC	NA	NA	The committee added standard 5.1.6 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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. The committee noted that laboratories have processes to meet these requirements already.
5.1.7 (New)	SC	NA	NA	The committee added standard 5.1.7 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1.7 Inspection** The organization shall ensure that products or services are inspected at organization-defined stages. The committee noted that laboratories have processes to meet these requirements already.
5.1.8 (New)	SC	NA	NA	The committee added standard 5.1.8 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1.8 Identification and Traceability** The organization shall ensure that all products or services are identified and traceable. The committee noted that laboratories have processes to meet these requirements already.
5.1.9 (New)	SC	NA	NA	The committee added standard 5.1.9 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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. The committee noted that laboratories have processes to meet these requirements already.
5.1.10 (5.1.2)	SC	NA	NA	The committee elected to replace the term "genetic system" with "locus or group of loci" for accuracy. The use of this clause ensures that the verbiage used matches the language used in the industry by AABB member laboratories. Where the term "genetic system" exists throughout the RT Standards, it has been replaced by either locus, loci or group of loci where appropriate. The standard reads as follows: **5.1.10** 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.
5.1.10.3 (5.1.2.3)	SC	NA	NA	The committee elected to replace the term "genetic system" with "locus or group of loci" for accuracy. The use of this clause ensures that the verbiage used matches the language used in the industry by AABB member laboratories. Where the term "genetic system" exists throughout the RT Standards, it has been replaced by either locus, loci or group of loci where appropriate. The standard reads as follows: **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.
5.1.10.3 (5.1.2.3)	RtC	In standard 5.1.10, it is written, "locus or group of loci", should 5.1.10.3 be rewritten to appear as "locus or group of loci" or is it accurate to have "loci" and "locus" appear as they do in the proposed standard.	NO	The committee reviewed this comment but did not feel that a change was appropriate at this time. The committee notes that there are instances where the term "locus" is appropriate.

5.1.10.4 (5.1.2.4)	SC	NA	NA	The committee elected to replace the term "genetic system" with "locus or group of loci" for accuracy. The use of this clause ensures that the verbiage used matches the language used in the industry by AABB member laboratories. Where the term "genetic system" exists throughout the RT Standards, it has been replaced by either locus, loci or group of loci where appropriate. The standard reads as follows: **5.1.10.4** When no formal graded external proficiency testing program is available for any of the loci used to report test results, the laboratory shall use one of the following methods: 1) Test on a monthly basis known samples that were originally tested when graded proficiency testing was available. 2) Test on a monthly basis a standard trio of samples developed from persons of an undisputed relationship. 3) Participate three times a year in a sample exchange program. Standard 5.1.11.1 applies. Also, in subnumber 1, the committee replaced the term "from" with "originally tested" for clarity.
5.1.10.5 (5.1.2.5)	SC	NA	NA	The committee elected to replace the term "genetic system" with "locus or group of loci" for accuracy. The use of this clause ensures that the verbiage used matches the language used in the industry by AABB member laboratories. Where the term "genetic system" exists throughout the RT Standards, it has been replaced by either locus, loci or group of loci where appropriate. The standard reads as follows: **5.1.10.5** When formal graded proficiency testing programs are available for some but not all loci,

				the laboratory shall test the loci not evaluated by a formal proficiency testing program using one of the following methods: 1) Test on a monthly basis known samples that were originally tested when graded proficiency testing was available. 2) Test on a monthly basis a standard trio of samples developed from persons of an undisputed relationship. 3) Participate three times a year in a sample exchange program. Also, in subnumber 1, the committee replaced the term "from" with "originally tested" for clarity.
5.1.11.1 (5.1.4.1)	SC	NA	NA	The committee elected to replace the term "genetic system" with "locus or group of loci" for accuracy. The use of this clause ensures that the verbiage used matches the language used in the industry by AABB member laboratories. Where the term "genetic system" exists throughout the RT Standards, it has been replaced by either locus, loci or group of loci where appropriate. The standard reads as follows: **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.
5.1.12.1 (5.1.5.1, 5.1.5.2)	SC	NA	NA	The committee added the terms "samples or profiles" to standard 5.1.12.1 for completeness. As a result of the inclusion of these terms, the committee was able to delete standards 5.1.13.1 and 5.1.13.1.1. This edit has not changed the intent of the standards. The standards deleted appeared as such: ~~5.1.13.1 The laboratory shall release an identifiable sample and/or profile of an individual only for purposes relevant to the~~

				~~actual relationship testing for which the sample was submitted.~~ ~~5.1.13.1.1 If additional relationship is requested to be evaluated, a court order or the written permission of the individual(s) who furnished the sample, or the individual(s) with legal authority to provide consent, is required.~~
Proposed new standard 5.1.12.2	RtC	I suggest creating a new standard that would read, "A DNA profile from a sample collected by consent shall not be entered into a database or compared in any way with profiles in a database, without the expressed written consent of the person who is the source of the profile on a standalone affidavit."	NO	The committee reviewed this proposed new standard but did not feel it would be appropriate. Adding this standard would not be possible, as there are instances where cases exist where a judge could compel the individual in question to provide this.
5.2	SC	NA	NA	The committee, in line with the updated quality template, has removed the clause "…have policies, processes and procedures…" for consistency and replaced the clause with the term, "ensure" for the standard to read appropriately. The committee also removed the list of terms included in the standard as they are all covered by the subsequent standards that flow from standard 5.2. The standard reads as follows: **5.2** The laboratory shall ~~have policies, processes and procedures for~~ **ensure:** ~~consent, collection, verification, and acquisition and maintenance of identification records~~.
5.2.2.1 (5.2.2)	SC	NA	NA	The committee created new standard 5.2.2.1 from what was previously the second sentence of standard 5.2.2. The committee moved the term "only" in the standard for legibility. The standard now reads as follows: **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.

5.2.2.1 (5.2.2)	RtC	Suggest modifying the standard as written to appear, "… and/or witnesses not otherwise involved in the case or with the tested individuals. Collection materials shall not be in the possession of any of the tested or potentially interested parties either before or after collection."	NO	The committee reviewed this comment but did not think a change was needed as the content suggested appears in standard 5.2.2.2.
5.2.2.3 (5.2.2.2)	SC	NA	NA	The committee, in line with the updated quality template, has removed the clause, "have policies, processes and procedures" for consistency and replaced the clause with the term "ensure" for the standard to read appropriately. The committee also included the clause "…the individuals who perform…" for completeness and legibility. The standard now reads as follows: **5.2.2.3** The laboratory shall ensure that the individuals who perform collections are trained. Standard 2.1.3 applies.
5.2.2.4 (New)	SC	NA	NA	The committee created new standard 5.2.2.4 at the request of AABB's representative from the State Department to ensure that samples collected at an embassy or consulate are shipped directly to the testing laboratory instead of a third party. The new standard reads as follows: **5.2.2.4** Samples intended for immigration, visa, passport, and citizenship testing cases for the United States of America shall be transported directly from the place of collection to the testing laboratory.
5.2.3.5	RtC	Please insert the element included below into the existing standard. This standard should read: Samples intended for immigration, visa, passport, and citizenship testing cases for the United States of America shall be accepted only if the case is initiated directly between the petitioner and a facility accredited by AABB for relationship testing activities. **Under no circumstances should a non-accredited facility be involved in the process of selecting a lab or scheduling the appointment.** Records of the initiation of this service by the petitioner shall be maintained in the facility's records. Standard 4.6 applies. The suggested inclusion is submitted as a result of the inclusion of "Initiate" to this edition of Standards as a potential alternative interpretations that are not	NO	The committee reviewed this comment but did not feel that the addition would be appropriate. The committee feels that the language, if included, could block individuals who currently are living in refugee camps or in the field. The language included would prove complicated for individuals to submit their documentation for citizenship. In some cases refuges require assistance and the petitioner in this case can be a citizen of the United States, but initiated by an NGO that begins the processing for the individuals who need assistance in preparing their application for citizenship.

		consistent with the true intent of this standard and policies for US Immigration DNA Testing. The element "Under no circumstances should a non-accredited facility be involved in the process of selecting a lab or scheduling the appointment." introduced above for RT Std 5.2.3.5 was extracted from the Department of State website and inserted to refocus back to the true intent of this standard. For additional information, see comments made for RT Std 4.2.3.1(6), revised definition of "Initiate" (see my submission for the Glossary and QSE 4 Term) and submission of "Immigration DNA Testing" article for the Appendix section of the 16th Edition Guidance for Standards for Relationship Testing Laboratories (see below, detailed description). References: https://travel.state.gov/content/travel/en/us-visas/immigrate/family-immigration/dna-relationship-testing-procedures.html (scroll down to "Step 1: Locating and Accredited Facility"; then click the expand/collapse functionality to expose the content) https://travel.state.gov/content/travel/en/legal/travel-legal-considerations/us-citizenship/US-Citizenship-DNA-Testing.html (scroll down to "DNA Testing Process")		
5.2.4.2 (5.2.4.2, 5.2.4.3)	SC	NA	NA	The committee elected to delete former standard 5.2.4.3 and incorporate the content into standard 5.2.4.2. This change was made for clarity. Standard 5.2.4.2 now reads as follows: **5.2.4.2** Race/ethnic background of all the tested parties, with the exception of a child in parentage cases.
5.3.1 #2 (5.3.3, #3)	RtC	We suggest deleting subnumber 2 that reads, "Results for nonautosomal markers exclude the relationship". If this is the case, the lab still has to report the autosomal data and the RT Lab Director provide a supplemental letter explaining the results. Not reporting autonomic data because the results for nonautosomal markers exclude the relationship is not a standard that should be included. We feel that Lab Directors are qualified to explain results regardless of the level of complexity.	NO	The committee reviewed this comment but did not feel that a change would be appropriate at this time. The committee notes that the inclusion of this requirement ensures that the exclusion of these individuals is of paramount importance. The committee wants individuals using the Standards to be able to test a sample once, and not have to test both samples if that is not needed.
5.3.1, #3 (5.3.3, #4)	SC	NA	NA	The committee edited subnumber 3 by including the clause "expected to be" as a means to ensure that subnumbers 2 and 3 support the removal of former subnumber 2. This change allows for the

				concept of an inconclusive result happening, while acknowledging that at times inconclusive results can be informative.
5.3.2 (5.3.2.2)	SC	NA	NA	The committee created new standard 5.3.2 through a combination of the content of former standards 5.3.2 and 5.3.2.1. By combining the requirements and requiring a minimum of 8 loci be attempted, the standard can accommodate both relatives of the tested individual and potentially random individuals. This editing to the content does follow the flow of normal work processes in a laboratory. Of note, the elements of former 5.3.2.1 were being maintained in the previous editions to cover situations where a laboratory still conducted RFLP testing. However, at this time, acquiring RFLP testing would be impractical and no laboratories perform this testing at this time. The standard reads as follows: **5.3.2** When autosomal markers are tested, a minimum of eight independent loci shall be attempted.
5.3.2 (5.3.2.2), 5.3.7.2 (5.3.8.1, 5.3.8.3)	RtC	Stating a minimum of 8 attempted in general and then 20 loci attempted for inconclusive relationships. This could leave room for some gray areas, and any clarification would be helpful.	NO	The committee reviewed this comment but did not feel that a change would be appropriate at this time. The committee noted that 8 excludes related men and an explanation of the math is included in the guidance. It should also be noted that most kits have 8 loci as a minimum. The 20 total was for inconclusive secondary relationships. Please note the guidance to these standards provide information on these requirements.
5.3.2 (5.3.2.2)	RtC	Note, not all loci are created equal. Was a minimum combined power of exclusion or discrimination considered?	NO	The committee noted this comment but did not feel that a change was needed at this time. The 8 is considered a minimum to ensure that individuals can differentiate and identify a sample from a relative.
5.3.3 (5.3.1)	SC	NA	NA	The committee elected to replace the term "used" with "reported" for clarity. It should be

				noted that the intent of the standard has not changed. The standard now reads as follows: **5.3.3** When autosomal markers are reported, multiple loci shall be the basis for the laboratory's findings.
5.3.4 (Deleted)	RtC	We suggest that Undo deletion of this standard. This standard is not in conflict with RT Std 5.3.3, is not duplicated elsewhere and is relevant. Clarify the reasoning for deleting 5.3.4. There's no clearly documented conflict between 5.34 and "standards cited above."	NO	The committee reviewed this comment but did not think it would be appropriate to reinclude this deleted standard. The committee notes that users are no longer deconstructing samples. It should be noted that it is not necessary to use autosomal markers if a potential grandparent or other related individual. The committee notes that removing this standard ensures that it is not necessary to have autosomals at all times. The previously delete standard read as follows, "~~When the genetic profile of the untested party can be reconstructed, the laboratory shall use autosomal markers. Nonautosomal markers may additionally be used. Standard 6.3.2 applies.~~"
5.3.6 (5.3.7)	SC	NA	NA	The committee elected to edit standard 5.3.6 for clarity. The committee replaced the term "relationship index" with "likelihood ratios." A relationship index is a form of a likelihood ratio as a part of a hypothesized relationship. The committee also added an additional sentence to provide additional clarity to the standard. The standard now reads as follows: **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.
5.3.6 (5.3.7), 5.3.7 (5.3.8), 5.3.7.1	RtC	We do not feel that this standard should force laboratories to report "relationship index" to purchase/modify software to accommodate the laboratories reporting in "likelihood ratios". "Combined Relationship Index" is the Traditional Relationship Testing Statistics Method. For more than a decade, "combined relationship index" has been used in the AABB RT Stds and is a	NO	The committee reviewed these comments but did not feel that the change would be appropriate. The committee recognizes that both terms can both work and are equivalent in these standards.

(5.3.8.2), 5.3.7.2 (5.3.8.1, 5.3.8.3), 5.3.7.3 (5.3.8.4)		widely accepted parameter in the peer-reviewed literature. When the RT Standards required the use of "combined relationship index", some labs were allowed to report in terms of "likelihood ratios" without resulting on what is clear a non-conformance. Likewise, Labs reporting "combined relationship index" must not be forced to adopt "likelihood ratios". There is no scientific basis to support that one term is better than the other. A Combined Relationship Index of 100 is equivalent to a likelihood ratio of 100 to 1. Both terms are correct as long as they are correctly used in the conclusions. Make this very clear that labs using Traditional Relationship Testing Statistics term "Combined Relationship Index" is acceptable. Furthermore, undo the changes made in the Glossary for "Relationship Index".		To remain consistent and in line with the current terminology the standards will retain the verbiage, "likelihood ratio." The committee also notes that the definition of likelihood ratio includes the concept of the relationship index.
5.3.7 (5.3.8)	SC	NA	NA	The committee elected to edit the content of the standard to mirror the style and tone of the updated quality template. The standard now reads, as follows: **5.3.7** For laboratories performing two-party tests to determine full sibling, half sibling, avuncular, or single grandparentage relationships, the following standards apply:
5.3.8.1 (Deleted)	SC	NA	NA	The committee elected to delete standard 5.3.8.1 as its content is now a part of standard 5.3.7.2. The standard previously read as follows, "~~5.3.8.1 Before reporting an inconclusive result, the laboratory shall use a minimum test battery of at least 20 autosomal short tandem repeat (STR) loci when testing.~~"
5.3.7.1 (5.3.8.2)	SC	NA	NA	The committee elected to edit this standard for clarity. The changes made to the standard ensure that the content of standard 5.3.7.1 mirrors the edits made to standard 5.3.6. The standard now reads as follows: **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 (5.3.8.1, 5.3.8.3)	SC	NA	NA	The committee elected to create new standard 5.3.7.2 from the content that previously appeared as former standard 5.3.8.1. The elements in the second sentence previously

				appeared as 5.3.8.1. The standard reads as follows: **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 short tandem repeat (STR) loci.
5.3.7.3 (5.3.8.4)	SC	NA	NA	The committee elected to edit standard 5.3.7.3 for clarity and parallel construction with other standards in this section. This standard was edited to mirror the changes made to standard 5.3.6. The standard reads as follows: **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).
5.3.7.3 (5.3.8.4)	RtC	Perhaps it is just semantics, but since we can never truly "exclude" a two party relationship by looking at non-obligate alleles, might saying the evidence "does not support the alleged relationship" be more appropriate than saying it supports the alternative?	YES	The committee reviewed this comment and agreed with its intent. The committee as a result elected to include the clause, "…and no supporting the alternative…" to standard 5.3.7.1.
5.3.7.4 (5.3.8.5)	SC	NA	NA	The committee elected to edit standard 5.3.7.4 for clarity and parallel construction with other standards in this section. This standard was edited to mirror the changes made to standard 5.3.6. The committee also included a crossreference to reference standard 6.4A for completeness. The standard reads as follows: **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.

5.3.7.4 (5.3.8.5)	RtC	I suggest that the standard be rewritten to appear as follows, "The laboratory shall include on the report an estimate of the percentage of truly related individuals that may yield an inconclusive, supportive, or unsupportive combined Likelihood Ratio for the tested relationship under the laboratory's test protocol"	YES	The committee agreed with the intent of this comment and updated the language of the standard to focus on the final report.
5.3.9 (5.3.10)	SC	NA	NA	The committee edited standard 5.3.9 to expand its scope. The standard has been edited to include the new concept of "non-traditional relationship testing statistics" and "traditional relationship testing statistics" which have been added to the proposed edition. This includes new definitions for the terms as well. This better reflects the current landscape of the field. The committee also added new definitions in the glossary to define "Non-Traditional Relationship Testing Statistics" and "Traditional Relationship Testing Statistics." The standard and definitions read as follow: **5.3.9** When using non-traditional relationship testing statistics, 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." **Non-Traditional Relationship Testing Statistics:** Methods where the likelihood ratio, or other measure of statistical support, is calculated using formulas that do not include the frequencies of specific alleles, genotypes, or haplotypes of the tested parties. Instead, statistical support is calculated using formulas that include other parameters (eg, shared centimorgans). These statistics are typically used for very large SNP or other nucleotide data sets. See Traditional Relationship Testing Statistics. **Traditional Relationship Testing Statistics:** Methods where the likelihood ratio is calculated using formulas that include the frequencies of specific alleles, genotypes, or haplotypes of the

				tested parties, as opposed to other parameters (eg, shared centimorgans). These statistics are required for standard STR loci, HLA types, and blood types, but may also be applied to other methods. See Non-Traditional Relationship Testing Statistics.
5.3.10.1 (5.3.11.1)	SC	NA	NA	The committee edited standard 5.3.10.1 to expand the standard by adding a new second sentence focused on SNP testing. The edits ensure that the standard mirrors current practice. The standard reads as follows: **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.
5.3.10.1 (5.3.11.1)	RtC	We suggest that the new sentence be deleted, specifically, "Laboratories shall validate and define confirmation parameters for single nucleotide polymorphism (SNP) testing" If I am interpreting this correctly, the sentence in question allows SNP-based data to bypass the requirement of an independent extraction/analysis. If this is the case, this should alarm everyone ordering SNP-based data as "confirmation parameters" does not replace the need for an independent extraction as sample swapping cannot be ruled out in exclusion cases. For Closed systems, it is also my understanding that this standard does not make a requirement for an independent extraction. That is fine if-and-only-if the Rapid DNA test is witnessed at the point-of-testing when sample swapping can indisputably be ruled out. In other words, if the collected sample is put directly into the cartridge at the point-of-collection, making unlikely sample swapping, then, I agree, the independent extraction is not necessary. If this is not how it is done (e.g. sample collected is analyzed later on along with other samples in the batch), then, there is nothing on the Closed system algorithm to rule out sample swapping in exclusionary outcomes.	NO	The committee noted this comment but did not make a change at this time. The committee feels that each laboratory should define how they will meet the intent of the standard. The committee feels that the edits made to the last sentence of the standard, specifically, "…to include an independent isolation…" to ensure that a loophole is not created for those performing SNPs. With regard to the comment surrounding the concept of an electronic equivalent included for witness of the test.

5.3.10.2 (5.3.11.2)	RtC	I would suggest a change in wording is necessary. Confirmatory testing is mandated only for exclusionary results. No confirmation is required for inclusions. Is there a better way to phrase this?	NO	The committee noted this comment but did not feel that a change was needed at this time. The committee points to standard 5.3.10 which covers exclusions.
5.3.11 (5.3.12)	SC	NA	NA	The committee replaced the term "genetic system" with "locus" for clarity and parallel construction. This change has been made throughout the edition. The standard reads as follows: **5.3.11** A standard method of nomenclature for describing phenotypes in each locus shall be used.
5.4.1.1	SC	NA	NA	The committee elected to edit the title of the standard for clarity. The committee removed the clause of "Nucleic Acid Testing" from the title as NAT is encapsulated by STR. The new title reads as follows, "~~Nucleic Acid Testing (NAT) for~~ Short Tandem Repeat (STR) and Other Fragment Analysis. The committee also removed the introductory sentence to standard 5.4.1.1 for clarity. The inclusion of the sentence services to introduce the concepts below it (1-8), however this introduction did not fully reflect the content that appeared below it.
5.4.1.1, #1	RtC/SC	Are "gel results" still relevant if all terms pertaining to RFLP and earlier technologies have been removed from this standard? Most laboratories currently use capillary-based DNA fragment separation which requires polymer.	YES	The committee reviewed this comment and agreed with its intent. The committee removed the clause "electropherogram or gel" as it limits the standard to one specific method. Much like the removal of standards related to RFLP testing, this removal ensures that the RT Standards remain in sync with current work practices in AABB accredited laboratories. The subnumber reads as follows: **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.
5.4.1.1, #1	RtC	Should all gel references been removed? In the significant changes section at the top it talks about removing gel to reflect what is currently being done in the field. There are a few other places in later standards that reference gels.	YES	The committee reviewed this comment and agreed with the intent. The committee removed the clause "electropherogram or gel" as it limits the standard to one specific method. Much like the removal of standards related to RFLP testing, this removal ensures that the RT Standards remain in sync with current work practices in AABB accredited laboratories. The subnumber reads as follows: **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.
5.4.1.1, #3	SC	NA	NA	The committee elected to remove the clause "hybridization" from subnumber 3 for clarity. This ensures that the standard mirrors current practice in accredited AABB laboratories. The subnumber 3 reads as follows: **5.4.1.1 Short Tandem Repeat (STR) and Other Fragment Analysis** 3) The conditions for amplification and detection shall be defined and controlled to ensure accurate allele determination.
5.4.1.1, #5	RtC	STR analysis today can be accomplished by capillary electrophoresis (CE; fragment-based typing by size) and by targeted, next generation sequencing (NGS, also known as massively parallel sequencing).	YES	The committee agreed with the intent of this comment and the title of the standard was updated based on this and other comments.
5.4.1.1, #6	SC	NA	NA	The committee elected to remove the clause, "…and NAT product contamination" from subnumber 6 for accuracy. With the edits made to the title of the standard, the clause had to be removed to ensure accuracy. The subnumber reads as follows: **5.4.1.1 Short Tandem Repeat (STR) and Other Fragment Analysis**

				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.
5.4.1.1, #6	RtC	My comments to this subnumber: • Validated NGS methods produce STR allele calls (using International Society of Forensic Genetics nomenclature) based on the nucleotide length of the STR (PCR product) and that are concordant with sizing-based STR allele calls from CE. • Validated NGS methods can further refine allelic dimensions beyond size/length to discern "isoalleles" where two STR PCR products of the same size/length differ at the nucleotide sequence level (intra-STR variation, basically SNPs that reside / are embedded inside the STR). • Practitioners that assay STRs using NGS can determine whether to define and report STR alleles based on length, and/or by nucleotide sequence. <u>Suggestions</u>: - Consider not limiting the STR analysis to fragment analysis as advancements are now available that improve on the method. - Include STR typing using NGS in the 16th edition so that AABB standards better reflect the field as NGS is implemented more and more in relationship testing labs, genetic genealogy testing laboratories, forensic testing labs and by service providers. - Reasonable, especially considering removal of RFLP wording and inclusion of SNP-based typing using whole genome sequencing, microarrays, *et al*.	YES	The committee agreed with the intent of this standard by editing the title of the standard for accuracy. This allowed for the focus of the standard to be on STR and fragment data analysis.
5.4.1.1, #6, 5.4.1.2, #6	RtC	Negative control language is not consistent; one contains extraction through analysis, and the other the analysis portion was deleted out and it just lists extraction and monitoring.	NO	The committee reviewed this comment but did not feel that a change was appropriate at this time. The inconsistency in this case was intentional as SNPs and STRs are not conducted in the same manner.
5.4.1.2	SC	NA	NA	The committee elected to edit the title of standard 5.4.1.2 to mirror the title change to standard 5.4.1.1. The committee removed the clause of "Nucleic Acid Testing" from the title as NAT is encapsulated by SNP analysis. The new title reads as follows: **5.4.1.2** Nucleotide Sequence Determination or SNP Analysis

5.4.1.2	SC	NA	NA	The committee removed the introductory sentence to standard 5.4.1.2 for clarity. The inclusion of the sentence services to introduce the concepts below it (1-8), however this introduction did not fully reflect the content that appeared below it.
5.4.1.2, #1 (New)	SC	NA	NA	The committee created new subnumber 1 and added it to the standard for completeness. This addition ensures that when SNPs are interpreted by the software in use, a human will review the result when a quality flag is found. The subnumber reads as follows: **5.4.1.2 Nucleotide Sequence Determination or SNP Analysis** 1) When an expert system is used to interpret the SNPs, results containing quality flags shall be interpreted by at least one human reviewer. If the reviewer makes a change, the change shall be confirmed by a second human reviewer.
5.4.1.2, #2	SC	NA	NA	The committee elected to remove the clause, "…allele determination…" for completeness and parallel construction. The subnumber reads as follows: **5.4.1.2 Nucleotide Sequence Determination or SNP Analysis** 2) When an expert system is used to interpret the SNPs, all phenotypes that pass the established and validated criteria may be interpreted solely by the expert system. Allele determinations that do not pass criteria shall not be used in the final relationship calculations.
5.4.1.2, #4	SC	NA	NA	The committee elected to edit subnumber 4 to expand the content of the standard and to mirror the change to the title. This edit ensures that this subnumber reflects the current practice of AABB accredited laboratories. The subnumber reads as follows: **5.4.1.2 Nucleotide Sequence Determination or SNP Analysis**

				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.
5.4.1.2, #8 (New)	SC	NA	NA	The committee created new subnumber 8 of the standard for completeness. By including this requirement understanding that STR alleles determined by nucleotide sequencing are done so in line with standard 5.4.1.1 which contains requirements on STR analysis. The subnumber reads as follows: **5.4.1.2 Nucleotide Sequence Determination or SNP Analysis** 8) When STR alleles are determined by nucleotide sequencing, Standard 5.4.1.1 applies.
5.4.1.2, #5, 6 (Deleted)	SC	NA	NA	The committee elected to delete former subnumbers 5 and 6 as this type of testing is no longer required and is no longer included as a part of any CAP surveys to indicate that this testing is occurring. This testing was previously included to allow for HLA testing, which is no longer performed for relationship determinations as well. ~~5) When a sequence-specific oligonucleotide probe (SSOP) method is used for allele determination, a control probe shall be used to ensure adequate target nucleic acid is available for analysis.~~ ~~6) When a sequence-specific primer (SSP) method is used for allele determination, a positive internal control primer shall be included to verify that amplification has occurred for each reaction.~~
5.4.1.2, #9 (Deleted)	SC	NA	NA	The committee has deleted former subnumber 9 as the content of subnumber 4 now includes this content. The former subnumber read as follows:

				~~9) The laboratory shall have policies and procedures to evaluate contamination, artifacts, and preferential amplification for each sample.~~
5.4.2	SC	NA	NA	The committee revised standard 5.4.2 to mirror the style, tone and language of the updated quality template. The standard now reads as follows: **5.4.2** A laboratory performing DNA testing using a closed system shall:
5.4.2.1 (New)	SC	NA	NA	The committee created new standard 5.4.2.1 based on the content of standard 5.4.2. The standard reads as follows: **5.4.2.1** Identify and investigate profile anomalies that may affect the result.
5.4.2.1 (New)	RtC	I suggest that the the standard be modified as written to appear, "Cite any observed profile anomalies and explain how they may have affected result interpretation."	NO	The committee reviewed this comment but did not feel that a change was appropriate at this time. However, the committee ensured that the terms "identify" and "investigate" both are included as this is the complete cycle of the requirements.
5.4.2.2 (5.4.2.1)	SC	NA	NA	The committee edited standard 5.4.2.2 based on the change to standard 5.4.2 (allowing for the creation of a list), changing the introduction to the standard. The intent of the standard has not changed. The standard reads as follows, **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 (5.4.2.2)	SC	NA	NA	The committee edited the introduction to standard 5.4.2.3 to allow the standard to read as a part of the list that begins with standard 5.4.2. The standard reads as follows: **5.4.2.3** Test a confirmatory sample(s) in cases where there is a finding of no relationship if:
5.4.2.3 (5.4.2.2)	RtC	Shouldn't this read more like 5.3.10.1 insofar as tests without a known parent have different requirements for confirmation than tests with a known parent? 5.3.10.1 for example wording - 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	NO	The committee reviewed this comment but did not feel a change was needed at this time. The committee noted standard 5.4.1.2 covers this content earlier in the chapter.

		independent isolation. Laboratories shall validate and define confirmation parameters for single nucleotide polymorphism (SNP) testing. For closed systems, Standard 5.4.2 applies.		
5.4.2.3, #1 (5.4.2.2, #1, 3)	SC	NA	NA	The committee moved the content of former subnumber 3 to appear as a part of subnumber 1. This change does not change the intent of the standard. The subnumber appears as follows, **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
5.4.2.3, #3 (New)	SC	NA	NA	The committee created new subnumber 3 to ensure that all confirmatory sample testing is needed in the case if a witness is not available, or the electronic equivalent was not used. This closes a potential loophole and mirrors current requirements in accredited laboratories. The subnumber reads as follows: **5.4.2.3** Test a confirmatory sample(s) in cases where there is a finding of no relationship if: 3) No witness or electronic equivalent is documented, as required by Standard 5.4.2.2.
5.4.2.3, #3 (New)	RtC	Please add a new subnumber "3) The sample is not tested immediately at the point-of-collection, when there is no doubt that the correct samples were tested."	YES	The committee agreed with the intent of this comment and created new subnumber 3 based on the content of the comment received. The subnumber reads as follows: **5.4.2.3** Test a confirmatory sample(s) in cases where there is a finding of no relationship if: No witness or electronic equivalent is documented, as required by Standard 5.4.2.2.
5.5.1	SC	NA	NA	The committee elected to edit standard 5.5.1 for consistency with changes made to standard 5.3.9. The inclusion of the concept of "traditional relationship testing statistics". This includes new definitions for the terms as well. This better reflects the current landscape of the field.

				Non-Traditional Relationship Testing Statistics: Methods where the likelihood ratio, or other measure of statistical support, is calculated using formulas that do not include the frequencies of specific alleles, genotypes, or haplotypes of the tested parties. Instead, statistical support is calculated using formulas that include other parameters (eg, shared centimorgans). These statistics are typically used for very large SNP or other nucleotide data sets. See Traditional Relationship Testing Statistics. **Traditional Relationship Testing Statistics:** Methods where the likelihood ratio is calculated using formulas that include the frequencies of specific alleles, genotypes, or haplotypes of the tested parties, as opposed to other parameters (eg, shared centimorgans). These statistics are required for standard STR loci, HLA types, and blood types, but may also be applied to other methods. See Non-Traditional Relationship Testing Statistics.
5.5.1	RtC	Should a definition of "significant" be included in the glossary?	NO	The committee reviewed this comment but did not feel that a change would be appropriate. The committee noted that a definition would be complicated due to the necessary broadness of how the definition would be.
5.5.1	RtC	We suggest deleting "calculating traditional relationship testing statistics". SNP-based tests are severely affected by linkage disequilibrium. It is my opinion that we should let the laboratories deal with the linkage disequilibrium issue at the present time since there is nothing the RT Stds can state to bring consensus. This topic should be revisited in the 17th Edition of the Standards	NO	The committee reviewed this comment but did not feel that a change would be needed at this time. The distinction here is between traditional and non-traditional relationship testing statistics. Either can be done with STRs or SNPs. Only traditional RT statistics are affected by linkage disequilibrium. Non-traditional RT stats, which are based on shared centimorgans, are not affected by linkage disequilibrium because they are not using allele frequencies for the calculations
5.5.2	SC	NA	NA	The committee elected to edit standard 5.5.2 for consistency by including the concept of "for

				calculating traditional relationship testing statistics" and for completeness. The standard reads as follows: **5.5.2** When linked loci are used for calculating traditional relationship testing statistics, the laboratory shall estimate and minimize the effects of linkage on nonparentage cases.
5.5.5.1	SC	NA	NA	The committee elected to edit standard 5.5.5.1 for clarity. The additions and edits were made in line with changes made throughout the 16th edition. The phrase "and algorithms (including software)" was added to expand the standards to include calculations done for genetic genealogy. The committee also added new subnumbers 1 noting that the content of Appendix 2 Formulas for Paternity Index and RMNE Values for Simple Codominant Systems is the formulae all relationship testing facilities must use to ensure accuracy. The committee also included subnumbers 2 ensures that the laboratory is also noting the use of two party non parentage calculations and any other testing algorithms in use in the laboratory. The standard reads as follows: **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).
5.5.5.2.2	SC	NA	NA	The committee elected to add the clause "sample size" to the standard for clarity, it does not however change the intent of the standard. The standard reads as follows: **5.5.5.2.2** The sample size from which tables are developed shall be scientifically adequate.

6.1	SC	NA	NA	The committee revised standard 6.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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.
6.1.2 (New)	SC	NA	NA	The committee added standard 6.1.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 (New)	SC	NA	NA	The committee added standard 6.1.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.1.3 Document Changes** Changes to documents shall be reviewed and approved by an authorized individual.
6.1.3.1 (New)	SC	NA	NA	The committee added standard 6.1.3.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.1.3.1** The organization shall track changes to documents.

6.1.7	SC	NA	NA	The committee revised standard 6.1.7 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 (New)	SC	NA	NA	The committee added standard 6.1.8 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.1.8 Document Retrieval** The organization shall ensure that documents are retrievable in a timely manner.
6.2	SC	NA	NA	The committee revised standard 6.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.2 Record Control** The organization shall maintain a system for identification, collection, indexing, accessing, filing, storage, maintenance, and disposition of original records.
6.2.2, #3 (6.2.4, #3)	SC	NA	NA	The committee revised standard 6.2.2, #3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.2.2** The records system shall ensure traceability of: The records system shall ensure traceability of: 3) Date the activity was performed.
6.2.2, #4 (6.2.4, #3)	SC	NA	NA	The committee revised standard 6.2.2, #4 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.2.2** The records system shall ensure traceability of: 4) Time the activity was performed, if applicable.
6.2.3 (New)	SC	NA	NA	The committee added standard 6.2.3 based on updates to the AABB Quality System Essentials. The standard reads as follows:

				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.
6.2.6 (New)	SC	NA	NA	The committee added standard 6.2.6 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.2.6** Records shall be created concurrently with performance of each critical activity.
6.2.8 (6.2.2)	SC	NA	NA	The committee revised standard 6.2.8 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.2.8 Confidentiality** The organization shall ensure the confidentiality of records.
6.2.9 (6.2.1)	SC	NA	NA	The committee revised standard 6.2.9 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 (New)	SC	NA	NA	The committee added standard 6.2.10 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.2.10 Record Review** Records shall be reviewed for accuracy, completeness, and compliance with applicable standards, laws, and regulations.
6.2.11, #3 (New)	SC	NA	NA	The committee added standard 6.2.11, #3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.2.11 Storage of Records** Records shall be stored to: 3) Permit ready identification.
6.3.1 (New)	SC	NA	NA	The committee added standard 6.3.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.1 Access to Data and Information**

				Access to data and information shall be controlled.
6.3.1.1 (New)	SC	NA	NA	The committee added standard 6.3.1.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 (New)	SC	NA	NA	The committee added standard 6.3.1.1.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.1.1.1** Electronic records shall include the date and identity of the person making a change.
6.3.2 (3.5.1, #4)	SC	NA	NA	The committee revised standard 6.3.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.2 Data Integrity** Data integrity shall ensure that data are retrievable and usable.
6.3.2.1 (New)	SC	NA	NA	The committee added standard 6.3.2.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.2.1** Data shall be accurately, reliably, and securely sent from the point of entry to final destination.
6.3.2.2 (6.2.6.1.1)	SC	NA	NA	The committee revised standard 6.3.2.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.2.2** Data shall be retrievable for the entire retention period.
6.3.2.2.1 (New)	SC	NA	NA	The committee added standard 6.3.2.2.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.2.2.1** The organization shall archive records or data from media and platforms no longer in use.
6.3.3 (New)	SC	NA	NA	The committee added standard 6.3.3 based on updates to the AABB Quality System Essentials. The standard reads as follows:

				6.3.3 Storage Media Data storage media shall be protected from damage or unintended access and destruction.
6.3.4 (New)	SC	NA	NA	The committee added standard 6.3.4 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.4 Backup Data** The organization shall back up all critical data.
6.3.4.2 (New)	SC	NA	NA	The committee added standard 6.3.4.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.4.2** Backup data shall be protected from unauthorized access, loss, or modification.
6.3.4.3 (6.2.6.1.3)	SC	NA	NA	The committee revised standard 6.3.4.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.4.3** The ability to retrieve data from the backup system shall be tested at defined intervals.
6.4, 6.4.1, 6.4.1.1, 6.4.1.2, 6.4.1.3 (6.3, 6.3.1, 6.3.1.1, 6.3.1.2, 6.3.1.3)	RtC	In almost every other kinship situation including sibship, grandparent, and "avuncular" (a not precisely accurate choice of word, for which by the way I'm responsible), "inconsistency" has no role. Therefore, statements like "6.4.1.1 A finding of no *relationship* shall not be rendered on the basis of a single inconsistency without supporting evidence" are very misleading and bound to confuse. It is in effect an invitation for the naive analyst to equate the sibship situation where a locus that exhibits no child/alleged-father allele sharing, with the paternity case with such a locus. But in fact there's a huge practical difference: With sibship there is no need to add extra complication for those loci; it's good enough to ignore mutation and compute likelihood ratio according to the same principles whether alleles are shared or not. But with parentage the opposite is true: Whether you account for non-sharing with an ad hoc rule such as 2 or 3 such loci to exclude, or do a proper likelihood ratio calculation, parentage analysis reasonably treats share-loci and non-share-loci quite differently. Or, a less technical way to understand why parentage and almost all other kinship situations are different categories is that with parentage the likelihood ratio contribution of "inconsistent" loci quickly overwhelm any positive evidence, like falling off a cliff, whereas with less intimate alleged relationships the negative contributions accumulate only gradually. So, it is in my opinionwrong to discuss "inconsistency" in a way that conflates	NO	The committee reviewed this comment but did not feel that editing the standards would appropriate at this time. The committee notes that there are cases where inconsistencies can apply for autosomal data. This would include: 2 grandparents and a child, 2 or more aunts/uncles and a child, 3 or more alleged siblings, etc. For X linked data: PGM and female child, 2 or more females alleged to have the same father, etc. There are many types of cases where inconsistencies can occur outside of parentage.

		kinship in general, with parentage, as the present draft AABB standards do. Perhaps they have done so for decades, but that would be a poor excuse to continue a long-outmoded approach. A second criticism - relatively minor compared to the above - is that even for parentage, labs should not be encouraged to "exclude" based on some threshold number of "inconsistencies". Instead, it has been understood for 30 years how to compute LR taking mutation into account. I believe the introduction of the word "inconsistency" as suggested in the AABB draft is due to my colleague and occasional co-author Dr. Jeffrey Morris (died last year) in the early 90's as an improvement on "exclusion", which it was. But of course, it was never more than a slang or shorthand way to say "inconsistent aside from the possibility of mutation". In the RFLP days rules of thumb were adopted that (one or) two inconsistent loci justifies a conclusion of non-paternity. With RFLP that's pretty reasonable and anyway there was nothing better as we never had a sufficient understanding of RFLP mutation. STR replacing RFLP changed that. A model that I suggested for computing STR likelihood ratios became fairly well known and accepted, something similar has been published, and the idea is implemented in the parentage software that I know of. In the last paragraph it may not be clear that I was writing about computation of likelihood ratios when a complication - possible mutation or null allele - is involved, not about LR computation in general. In the simpler situation of a routine positive paternity case even with RFLP how to compute a likelihood ratio was adequately understood. But nobody knew (and I at least still do not) enough about RFLP mutation to account for it with an likelihood ratio computation. STR mutation is more tractable, and in referring to "a model that I suggested for computing STR likelihood ratios" I meant a model of mutation. to add an argumentative point: I think it's fine to never use words alleging certainty of relationship, no matter how large the likelihood ratio, but strange that people do not treat negative results correspondingly. With positive results it's usual to report even a very large likelihood ratio as less than infinity or a posterior probability (with the presumed prior explicitly stated we hope) less than one. But on the other side of the coin no one says likelihood ratio <0.0001 for example, we say "excluded", which implies likelihood ratio =0. (The compromise/workaround implemented in DNA-VIEW is that an LR incorporating mutation etc is always calculated, then it is instead reported as "exclusion" if the LR is less than some laboratory-specified threshold such as 1/1000.)		
6.4.2 (6.3.2)	SC	NA	NA	The committee edited standard 6.4.2 for clarity. The intent of the standard has not changed. The

				committee rearranged the order of relationship. The standard reads as follows: **6.4.2 Nonautosomal Findings** Nonautosomal results, when tested for parentage, full siblings, half siblings, avuncular and/or grandparentage relationships, shall be incorporated with autosomal results into the likelihood ratios. In addition to the likelihood ratios, the laboratory shall be permitted to discuss autosomal and nonautosomal findings separately.
6.4.2 (6.3.2)	RtC	This standard should read “avuncular/materteral" to show the female sibling of a parent.	NO	The committee noted this comment but did not feel that a change was necessary at this time. The committee did however the definition of “avuncular” has been created to address this request. The definition reads as follows: **Avuncular:** Pertaining to an uncle or aunt.
6.4.4 (6.3.4)	SC	NA	NA	The committee elected to edit standard 6.4.4 to ensure that the edition is able to be expanded to allow for forensic genetic genealogy testing activities to be accredited. These additions are in line with other additions and edits made to this edition. The standard reads as follows: **6.4.4** When the facility determines the final conclusion: 1) For large nucleotide datasets, the results of the algorithm analysis shall be presented. 2) For all others, the individual likelihood ratios shall be reported for each independently calculated locus or linked loci.
6.5 (6.4)	RtC/SC	We suggest relacing “Standards 5.2.3.5 and 6.5.2 apply” with: “Standards 4.2.3.1 (4-6), 5.2.3.5 apply.” This modification makes relevant references and removes sub-standard reference under 6.5.	YES	The committee reviewed this comment and agreed with its intent. The committee has added standard 4.2.3.1 as a crossreference to standard 6.5. The standard reads as follows: **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.

6.6 (6.4.6)	RtC	Since the laboratories are making data contribution, on the RT Annual Report: • List the name of the RT Laboratories that submitted data on the acknowledgments. • All RT Lab Directors should be given the opportunity to comment on the draft of the Annual Report to be certain that the material in the Report is scientifically vetted.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee feels that allowing laboratories to remain anonymous ensures that AABB receives the best data and the highest level of participation.
6.4A, II, 1.(6.3A, II. 1)	SC	NA	NA	The committee elected to edit this entry to mirror other changes made to this edition of Standards. The entry reads as follows: **A statement as to whether the alleged relationship can be excluded.** ~~Report the phenotypes of tested individuals for all genetic systems that meet the laboratory's minimum performance thresholds, as applicable with the exception of Amelogenin, other markers used for gender determination, and linked loci, as defined in standard 5.5 (Standards 5.3.12 and 5.3.13 apply).~~
6.4A, II., 2, 1, 2 (6.3A, II., 2)	SC	NA	NA	The committee edited this entry to mirror other changes made to this edition of Standards concerning "traditional" and "non-traditional" relationship testing statistics. The entry reads as follows: Then the report shall include the following information: 1) For traditional relationship testing statistics: ~~Then~~ the STR loci providing the basis for the finding shall be indicated in the statement of non-relationship. ~~For large array SNP assays the number of loci tested, the number of informative loci, and the number of loci that successfully yielded a result.~~ 2) For ~~large~~ non-traditional relationship testing statistics the number of loci tested, the number of informative loci, if applicable, and the minimum percentage of loci that successfully yielded a result.

6.4A, II, II, 4 (6.3A, II, 2)	RtC	Prior Probability is a critical parameter in the calculations. Labs do not have the qualifications or criteria to weigh in on the strength of the non-genetic evidence that the hypothesized relationship is correct. That's why the consensus in the Parentage/Relationship establishment and Legal community is to use 0.5 prior probability. In the USA, the use of 0.5 prior probability is a requirement for Legal DNA Tests. The Courts and USCIS/DOS do not allow labs to assign a different weight on non-genetic evidence.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee noted that there are instances and some states that require a performance of a full probability and that a 0.5 prior probability calculation would not be sufficient. Some states have also asked for increments of 0.1 for this calculation, and it should be noted that for some enrollment purposes 0.5 prior probability is insufficient.
6.4A, II., 3, (6.3A, II., 2)	SC	NA	NA	The committee elected to mirror other changes to differentiate between "traditional" and "non-traditional" relationship testing statics, through the division of the reference standard.
6.4A, II., 3, header (6.3A, II., 2)	SC	NA	NA	The committee moved Subnumber 3 from where it previously appeared as the header for number 1 of II, Findings, based on the overall adjustment to the table. The content and intent of the entry has not changed.
6.4A, II., 3, 2 (6.3A, II., 2)	SC	NA	NA	The committee edited number 2 to mirror the edits made throughout the edition, replacing "genetic system" with "locus or group of loci." The entry reads as follows: 2) The individual relationship index for each locus or group of loci used in the conclusion.
6.4A, II., 3, (6.3A, II., 2)	SC	NA	NA	The committee added new elements 1 – 6 to the new section on "non-traditional relationship testing statistics" of the reference standard. These additions mirror the content of entries in the "traditional relationship testing statistics" section above. The content was included for completeness. The additions read as follow: Then the report shall include the following information for nontraditional relationship statistics:

				1) The number of loci tested, the number of informative loci, if applicable, and the minimum percentage of loci that successfully yielded a result. 2) An explanation of the evaluation, the equivalency to the 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. The prior probabilities used to calculate the probability of relationship shall be stated. 3) When autosomal loci are not tested, the conclusion shall not overstate the relationship. An explanation of nonrecombining haplotype inheritance and limitations of these markers shall be provided. 4) When autosomal likelihood ratios are not in agreement with nonrecombining haplotypes (leading to a different conclusion), 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.
7.0	SC	NA	NA	The committee revised standard 7.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 (New)	SC	NA	NA	The committee added standard 7.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 (7.1)	SC	NA	NA	The committee revised standard 7.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **7.2 Nonconformances** Upon discovery, nonconforming products or services shall be evaluated and their disposition determined.
7.2.1 (New)	SC	NA	NA	The committee added standard 7.2.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **7.2.1** Nonconforming products shall be quarantined and/or destroyed.
7.2.2 (7.1.1)	SC	NA	NA	The committee revised standard 7.2.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **7.2.2** The unintended distribution or use of products or services that do not conform to specified requirements shall be prevented.
7.2.4 (New)	SC	NA	NA	The committee added standard 7.2.4 based on updates to the AABB Quality System Essentials. The standard reads as follows:

				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 (New)	SC	NA	NA	The committee added standard 7.2.4.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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.
7.3 (New)	SC	NA	NA	The committee added standard 7.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **7.3 Adverse Events** The organization shall detect, monitor, evaluate, manage, and report adverse events related to safety and quality.
7.3.1 (New)	SC	NA	NA	The committee added standard 7.3.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **7.3.1** Records of adverse events and the related investigations, evaluations, and notifications shall be maintained.
7.3.2 (New)	SC	NA	NA	The committee added standard 7.3.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **7.3.2** Investigation results and analysis shall be communicated among all facilities involved, if applicable.
8.1 (New)	SC	NA	NA	The committee added standard 8.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 (New)	SC	NA	NA	The committee added standard 8.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **8.2 External Assessments** The organization shall participate in an external assessment program applicable to the activities performed in the organization.
8.3, #2 (8.1.2)	SC	NA	NA	The committee revised standard 8.3, #2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **8.3 Management of Assessment Results** The results of assessments shall be: 2) Evaluated to determine the need for corrective and preventive action.
8.3, #3 (8.1.4)	SC	NA	NA	The committee revised standard 8.3, #3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **8.3 Management of Assessment Results** The results of assessments shall be: 3) Communicated to the appropriate staff.
8.3, #4 (8.1.4)	SC	NA	NA	The committee revised standard 8.3, #4 based on updates to the AABB Quality System Essentials. The standard reads as follows: **8.3 Management of Assessment Results** The results of assessments shall be: 4) Reported to executive management.
8.4.1 (New)	SC	NA	NA	The committee added standard 8.4.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **8.4.1** The organization shall provide data generated to the personnel who have responsibility for the quality indicator data collected.
9.0	SC	NA	NA	The committee revised standard 9.0 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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, #2 (9.1.2)	SC	NA	NA	The committee revised standard 9.1, #2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **9.1 Corrective Action** The organization shall have a process for corrective action that includes: 2) Investigation of the root cause(s) of nonconformances relating to the product or service, the process, and the quality system.
9.3 (New)	SC	NA	NA	The committee added standard 9.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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.
10.2 (10.2, 10.2.1.1)	SC	NA	NA	The committee revised standard 10.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **10.2 Biological, Chemical, and Radiation Safety** The organization shall monitor adherence to biological, chemical, and radiation safety standards and regulations.
10.2.1	SC	NA	NA	The committee elected to edit standard 10.2.1 by adding a cross reference to standard 5.2.1 for completeness. Standard 5.2 focuses on sample collection and the consent issues surrounding chain of custody cases The standard reads as follows: **10.2.1** The laboratory shall define the environmental conditions that have the potential to cause harm to staff, clients, and visitors to the facility. Standard 5.2 applies.

10.3 (New)	SC	NA	NA	The committee added standard 10.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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.
Glossary - Accredited by AABB (Proposed by a commenter)	RtC	Please define the term "AABB Accredited Facility "AABB Accredited Facility: An AABB assessor has been on the facility's premises and the facility practices were found to conform to AABB standards of practice." This definition was taken from AABB's website at https://aabb.org/dna	NO	The committee noted this comment but did not feel that a change was needed at this time. The committee feels that this is understood.
Glossary – Allelic Drop-out	RtC	Allelic drop-out only states in relation to STR analyses, but allelic drop-out can occur in SNP analysis as well.	YES	The committee agreed with the intent of the comment and elected to edit the definition of allelic drop-out. The definition now appears as follows: **Allelic Drop-Out:** Where one or both allelic copies at a locus fall below the detection threshold.
Glossary - Avuncular	SC	NA	NA	The committee added a definition of "avuncular" for completeness. The definition reads as follows: **Avuncular:** Pertaining to an uncle or aunt.
Glossary – Confirmatory Testing	RtC/SC	I would suggest an edit to this glossary term: "Repeat testing performed to confirm the phenotype of the questioned parent in a parentage case which has demonstrated parental exclusion. In cases where a known parent has not been tested, confirmatory testing is also performed on the child."	YES	The committee reviewed the comment received and based on the feedback elected to delete the entire second sentence of the definition for clarity and to simplify the definition. The definition appears as follows: **Confirmatory Testing:** Repeat testing to confirm an initial test result.
Glossary - Database	RtC/SC	I would suggest an edit to the the glossary, edit the term with either "statistical support" (delete "a"), or "a statistical result."	YES	The committee noted this comment and felt that the addition would be appropriate. The definition now reads as follows: **Database:** In the context of these RT Standards, "database" means the source of the population data used to provide statistical support.
Glossary – Independent Locus or	SC	NA	NA	The committee, based on other edits to the standards have created a new definition for independent locus or group of loci, have deleted

Group of Loci				the terms “genetic system”, and “multiple genetic systems.” The definition reads as follows: **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.
Glossary - Initiate	SC	NA	NA	The committee elected to add a new definition of the word “initiate” for clarity. This definition was built off of feedback from AABB’s accredited laboratories and the Department of State. The inclusion of this definition mirrors the use of the term in chapter 4 of this edition of RT Standards and ensures that it is understood what is meant by the opening of the process to start the activities of collection and identification. The definition reads as follows: **Initiate:** Direct contact between the petitioner (or other parties permitted under current US immigration rules) and the accredited facility before commencing relationship testing activities.
Glossary - Initiate	RtC	In the context used in RT Stds 4.2.3.1(6) and 5.2.3.5, “Initiate” can only have one definition, and that is: “To begin the Immigration DNA Testing process at the request of the US Department of State, a US Passport Agency, USCIS and the Department of Homeland Security, the Petitioner (you) is instructed to go to https://aabb.org/dna to select an AABB accredited facility and contact the laboratory chosen directly. The directive further stipulates that under no circumstances may a third party be involved in the process of selecting a lab or to make other arrangements.” The Draft of the 16th Ed RT Stds has the word “Initiate” incorrectly defined. “Initiate” is in reference to its intended use in RT Stds 4.2.3.1(6) and 5.2.3.5 according to USDOS and USCIS requirements to AABB Accredited Laboratories; these federal agencies expectations for AABB-Accredited Labs is to adhere to their stated policies. The true definition of the term “Initiate” is the one Suggested above. Any other	YES	The committee noted this comment and agreed with a suggestion to ensure that the definition was read to be clear that the focus was allowed under current US immigration rules. This clause was not included in the proposed version of the RT Standards. The updated definition reads as follows: **Initiate:** Direct contact between the petitioner (or other parties permitted under current US immigration rules) and the accredited facility before commencing relationship testing activities.

		definition of the term that changes the true intent of its use is inappropriate and must be rejected by the RTSC. Those arrangements between accredited labs and non-accredited entities are expressly prohibited in USDOS website, travel.state.gov and are not consistent with USDOS and USCIS expectations to AABB Accredited Laboratories. To address this deficiency: i) I am submitting the true meaning of the term "Initiate" (see above) and verbiage for RT Std 4.2.3.1(6) and 5.2.3.5 to be consistent with US Government policies and the true intent of these two standards. ii) I am also submitting an article to be used as supporting documentation for the Guidance for RT Stds 4.2.3.1(6) and 5.2.3.5. This article thoroughly addresses the Federal agency's policies and expectations to AABB Accredited RT Labs and brings clarity to the term "Initiate".		
Glossary – Laboratory Director Designee	SC	NA	NA	The committee elected to create a new definition for the laboratory director designee term, including technical leader position. This definition provides clarity for the users of the RT Standards to ensure that it is understood what tasks a designee can perform and that they are at the discretion of the laboratory director while maintaining ultimate responsibility. The definition reads as follows: 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.
Glossary – Likelihood Ratio	SC	NA	NA	The committee elected to edit the definition of the term "Likelihood Ratio" by removing the term, "or a possible alleged." The definition reads as follows: **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.
Glossary – Non-Traditional Relationship Testing Statistics	SC	NA	NA	The committee created a new definition for the term non-traditional relationship testing statistics reflecting the inclusion of this term throughout the RT Standards, most specifically in reference standard 6.4A. The definition reads as follows: **Non-Traditional Relationship Testing Statistics:** Methods where the likelihood ratio, or other measure of statistical support, is calculated using formulas that do not include the frequencies of specific alleles, genotypes, or haplotypes of the tested parties. Instead, statistical support is calculated using formulas that include other parameters (eg, shared centimorgans). These statistics are typically used for very large SNP or other nucleotide data sets. See Traditional Relationship Testing Statistics.
Glossary – Nucleotide Datasets	SC	NA	NA	The committee created a definition of the term nucleotide datasets to recognize the expansion of the testing methods section in standard 6.4.4. The definition reads as follows: **Nucleotide Datasets:** Datasets generated by nucleotide sequence determination.
Glossary – Nucleotide Sequence Determination	SC	NA	NA	The committee created a definition of the term nucleotide sequence determination to recognize the expansion of the testing methods section in standard 6.4.4. The definition reads as follows: **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.
Glossary – Promotional Materials	SC	NA	NA	The committee created a new definition of the term promotional materials based on requests from AABB members who wanted to ensure

				that users were clear on what would consist of a promotional material. The definition reads as follows: **Promotional Materials:** Marketing, education, website, and advertising materials (both printed and electronic) related to activities covered by these RT Standards.
Glossary – Relationship Index	RtC	Undo the proposed modification. Leave the definition intact as on the 15th Ed of the RT Standards. Otherwise, the proposed modification will create contradictions all over the place in the Standards. "Relationship Index" is the Traditional term, and it must stay intact.	NO	The committee noted this comment but did not feel that a change was needed at this time. The committee feels that the update of the definition to direct users to "Likelihood Ratio" best reflects the intent of the standard.
Glossary – Traditional Relationship Testing Statistics	SC	NA	NA	The committee created a new definition for the term traditional relationship testing statistics reflecting the inclusion of this term throughout the RT Standards, most specifically in reference standard 6.4A. The definition reads as follows: **Traditional Relationship Testing Statistics:** Methods where the likelihood ratio is calculated using formulas that include the frequencies of specific alleles, genotypes, or haplotypes of the tested parties, as opposed to other parameters (eg, shared centimorgans). These statistics are required for standard STR loci, HLA types, and blood types, but may also be applied to other methods. See Non-Traditional Relationship Testing Statistics.