Significant Changes and Response to Comments Received to the 15h edition of Standards for Relationship Testing Laboratories

Please note that public comments that were submitted address the proposed 15th edition of RT Standards, and not the final version. The changes are best understood when the proposed Standards are compared to the final published version. The program unit has elected to make the substance of public comments that were submitted a part of this document. Guidance that appears with the 15th 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 that what appears below.

Standard	SC/RC	Comment	Change made?	Outcome
1.2.2.1	SC/RC	Suggest adding the clause, "…to stop or suspend laboratory operations."	YES	The committee agreed with this comment and edited the standard by adding the clause "…and to stop or suspend laboratory operations." to the end of the standard. This addition will ensure that it is understood that when lab operations need to cease for any particular reason, the lab director has the responsibility to do so.
1.2.4	SC	NA	NA	The committee added the clause, "…for relationship testing purposes…" to standard 1.2.4 for clarity. This ensures that the focus of this individual's role could only be in a forensic DNA laboratory.
1.2.4	RC	Was it intentional for the technical leader acting as laboratory director to have a doctoral degree? The phrasing "…qualified by education…" isn't really clear on that point. Standard 1.2.1, for an ordinary lab director, specifies the advanced degree(s) but a forensic tech leader needs to have only a Master's degree and the forensic tech leader needs to "train under" a director, but that in itself doesn't answer the question.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The Quality Assurance Standards cited in the standard are clear that the individual serving in this role need only have a Master's Degree and not a Doctoral Degree. The guidance to the standard has been edited to reflect this information.
1.2.5	RC	The requirement for the Lab Directors to sign reports, when otherwise fully qualified personnel is processing and reviewing tests, places undue burden to the Lab Director. As a Lab Director, I am confident that a Quality Manager with specific credentials can be fully-qualified to certify DNA test results for any Legal proceedings. Recommendation: A new standard is proposed to expand the scope of professionals to be	NO	The committee reviewed this comment, but did not feel that a change was needed at this time. It should be noted that the individual in the role of quality manager cannot serve in this role if the rationale is that another individual has too much they are responsible for., This would also include not

		qualified by education and experience to sign reports. A Quality Manager with a Master's degree in related field and a relevant experience is fully knowledgeable of the testing and reporting requirements and the lab's quality system and thresholds, thus, he/she is fully qualified (at least in my opinion) to act as Certifying Scientist to the accuracy and validity of the Legal DNA test. The sole authority to train, qualify and authorize who signs reports should be on the Lab Director. And the sole authority to accept or not a report signed by a Lab Director-qualified Certifying Scientist should be on the Officially Interested Third-Party (e.g. courts, USCIS, DOS, etc). If approved, the report signed by the Certifying Scientist must also have the name of the Laboratory Director name/title printed in a prominent location on the report—e.g. as part of the report's letterhead. Additional comments: The Certifying Scientist is not substituting the Lab Director Designee position. Unlike the Lab Director Designee, the Certifying Scientist does not necessarily have the qualifications required for promotion to Lab Director.		having the ability to hire a qualified laboratory director designee. It should be noted, a quality manager can serve in the designee role if they meet the requirements as stipulated in standard 1.2.3.
1.6, 1.6.1 (NEW)	SC	NA	NA	The committee incorporated new standards 1.6 and 1.6.1 focused on risk assessment into the 15th edition of RT Standards based on similar standards in the 10th edition of Standards for Cellular Therapy Services and the proposed Quality Systems Framework. The requirements to perform risk assessments of activities performed in a laboratory is a practice that should be occurring at this time already.
1.6, 1.6.1 (NEW)	RtC	The wording implies that management should assess risks regularly. Typically, there is a prompt that leads to the need to assess risk, e.g., major change in an organization. This implies (to me) that mgt must ID, Assess and address risks with activities performed – meaning any activity or any data.	YES	The committee noted this comment and broadened the language in the standard from what was included in the proposed edition of Standards. It should be noted that a risk assessment can be encompassing of many factors, employee safety, laboratory safety and the issuance of reports that could

				contain errors just to name a few examples. In an effort to provide further information, Guidance to these standards have been created that should provide users with assistance in their incorporation into their policies, processes and procedures.
1.6, 1.6.1 (NEW)	RtC	What exactly would executive management be looking for and what sort of mitigation might be involved?	NO	The committee reviewed this comment and has crafted guidance to assist users in the implementation of the new standards.
3.5.6 (New)	SC	NA	NA	Standard 3.5.6 is new to the 15th edition. This standard has appeared in other sets of Standards AABB provides accreditation for and is also an element in the proposed Quality Systems Framework. The requirement to have process in place to minimize the risk of internal and external breaches is paramount to ensuring the confidentiality of records.
4.3.3	RtC	Please consider adding the following elements to the standard: "As this is prohibited, AABB-accredited laboratories may not delegate prospecting to third parties."	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee feels that entry #6 would already cover this requirement. Entry #6 reads as follows: Unless accredited for collection or verification activities by AABB, third-party administrators are prohibited from init iating cases for United States of America immigration, visa, passport, and citizenship testing.
4.4.1 (New)	SC	NA	NA	The committee created new standard 4.4.1 under supplier qualification to ensure that third party administrator's promotional materials are reviewed by accredited laboratories to ensure that the information contained in

				those materials meet the requirements of the Standards.
Chapter 5	RtC	Please consider the creation of a Public Interest Exclusion (P.I.E.) list like the ones used by the DOT/FMCSA in their drug/alcohol testing program. https://www.transportation.gov/odapc/pie	NO	The committee reviewed this comment but did not feel that this change could be made at this time. This request should be sent to the US Government or Department of State as the Standards are not capable of this.
5.1.1	SC	NA	NA	The committee added a cross reference to standard 1.1 in this standard for clarity, ensuring that executive management is involved and aware of all aspects of change control.
5.1.1	RtC	We see that 5.1.1- changes to processes and procedures - is included but are there other areas that should also be reviewed? Is the standard suggesting that review could be performed only once every 2 years (6.1.4) because it seems that at least the lab director would want to look at risks whenever a change is made? We understand that it says "at facility defined intervals" but maybe pointing to 6.1.4 is suggesting that a minimum of every 2 years is an appropriate interval? Perhaps guidance will answer our question?	YES	The committee noted this comment and felt that the addition of a cross reference to standard 1.1 would ensure that the laboratory director was involved. It should be noted, that all changes to processes or the creation of new ones processes have to be reviewed and approved by the laboratory director when they occur, not at a predefined yearly/every two year cycle.
5.1.5.2	SC	NA	NA	The committee added the clause “and/or profile” to this standard as there are cases when a sample can be released, or potentially only the profile is provided. This expansion ensures that the standard better reflects current practice. The committee also added the term “relationship” before “testing” to match the language in standard 5.1.5.1 ensuring that it is understood what type of testing is being performed.
5.1.5.2	RtC	Without reading the guidance, the intent of this Standard is unclear. Recommendation: “The Consent granted is for the specific test ordered. To re-use the DNA profile on another case requires a separate permission release.”	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee feels that the concepts here are included in standard 5.1.5.2

				already, however, the addition of the term "relationship" before "testing" will ensure that this understood. The committee has updated the guidance for clarity as well.
5.1.5.2.1 (5.1.5.2)	SC	NA	NA	Standard 5.1.5.2.1 is new to this edition however the content is not. In the 14th edition, the content appeared as the second sentence of standard 5.1.5.2. The committee broke this requirement out as a separate standard for clarity. The intent of the standard has not changed.
5.2.3.2	RtC	The guidance implies that donor's verification does not have to be on the sample envelope. This is actually not a good recommendation for Legal DNA Testing. To ensure the integrity of the sample collected, it is critical that the acknowledgements are also made on the sample envelope by both the collector and the donor (legal guardian when required). Recommendation: After witnessing that the sample collected was placed inside the envelope with the donor's name and that the envelope was sealed, the following acknowledgments should be made (on the envelope flap is highly recommended): i) Dated/Initialed (or signed) by the person collecting the sample; ii) Initialed (signed) by the person whose sample is collected or by the individual with legal authority accompanying a minor or legally incompetent adult.	NO	The committee reviewed the content of this comment but did not feel that a change was needed at this time. With this standard, the committee wishes to ensure that laboratories are able to meet the intent of this standard in multiple ways. This would include ensuring that the information is contained on an envelope or the report itself. This could include another validated mechanism as determined by a laboratory.
5.2.3.5	SC	NA	NA	The committee added the clause, "…directly between the petitioner and a facility accredited by…" for clarity. The committee also added a new requirement which reads, "Records of the initiation of this service by the petitioner shall be maintained in the facility's records." This requirement ensures that the facility maintains records of the direct communication between the accredited

				facility and the petitioner for the initiation of relationship tests for U. S. immigration purposes.
5.2.4	SC	NA	NA	The committee added the clause "including but not limited to" to this standard for clarity, understanding that individual laboratories can add more information to these records if they wish to do so.
5.2.4.1	SC	NA	NA	The committee added a new element to the standard which reads, "…and untested person(s) signing consent for a minor child or legally incompetent adult." This addition was included for completeness as it relates to identification records.
5.2.4.4	RtC	The time of sample collection (hr:min am/pm) is an element of chain-of-custody protocols and is missing as a requirement in this standard. Recommendation: Add "time" as a requirement in this standard.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. It should be noted that this test is not time dependent, unlike blood (for clinical purposes) that has a specific expiration time that needs to be included as a part of identification records. Laboratories can include this information if they wish.
5.2.4.8	SC	NA	NA	To ensure parallel requirements and construction, with standard 5.2.4.1, the committee added the phrase, "…for each individual tested and untested person(s) signing consent for a minor child or legally incompetent adult."
5.2.4.8.1	RtC	This standard's requirement that a photograph suitable for ID and a copy of the government-issued photo ID be submitted for each individual tested in U.S. immigration cases is troublesome, for two reasons. First, it is painfully problematic, if not impossible, to routinely achieve compliance with this standard for a fairly large group of immigration cases. Such cases include a significant proportion of ACS/CRBA cases involving applicants who are minor children that have no government-issued photo identification. Of course, being difficult to comply with is	YES	The committee reviewed this comment and agreed with the intent behind it. To accommodate the request, the committee has edited the standard into a list of two options. The first being, "For an adult being tested, a legible copy of the government-issued photo ID and a photo suitable for positive ID."

		not sufficient justification for removal of a standard, which brings me to my second reason. When standard 5.2.4.8.1 was originally introduced (13th edition), the Guidance document stated that the standard was added at the request of the U.S. Department of State. However, through our own immigration casework, I discovered that standard 5.2.4.8.1 directly contradicts the Department of State's own written DNA sample collection policies and procedures, to which consular staff members are required to adhere. This came to my attention thanks to the diligence of a sample collector for the U.S Consulate in Tijuana, Mexico. For one of our cases involving this consulate, specimens from a toddler were submitted for testing without a copy of a government-issued photo ID. The collector did, however, submit the following written explanation on the U.S. Consulate's letterhead: "Due to effective Jan 01, 2018 U.S. Department of State, MBB Relationship Testing Standards 5.2.4.8.1 we extended the following written explanation; On July 22, 2019, certified collector Chemist Elvira Castro Diaz proceeded with referred DNA test procedure at Post. Per 9 FAM 601.11-1 I DNA Testing Procedures regulation applicable to minors, both parents government-issued photo ID's and birth certificate for children were requested." Ms. Castro Diaz's citation was taken directly from the U.S. Department of State Foreign Affairs Manual (FAM) and Handbook's section entitled "Visas and DNA", in a subsection pertaining to DNA testing to verify relationships for U.S. immigration. This procedure—which clearly does not require a government-issued photo ID to be submitted for minor tested children—was published on October 19, 2018, 10 months AFTER the 13th Edition AABB RT Standards went into effect. In other words, the year AFTER RT Standard 5.2.4.8.1 originally became effective, the U.S. Department of State—the entity to which the 13th Edition Guidance document attributed the addition of Standard 5.2.4.8.1—implemented a DNA sample collection policy for its own consular staff that directly contradicts that very standard. So, it begs the question...if the sample collection procedures published by the U.S. Department of State and followed by U.S. Department of		The second being, "For a child being tested, a copy of the government-issued photo ID or the birth certificate and a photo suitable for positive ID." The split of these requirements that better reflects the current practice in AABB accredited laboratories.

		State employees directly violate the AABB standard that was purportedly added at the Department of State's request, is it possible that the RT Standards committee misunderstood what the Department of State was requesting? Does the committee realize that, in order to meet this standard, AABB-accredited facilities must employ procedures that are designed to persuade Embassy sample collectors to violate their own internal, written policies? I therefore propose that RT Standard 5.2.4.8.1 either (1) be revised so that it is at least consistent with the Department of State's own existing sample collection policies and procedures, or (2) be removed altogether. If the committee is unwilling to entertain such changes to this Standard, then the Guidance document should be revised to include, at a minimum: (a) a detailed explanation as to how and why the requirements of this standard contradict with the existing published policies and procedures of the U.S. Department of State; and (b) guidance that will assist AABB-accredited RT facilities in complying with requirements of this standard that directly conflict with the procedural requirements imposed by the Department of State on its own consular DNA sample collection staff.		
5.3.8	SC	NA	NA	The term "combined" was included in the standard for accuracy. The crossreference to 6.3A was added for completeness.
5.3.11.2	SC	NA	NA	Standard 5.3.11.2 was re-written for clarity. The standard is now written in a way that focuses on confirming the phenotypes of each tested party which was and is the intent of the standard.
5.3.14.3	SC	NA	NA	The committee added the clause, "new multiplex kits" to the standard for clarity. This addition reflects current practice in AABB accredited laboratories.
5.5	SC	NA	NA	The committee rewrote this standard to match the style in which standards are typically presented. The intent and content has not changed.

5.5.2 (New)	SC	NA	NA	This standard is new to the 15th edition and was added for completeness. These elements were introduced in a previous edition of Guidance and should be familiar to AABB accredited member laboratories. The standard reads as such, "When linked loci are used, the laboratory shall have policies, processes, and procedures for estimating and minimizing the effects of linkage on non-parentage cases."
6.3.2	SC	NA	NA	The committee added a clause to the standard for clarity. This addition ensures the standard and Standards reflect current laboratory practice. The addition reads as such, "In addition to the combined relationship index, the laboratory shall have the opportunity to discuss autosomal and nonautosomal findings separately."
6.3.2	RtC	In a case with multiple typed children, but no typed parents, the account indicates that both parents are in question for all pairs of alleged siblings. So, we are testing full vs half vs unrelated for all children. If we reach a conclusion that one or more of them is a half sibling, the autosomes cannot determine if they share a mother or a father. The non-autosomal loci may be able to resolve this, depending on the situation. While all possible pedigrees could be compared with both autosomes and X-loci, there currently is no software that can do this analysis in a straight forward way and it is probably unnecessary, if the autosomes are sufficiently conclusive for the half siblings. For example, if we have 3 female children, and the autosomes are conclusively indicating that 2 are full siblings and 1 is a half sibling (probability >99%). Then shouldn't we be allowed to simply test maternal half siblings vs paternal half siblings, using non-autosomes (e.g. X-loci)? Instead of trying to test all of the sibling relationships that	YES	The committee agreed with the intent of the comment and felt that the addition of the second sentence in bold was appropriate. This ensures the standard and Standards reflect current laboratory practice. However, the change requested in the first sentence could not be made at this time. The committee feels that this should be discussed in guidance and then potentially included in the proposed version of the 16th edition of Standards for Relationship Testing Laboratories for member comment and feedback.

		are possible. It is clear that under this situation, the X-loci are addressing a different question than the autosomes. Therefore, I propose the following change: 6.3.2 Nonautosomal Findings Nonautosomal results, when tested for parentage, avuncular, full sibling, half sibling, and grandparent, **and when testing the identical set of hypotheses**, shall be incorporated with autosomal results into the combined relationship index. **In addition to the combined relationship index, the laboratory shall have the opportunity to discuss autosomal and nonautosomal findings separately.**		
6.3.2.2	SC	NA	NA	The element added the term "linkage" to the standard for consistency with other changes made to the Standards. This ensures parallel language is used throughout the edition.
6.4	RtC	For marketing involving Immigration/Visa/Citizenship/Passports, it needs clarification to what extent can a laboratory be allowed to do marketing (for example) using websites that are not their official website. For example, there is an accredited laboratory that is setting up collection sites with their customized website in other countries with high volume of US Immigration cases, and that lab is prospecting immigration/USCIS/Visa/Citizenship/Passports cases from their non-accredited locations abroad. It needs to be made clear if this practice is acceptable as many of us are under the impression that Immigration/Visa/Citizenship/Passports case can only be initiated by Accredited Facilities. For instance, if one wants to prospect from other locations, then, one would accredited more facilities (e.g. Collection/Verification/Reporting site)--otherwise, what is the point of accrediting more locations. Recommendation: Marketing involving Immigration/Visa/Citizenship/Passports is only allowed from the lab's main URL. Any other URL is prohibited.	NO	The committee noted this comment but could not make the suggested edit at this time. The RT Standards cannot take this step as it is beyond the purview of the edition. The committee feels that the content of standards 6.4 – 6.4.5 is the extent to which the Standards can monitor its accredited laboratories.
6.4	SC	NA	NA	The committee added cross references to standards 5.2.3.5 and 6.4.2 for completeness.

6.4.4	RtC	This standard needs clarification to what extent a laboratory be allowed to do marketing (for example) using websites and contact information that are not their official website.	NO	The committee reviewed this comment but could not make a change at this time. The Standards cannot review or assess against activities that are not covered under the purview of the Standards.
6.3A, A #5	SC	NA	NA	The committee added the clause "… as designated by the participants or closest available frequency database" to ensure that member laboratories do not use an allelic frequency database compiled from multiple populations or racial groups as standard practice. Wherever possible, an allelic frequency database closest to the self-identified racial designation of the tested parties should be used to provide the most accurate determination of relatedness.
6.3A, B, #3, d	SC	NA	NA	The committee expanded subletter "d" was added for clarity to ensure that any report articulates the limitations inherent with non-recombining haplotypes in terms of identifying a familial link, ie determining a specific relationship of two individuals who are distantly related vs identifying lineage from a common relative. The addition reads as follows, "An explanation on non-recombining haplotypes inheritance and limitations to these markers shall be provided."
6.3A, B, #3, e (New)	SC	NA	NA	Subletter "e" is new to this edition and was added based on the expansion of subletter "d." A very high likelihood ratio obtained from non-recombining haplotype markers used in combination with autosomal markers CRI of < 1.0. The addition reads as follows, "When autosomal likelihood ratios

				are not in agreement with nonrecombining haplotypes (leading to a different conclusion) an explanation on nonautosomal inheritance and limitations to these markers shall be provided.”
Glossary - Linkage Disequilibrium	SC	NA	NA	This definition is not new but was merely relabeled as “linkage disequilibrium” for clarity. The content of the definition has not changed.
Glossary - Non-Recombining Haplotypes	SC	NA	NA	This definition is new to this edition and was included in concert with the update to reference standard 6.3A, #3, d and e. The definition reads as follows, “A set of genetic markers that are inherited as a group from one parent in its entirety, e.g., commonly used Y chromosome markers.”