Response to Comments Received to the 13th edition of Standards for Relationship Testing Laboratories

Please note that public comments that were submitted address the proposed 13th 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. This document does not represent a full summary of significant changes to the 13th edition of RT Standards. Guidance that appears with the 13th 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	RC/SC	Comment	Change made?	Outcomes
General	RC	Federal, State and Local laws. The standards should strengthen the language stating where AABB stands on regards to compliance with Federal, State and Local laws. While it is challenging for AABB to be aware of the law at the state and local levels, the responsibility to follow the applicable laws lays entirely in the accredited facility. However, AABB is in a prominent position to enforce consistency in the standards and the Federal laws for Immigration DNA Testing.	No	The committee noted this comment, and would point the commenter to the index and preface of the Standards which requires that all laboratories, in addition to following the *RT Standards* are required to follow all local, state and federal laws where applicable.
1.1.3, 1.1.3.1	RC	We are proposing to formalize and strengthen the idea of a Quality Manager to replace the "quality representative" as described in Standard 1.1.3. A new standard within the 1. Organization Section with the following sub header is proposed: Quality Manager Qualifications and Responsibilities. The Quality Manager oversees the control systems necessary to ensure that information generated by the laboratory is generated in conformance with the quality management program. Here the term "equivalent"—as used in the proposed verbiage of Standard 1.2 of the 13th edition—is more appropriate for the description of the Quality Manager Qualifications and Responsibilities as the individual with experience from an "equivalent" accredited laboratory can serve well in this position with minimal training even if he/she has not previous work experience on a AABB Accredited laboratory—but this is not necessarily the case for the Lab Director.	No	The committee noted this comment but did not feel that a change was needed. The committee feels that the individual designated the quality representative can serve in this role.
1.2	RC	A new standard should state clearly if remote Lab Directors are allowed at accredited collection/verification sites. The remote Lab Director is justifiable when outsourced by	No	The committee noted this comment, and responds

		a laboratory—and there should be also another standard addressing their important role in the accreditation process. However, the role of Remote Lab Director in an accredited collection/verification facility is largely unclear. For instance, is AABB going to accredit a room with a desk and a computer system for the lab Director to work remotely and visit once a month to turn the light on to show signs that someone has been there?		that if a laboratory has a director that works remotely, that as long as this is detailed in the facility's policies, processes and procedures and those same policies, processes and procedures are validated, they would be in conformance with the standard.
1.2.2	RC	The description should be expanded to allow a "Lab Director in training" to sign reports under the guidance of an AABB-qualified Lab Director as part of the training. The Lab Director should be given the authority to determine when the Director Designee is ready to work independently.	No	The committee reviewed this comment and notes that reference standard 6.3A(6) defines who has the authority to sign reports. In this case it is the discretion of the laboratory director to define who can sign a report, though they retain ultimate responsibility.
3.4.3 #1 (New)	RC	1) The term, 'Assessment reports', needs to be more well defined. The term 'Assessment' is defined in the glossary but that definition with 'report' after it is not what is meant in this context. Perhaps a different word than Assessment should be used. We suggest, 'an equipment and calibration report shall be completed', world be clearer.	No	The committee noted this comment but did not feel that a change was needed at this time. The standard in question has a focus of an assessment report and not an assessment of the report.
4.3.3	RC	Please add the following item: 6) "DNA testing for immigration must be initiated by the AABB Accredited laboratory only". USCIS policy states that "under no circumstances should petitioners use third-party vendors to select their lab, arrange appointments, or to transport specimens outside of the lab chain of custody controls"—9 FAM 601.11(b, 1-4).	No	The committee noted this comment and points out that this requirement is already covered in standard 5.2.3.5. To ease confusion a cross

				reference to standard 5.2.3.5 has been added.
4.5	RC	There's redundancy between items 1, 2, and 3. It seems to me that #1 could be deleted with no loss of information or intent.	No	The committee reviewed this comment and notes that the redundancy is intentional in this case. The redundancy ensures a broader understanding of the standard and its implementation.
5.2.2	RC	We feel this standard contradicts 5.2.2. (The words “or witnessed by a competent person” imply that anyone can collect the sample as long as a competent person is the witness.) We feel that if the standards of 5.2.3 (and subordinate clauses) are met, a sample shall be deemed acceptable. Collections performed at a US Embassy must use embassy personnel. The AABB accredited lab has no say in this.	No	The committee noted this comment but did not feel that a change was needed at this time. The committee points out that this is all covered in the guidance associated with this standard.
5.2.2.2 (New)	RC	Maybe there's something elsewhere that addresses this, but what is to constitute "training" or "trained"? Without it being entirely subjective, what should be the minimum that a collector should be expected to know or do? I know that the AABB certification covers whatever is expected, but what standards does a non-AABB certification have to reach?	No	The committee reviewed this comment and noted that it is the responsibility of each laboratory to ensure compliance with the standards. The guidance to the Standards do delve into this further.
5.2.4.2	RC/SC	Add at the end of the sentence: …unless for sibling-only cases only where the race of the child is necessary.	No	The committee noted this case, and feels that sibling study does imply two children which would not apply here. The committee has created new standard 5.2.4.3 to address this situation.
5.2.4.8.1 (New)	RC	Please check the verbiage with the State Department. They also require that the original is seen and compared with the copy. They do not accept a legible copy of the	No	The committee reviewed this comment and noted

		government issued ID alone nor they accept an ID that expired. The collector has to actually see the ID and either makes copy of it or compares it with the copy that the testing donor might bring in.		that the Department of State was involved in the crafting of the language of this standard. Guidance will assist with the understanding of how this standard will be implemented.
5.3	RC	We request that AABB standardize formatting of test results across accredited labs to include a field for the number of loci tested.	No	The committee did not feel that a change was needed at this time and notes that the loci tested are already required to be listed on the reports already.
5.3.2.1	RC	"...three or more independent autosomal loci." A more meaningful statement of necessity would be testing to a certain power of exclusion. Three loci would be informative only for something with a POE of the sort attained by RFLP methods, which pretty much nobody uses any longer. Just saying "three loci" is as misleading as those labs who brag that they can test several dozen loci. It's the scientific power of those loci that is the real requirement.	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee will strengthen the guidance and consider a potential change for the next edition.
5.3.2.2	RC	In 5.3.2.2 drop the phrase “is the biological parent” it should read: 5.3.2.2 When the null hypothesis is that a child inherited its parental obligate allele (POA) from a person with the genotype of the alleged parent and the alternate hypothesis is that the child inherited its POA from a person who is related to the tested alleged parent, and there is a failure to exclude, the laboratory shall test eight or more independent autosomal loci.	Yes	The committee agreed with the comment submitted and the change was made.
5.3.8 (New)	RC	The AABB is promoting two party biological relationship testing which is not as informative as testing multiple family members. The proposed support of two party testing contradicts the spirit of prior AABB’s guidance on including additional family members in the testing. See: ● Section 5.3.7 of the 12th Edition Guidance Document for the inclusion of	No	The committee reviewed this comment and does not feel that the standard promotes two party testing. The guidance document does indicate that testing a parent is the

		mothers rather than two party paternity testing ● AABB's Guidelines for Mass Fatality DNA Identifications Operations Section II.B.1.c where the recommendation is to collect samples from as many family members as possible. Testing additional relatives will: ● Provide significantly more information to make informed conclusions in determining relationships ● Offset current inherent errors in the statistical analysis due to US allele frequency databases being used in the statistical analysis of persons from countries with potentially significant population substructure. For example, US Caucasian databases are used for families from Afghanistan where close biological relatives have been known to mate and therefore significant subpopulations may exist. ● Identify cases of fraud for example where a cousin may be posing as a sibling.		best option, however recognizes that there are instances where this is not possible. This standard should assist those involved in immigration testing.
5.3.8.1 (New)	RC	Twenty autosomal STRs being required before we can report out an inconclusive result in a 2 party second degree relationship test is too high a bar to set. With the new multiplex Fusion kit we have only 22 markers to begin with and in 2 degree relationship we are not including vWA based on the linkage with D12S391 reducing the possible number to 21. If you have some degradation or inhibition the larger markers such as D22S1045 or the Penta loci drop out and now you only have 18 or 19 markers. In a perfect world all samples would give full profiles but we don't live in a perfect world. More markers are not always better due to mutations and other possible genetic anomalies. We suspect that this change related to the 'error rate' requested in 5.3.8.5 or a request from Homeland Security; however, we do not believe this will do anything to change the possible error rate. We would recommend a more attainable 16 marker minimum for reporting an inconclusive result in 2 party 2nd degree relative cases.	No	The committee noted this comment, and wanted to clarify that the 20 sample study is only required if the report is inconclusive and not in all cases.
5.3.8.1 (New)	RC	There is no scientific evidence supporting that at least 20 autosomal STR loci will make the results conclusive. This requirement will unnecessarily place some laboratories on a difficult position as testing for 20 STR markers require the purchase of very expensive instrumentation. Mandatory extended STR markers are only relevant in Forensics Identity efforts, but it is yet to be proven that this is the case in the parentage/relationship establishment. Mandatory extended STR markers are also a form of forcing the laboratories to buy highly priced equipment. Don't make them do that if there is not a merit.	No	The committee noted this comment but feels that the standard as written will encourage further testing when test results are determined to be inconclusive. The committee does not feel

		I am aware that: "The data on which these requirements are based will be submitted for publication in the near future." But please know that there are plenty of examples showing that this is not necessarily the case. For a laboratory that uses <20 STR markers, the best way to handle an inconclusive report is with right word choice in the conclusion statement of the report.		that the wording of the standard should require the purchase of any new equipment.
5.3.8.1 (New)	RC	This standard is not necessary if a Bayesian analysis is used and a Probability of Relationship is reported. Without further information, it is difficult to comment on how error rates would be appropriately identified. Will they incorporate the race of the tested individuals and account for population substructure? An error rate typically describes how often a laboratory issues the incorrect answer as a result of an inherent activity within the laboratory. The use of "error rate" is not appropriate in this context. This topic can be addressed during the HITA workshop. If the standards committee believes important to report error rates, the Standards committee should consider providing guidance so that smaller laboratories can comply with the standard. For example, small Medical Examiner's Offices do not have the resources to conduct large studies that may not be necessary if they use a Bayesian Analysis.	No	The committee noted this comment and points out that reporting a probability of relationship is required, and reporting an error report would need to be included as well. The committee will expand the guidance accordingly.
5.3.8.2 (New)	RC	For 2nd degree relative associations we have always used the very effective and statistically valid predicates from Konrad Hummel. We see no compelling reason to abandon our system for interpreting a likelihood ratio between 9 and 1/9 (.1111) as being inconclusive as described by Hummel. We believe the basis for this determination, statistically and logically, has not changed. We believe this is a statistically valid method that should be sufficient to meet the requirements for reporting our results. If a lab currently does not have such a procedure your rule could be applied.	No	The committee reviewed this comment and feels that the standard as written addresses this already, as such, no change was made to the standard.
5.3.8.2 (New)	RC	This standard appears to be created in an effort to provide a reliable answer to DHS for cases that DHS does not currently accept (sibship, etc.). A likelihood ratio (LR) of 10 is not sufficient to provide any statement about an immigration case. A large percentage of these cases are from countries where there is a sub population structure and appropriate population databases are not available. While we routinely use accepted US population databases to represent these populations, it must be understood that there has to be a large cushion for error to address these sub structure issues. For example, a LI of 10 does not have a margin of error that takes into account that a US black population database may over or under represent allele frequencies of a small village's population in Africa.	No	The committee reviewed the comment but did not feel such a change was appropriate at this time. The committee notes that correction factors such as theta can be applied to the calculations if significant inbreeding exists. Guidance to standard

		Does the data provided by the cited studies to support the conclusion that a LR of 10 is sufficient include studies of subpopulations of groups in Africa or third world Asian or Hispanic countries? Studies to determine an appropriate LR need to include databases for the appropriate population groups and family structures in an effort to determine the acceptability of a LR that is based on an American Population database. The minimum acceptable LR number needs to provide some reasonable protection that even if the population databases utilized are not specific to the population group that is being tested, a reliable answer can be obtained. Has this new standard accounted for the possibility of other relatives? Does the cited study include comparisons of other possible biological relationships other than those described by a petitioner? In most cases when a person is falsely represented as a sibling, half sibling or child for immigration purposes, the tested parties are not completely unrelated people. When such a low threshold is set there will often be occasions when relatives other than siblings meet the standard. Since the goal of DHS and USCIS is to determine if individuals are related in the way that is stated in their application, this standard may fail to meet that goal. If the study that is used to support this standard fails to address what occurs when other relatives, such as cousins, are tested then there may be a significant percentage of the time when other relatives will meet this minimal standard.		5.5.3.4 is available to provide further information.
5.3.8.2 (New)	RC	I don't understand the committee's thinking on putting into standard that a LR of 10 in a case of half-sibship must be considered evidence supporting the claimed relationship. In a paper (published in Transfusion) from 2007 published by Allen et.al. we showed that an LR of about 40 was needed to have any confidence that the questioned relationship was valid. Seems the Committee has ignored the scientific literature and made a decision that does a dis-service to consumers of relatedness testing.	No	The committee reviewed this comment and did not feel that further change was needed. The data reviewed included this study. However the totality of the data reviewed supported the use of a LR of 10.
5.3.8.2 (New)	RC	If supporting evidence requires PI>10, then the inconclusive should state $0.1 \leq PI \leq 10$ which is greater than or equal to 0.1 to less than or equal to 10, not “between” 0.1 and 10, and the non-supporting PI would be <0.1. Whatever number is used, the upper limit can’t be in both inconclusive and conclusive, and the lower limit can’t be in both inconclusive and non-supporting.	Yes	The committee reviewed this comment and agreed with the intent. The standard was edited to include the less than or equal to sign in the standard.

5.3.8.2 – 5.3.8.4 (New)	RC	The number "10" should be changed to "100". "0.1" should be changed to "0.01". This should apply to *all* alleged relationships. A likelihood ratio (LR) of 10 means an approximately 9% chance that the alternative hypothesis – that a random individual is the true relative - is correct (assuming 50% prior odds). We think that is too high. The combined weight of the genetic evidence required to render an opinion of relationship (or non relationship) should be standardized across *all* accredited facilities. Unlike laboratory methods (such as the concentration of a reagent to use in a reaction), the principles of genetics, mathematics, probability, do not vary from lab to lab. We think a minimum LR of at least 100, or below 0.01 for an opinion of non relationship, should be set in all cases. This gives an approximately 99% probability that the hypothesized relationship is the correct relationship (assuming 50% prior odds). The fact that many alleged relationships such as single grandparentage, sibling, half sibling, avuncular, some genetic reconstructions, etc. may not produce a LR greater than 100 should not matter. The AABB should set a minimum threshold of at least 99% to state that an alleged relationship is supported.	No	The committee reviewed this comment but did not feel that any changes to the standard was appropriate at this time. The standards need to maintain a balance of falsely finding a relationship versus an inconclusive finding or no relationship at all.
5.3.8.2 – 5.3.8.4 (New)	RC	We suggest that laboratories also establish policies for verbal qualifiers that best address the situation being reported.	No	The committee noted this comment but did not think it would be appropriate to make this change at this time. The committee will consider such a change for the 14th edition.
5.3.8.2 – 5.3.8.4 (New)	RC	Standard 5.3.8 alters decades of relationship testing practice by removing the prior probability from the statistical evaluation process. Such a significant deviation from standard practice should not be taken without careful consideration and open evaluation and dialogue between relationship testing practitioners, statisticians and forensic mathematicians. Specifying a likelihood ratio threshold value of 10 without any indication of the number of locations and heterozygosity values of the locations has significant potential to result in inaccurate determinations of biological relationships. If and when the biological relationship testing community stakeholders have determined that relying solely on likelihood ratios is scientifically acceptable, rather than a Bayesian analysis then the number of locations and (along with minimum heterozygosity values) should be specified and the appropriate use of allele frequencies.	No	The committee reviewed this comment and notes that this the use of prior probability is required and covered in reference standard 6.3A, subletter B, 3 c.

		The Human Identity Trade Association will be hosting a workshop at the International Symposium for Human Identification (HITA) this fall. The goal of the workshop is to bring subject matter experts from around the world together to explore the possibility of simplifying the statistical analysis of kinship testing. This HITA workshop will be an ideal opportunity for an open discussion among international practitioners, statisticians and mathematicians to make recommendations for moving forward with such a significant change to established practice.		
5.3.8.4 (New)	RC	The exclusionary side of the testing process is less impacted by sub populations than inclusionary cases. However, a LR 0.1 occurs in full sibling (and more frequently in half sibling) cases even when a reasonable amount of testing is performed. In a DHS case, the personal impact of this decision could be devastating for a family who will never have the chance to redo or defend themselves. An average person often views DNA evidence as infallible. Cases in this range are fallible and the statements and conclusions drawn from them are viewed as "right" and final. When a DNA test is used as evidence to persecute or deny a family, we are doing harm if the conclusion drawn from the DNA information is not actually correct. This number should be at least one order of magnitude lower in order to make such a condemning and permanently impactful statement. Using databases that are not directly relevant to the subpopulation groups can have significant impact on these cases. There will be occasions when a specific allele is rare for a subpopulation but common in the database that is used for the calculation. This situation could lead to an artificially low LR. Additional testing in these cases will often resolve the issue. When considering a statistic as insignificant as 0.1 as an exclusion, it must be noted that the addition of a single locus can completely change the conclusion of the test. More evidence is absolutely necessary in order to provide a reliable answer.	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that much of what is included in this comment is already addressed in new standard 5.3.8.5.
5.3.8.4 (New)	RC	For sibling relationships, this threshold appears reasonable, but for half-sib/avuncular/grandparent, this threshold seems to be over-reaching. Given the fact that a number of studies have demonstrated that true-half sibs can have LRs far less than 1, granted testing only 15 STR loci, a finding of inconclusive is more appropriate. See J Forensic and Legal Med 2008;15:373-377.	Yes	The committee agreed with this comment and added new standard 5.3.8.5 to address this.
5.3.8.4 (New)	RC	Likelihood ratios less than 0.1 shall be considered evidence supporting no relationship. USCIS remains concerned that this standard definitively excludes a percentage of legitimate known half-sibling relationships. Based on the data provided by the AABB RT Subcommittee, five percent of known half-sibling relationships will be erroneously excluded by this standard. USCIS appreciates the AABB RT Subcommittee desire to	Yes	The committee agreed with this comment and added new standard 5.3.8.5 to address this.

		prevent any known unrelated half-siblings from being falsely categorized as legitimately related. However, under this standard 35 percent of false half-sibling relationships will be classified as inconclusive instead of being excluded. USCIS requests distinct standards for full siblings and half siblings, to allow a likelihood ratio of less than .1 to be considered inconclusive for half siblings. This would ensure that legitimate half siblings are not incorrectly excluded. If modification is not universally possible, USCIS alternately requests that the AABB RT Subcommittee consider adding a qualifier for tests conducted for immigration purposes, to allow a likelihood ratio of less than .1 to be considered inconclusive for half siblings. This would ensure that legitimate half-siblings do not fall into the "evidence supporting no relationship" category, and would operationally assist USCIS in evaluation of the lab result.		
5.3.8.5 (New)	RC	How would a lab know that the conclusion was false?	Yes	The committee agreed with this comment and edited the standard to read as follows, " The laboratory shall report the estimate of the percentage of individuals of known relationship that may have a combined likelihood ratio that is inconclusive, or supportive, or not supportive of the tested relationship for the laboratory's test protocol at the combined likelihood ratio reported for the case work."
5.3.8.5 (New)	RC	How is this error rate to be calculated? Will it be hypothetical based upon an inverse relationship to the sibling index or HS index? These questions will, I presume, be answered in guidance, but without that, it is unclear how we are to follow this standard.	Yes	The committee agreed with this comment and edited the standard to read as follows, " The laboratory shall report the estimate of the

				percentage of individuals of known relationship that may have a combined likelihood ratio that is inconclusive, or supportive, or not supportive of the tested relationship for the laboratory's test protocol at the combined likelihood ratio reported for the case work."
5.3.8.5 (New)	RC	An accurate 'error rate' for false conclusions of no relationship is not available through our data. It may be obtained within a range based on statistical modeling but we have no data to support a meaningful number of times we have issued a report of no relationship for a 2 party 2nddegree relative test that was incorrect. We are not aware of any case that we reported where the relationship is unlikely, very unlikely, highly unlikely, or practically excluded (per Hummel's predicates) that was later determined to be incorrect. Our verbal predicates do not include a statistical evaluation for a 2 party comparison that would result in a determination of 'no relationship'. Even with a CRI of 1/399 (.0025) or smaller we would report that the probability of this relationship is practically excluded but never 'no relationship'. This data is obtained from the qualitative allele assignments which we have always believed remains outside the realm of quantifiable margins of errors followed by a statistical evaluation of the likelihood ratios determined from two mutually exclusive hypotheses yielding the final probability. How is it an error if you have analyzed the data correctly and applied the correct statistical evaluation to the results and reported the correct probability of the outcome. The error would be in the laboratory reporting a 'no relationship' in a 2 party 2nd degree relationship analysis even with a very small CRI. You can always try to add more genetic data by including additional parties. In many cases this will provide enough information to confirm a relationship (but not always). This is now no longer a 2 party test. We believe this requirement should be struck from the standard.	Yes	The committee agreed with this comment and edited the standard to read as follows, " The laboratory shall report the estimate of the percentage of individuals of known relationship that may have a combined likelihood ratio that is inconclusive, or supportive, or not supportive of the tested relationship for the laboratory's test protocol at the combined likelihood ratio reported for the case work."

5.3.8.5 (New)	RC	This "error rate for false conclusions of no relationship" may be a very challenging set of numbers to produce. The rate for each relationship (full siblings, half siblings, avuncular, grandparentage) will of course be different, but how much does each vary by the number of systems tested? The particular combination of systems tested? The ancestry/race of the participants (and thus the population frequencies used)? Large numbers of pairs are easier to come by for siblings than for the other relationships considered--how large a data set is sufficient to come up with a meaningful error rate? It seems to me that if you want reliable error rates that are meaningful to the particular sets of loci and frequency tables in use by each laboratory, that some sort of open-access (i.e., member access) pedigree generator with frequency table input and flexible number and identity of systems would be necessary. Short of that kind of technical support, each laboratory will be forced to either troll their cases for confirmed usable data (probably limited, especially for the multi-generational relationships), undertake large population studies from volunteer families, or rely on published data that may not be representative of the particular testing parameters that the laboratory employs.	Yes	
5.3.8.5 (New)	RC	The error rate is going to vary from case to case based on the population of the test participants. Was this the intention from this standard? Given that appropriate population databases are not always available, this may need to be clarified to include some amount of inherent error due to incorrect, but as similar as possible, population database usage.	Yes	The committee agreed with this comment and edited the standard to read as follows, " The laboratory shall report the estimate of the percentage of individuals of known relationship that may have a combined likelihood ratio that is inconclusive, or supportive, or not supportive of the tested relationship for the laboratory's test protocol at the combined likelihood ratio reported for the case work."

5.4.2.2 (New)	RC	Why wouldn't you require a "closed system" method of parentage analysis to repeat sample testing in cases of exclusion? I don't understand how a closed system is any different that traditional STR typing, especially when it comes to protecting against sample switches and mis-labeling. The fact that the closed system is more expensive/test is irrelevant. Someone still has to identify the samples to test and to load the machine. Repeat testing for exclusion results protects against human error as much as instrument error.	No	The committee reviewed this comment and noted that guidance to the standard concerning labeling, specifically that it must be witnessed by two individuals to ensure that the process is done accurately.
5.4.2.2, #3 (New)	RC	We are not sure why in a closed system you would allow flagged loci that are found not to impact the results of the relationship finding be ignored. We would expect the same level of confidence concerning the identity of any peak between 80 and 500bp to meet the required standard and not be ignored just because it does not impact the results of the relationship finding. Do these closed systems regularly produce this kind of data and if so why are you willing to suspend the high quality standards set for labs not running closed system? We believe it is bad practice to allow unexplained data to be ignored at any time.	No	The committee reviewed this comment and notes that since the testing is being performed by an accredited laboratory, the data received would be further explained and not ignored.
6.3.3.1 (New)	RC	Replace “facility” for “laboratory”. Only a laboratory can manage all processes.	Yes	The committee noted this comment and updated the definition of facility accordingly.
6.3.3.1.1 (New)	RC	Replace “facility” for “laboratory” to be in agreement with the Federal laws for Immigration DNA Testing. The Federal law for Immigration DNA Testing clearly states that only an AABB accredited laboratory shall manage all processes. There is neither mention nor a suggestion that a collection/verification facility has been given a role. If the intent of the semantics facility vs laboratory is to have collection/verification sites take a role in immigration DNA testing, the best approach is to do things in the right order: First the written law, then the standards, but not the way around. The way the law is currently written is that Immigration DNA Testing is exclusively reserved for AABB Accredited Laboratories.	No	The committee reviewed this comment but with the adjustment of the definition of facility in the Glossary, no change was determined to be needed.
6.3.4.1	RC	The terminology "shall, if applicable, discuss the other alternatives" is unclear. "Shall" is a mandate, but "if applicable" is an escape hatch. When is it	Yes	The committee agreed with this comment and re-wrote the proposed

		applicable? When is it not? Is it applicable every time the laboratory "evaluates more than one possible relationship"? If so, then I think the start of the standard already creates that scenario and the later "if applicable" is an unnecessary and confusing qualification. If there are other criteria that factor into applicability, what are they? And what does "discuss" mean? The standard goes on to say that alternative individual likelihood ratios are unnecessary, but does "discuss" involve comparing the CLR of the final conclusion to the alternatives, or simply stating that the final conclusion relationship was more likely than the alternative(s)? I hope that the Guidance for this standard would flesh this out more.		standard to appear as such, " If the laboratory evaluates more than one possible relationship (e.g. Full Sibling versus Unrelated and Half Sibling versus Unrelated) and presents one of the relationships as the final conclusion, the other relationships considered may also be reported without presenting the alternative individual likelihood ratios. A record of the alternative likelihood ratios shall be maintained."
6.4	RC	We suggest the creation of a new standards to address the following: i) Name on the AABB listing must match the name on the accreditation certificate and the name used in the marketing material. A DBA in marketing material should not be allowed to make claims of accreditation, unless the DBA is the one on the AABB listing and the accreditation certificate. ii) If a business name and the DBA have the same physical location—even if they are owned by the same person—only one can be associated with the AABB logo, the claim of accreditation and the marketing material.	No	The committee noted this comment but did not feel a change was needed at this time. Substantial guidance is provided after 6.4