

Response to Comments Received to the 14th edition of Standards for Relationship Testing Laboratories

Please note that public comments that were submitted address the proposed 14th 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 14th edition of *RT Standards*. Guidance that appears with the 14th 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	Comment	Change made?	Outcome
General - Accreditation	<p>The certificate of facility accreditation should indicate clearly what a facility has been accredited for. Currently, the language used for fully-accredited facilities is: “<i>Certificate of Accreditation for the following activities: Relationship Testing Activities</i>”. This description not only fails to identify a facility that is fully-accredited, but also it does not match the language used in the Accreditation/Accreditation-Renewal Form. Please match the language in the Certificate with that used in the Accreditation/Accreditation-Renewal Form, and state clearly when a facility is fully-accredited. This is how is presented in the Accreditation/Accreditation-Renewal Form:</p> <ul style="list-style-type: none"> • Relationship Testing _ ALL • Collection and verification/reporting • Testing and verification/reporting 	NO	<p>The committee noted this comment, and while it does not relate to the Standards specifically, the information has been passed forward to AABB’s Accreditation Department. Accreditation will consider a revision to the certificate to ensure that they clearly represent what activities that laboratory is accredited for.</p>
General - Accreditation	<p>I believe that laboratories that do not have separate subsidiaries for their non-accredited activities are worthy of higher regard as the staff and equipment meet AABB requirements. Let's not get hung-up in minor technicalities such as specimen retention. The fact is, there is every reason to prefer a non-accredited test from an accredited laboratory than from one that is not accredited.</p> <p>The robots get the glory however accessioning is where the errors that frighten clients occur. Clearly high quality accessioning must be performed because the laboratory cannot know a `priori` whether a FedEx envelope contains specimens for a chain or non-chain test.</p> <p>Properly worded, I believe this can be good for the AABB brand world-wide.</p> <ul style="list-style-type: none"> • I suspect that a standard for AABB accredited specimen collectors exists and would be interested in review and commenting if permitted. • I have already provided my opinion that laboratories cannot authoritatively speak to activities that occur outside of their direct control and that the language of the reports should be quite clear about this. I have some knowledge of the history of welfare reform and the extrajudicial hearings that arose at the State-level in response. To my mind, the matter can be easily and 	NO	<p>The committee reviewed this comment but did not feel that a change was needed at this time. The RT Standards currently cover all of the contents described in the comment, therefore no addition was needed. The committee noted that specimen collection is covered specifically in the <i>Standards</i> and that chain of custody and reporting are required to be maintained.</p>

	more properly addressed by presenting two documents at preliminary hearings One attesting to specimen collection and the other to the laboratory services.		
1.2	The difference between “ <u>the</u> ” Lab Director and “ <u>a</u> ” Lab Director Designee has to be made clear. There is only one Laboratory Director, and he/she is “ <u>the</u> ” Laboratory Director of the Testing Laboratory. Other lab directors, including those associated with Collection and Verification/Reporting facilities, are Lab Director Designees.	YES	The committee reviewed this comment and noted that this concept could be made more clear in the <i>Standards</i> . However the committee felt that this change should be articulated in standard 1.2.1 and 1.2.1.1
1.2.1 (1.2)	NA	NA	The committee added the clause “laboratory” into standard 1.2.1 to ensure that was it clear that the director in question here was the laboratory director and not possibly a designee or other director.
1.2.1.1 (1.2)	NA	NA	The committee replaced “a” with “the” in this standard to ensure that it was understood that the tutelage had to be under the laboratory director of record of an accredited laboratory.
1.2.1, 1.2.1.1 (1.2)	It appears that the new standard (1.2.1.1) is being created solely so that standard 1.2.4 can be introduced more seamlessly. There is nothing wrong with the format of the older standard 1.2, and it should be retained if 1.2.4 is not adopted.	YES	The committee noted this comment but did not make a change, as new standard 1.2.4 was incorporated into the final 14 th edition.
1.2.4 (NEW)	This proposed standard has many flaws in our view. First of all, a typical forensic laboratory is a conglomeration of multiple fields (e.g.: trace, DNA, toxicology, fingerprint, ballistics, etc.) overseen by a single director of the laboratory, and each subfield is lead by one or more technical leader(s). Since the older standard 1.2.1.1 states that “the laboratory director shall have responsibility and authority for all policies, processes, and procedures,” the DNA technical leader/laboratory director may now have to be responsible for the entire forensic laboratory. In our experience, forensic lab technical leaders lack exposure to enough relationship cases to get adequate experience or retain their training / skills. For example, we are intimately close to the forensic DNA laboratories of both Los Angeles Police Department and the Los Angeles Sheriff’s Department. Between these two behemoth labs, they handle more forensic DNA cases than most states. Yet, they will perform less than twenty routine paternity or maternity tests a year (based on a quick phone call to one senior technical leader of the LAPD). When they get a relationship case, it often involves complex relationships frequently with DNA mixtures—cases which even seasoned RT lab directors would be hesitant to tackle. These two particular forensic labs are not naïve to assign the case to one of their analysts / tech	NO	The committee reviewed this comment but did not feel that eliminating the standard would be appropriate at this time. The committee noted that there are multiple facilities that focus solely on DNA testing and not the list of items included in the comment. Regardless of that, the individual in this position would need to be able to provide evidence of that they had the expertise required to be in this position and is the Technical Leader of a forensic DNA Testing Laboratory.

	<p>leads and will almost always call in outside RT experts/statisticians to help with testimony and calculations for these types of RT cases. From our observation, the technical leaders are accustomed to dealing with “match probability” and not with relationship calculations. Not only will they need to learn the routine RT calculations which is very different from match probability, they will need extensive training in calculations with degraded remains, mixtures, mutations, and complex relationships. With this combination of limited RT case volume and complex cases, interest in RT accreditation may come only from naive forensic departments and/or technical leaders who probably believe that simply running a relationship calculation-based computer program (and believing that it is infallible) is enough to be considered “trained” in RT.</p> <p>It also seems ridiculously unjust to suggest that forensic technical leaders should be given some preferential treatment that is not afforded to many RT laboratory supervisors who also possess a Master’s degree and, more importantly, much more exposure / experience to routine RT cases than any forensic tech leader.</p> <p>Allowing technical leaders (with lowered degree requirements and decreased exposure to relationship cases) to become RT laboratory directors certainly doesn’t improve the quality of the RT field; conversely, it lowers the overall standard of the entire field.</p>		
1.2.4	<p>The FBI QAS do not state that the technical leader is the DNA Laboratory Director; a search of the standards and the audit document reveal no mention of that TL acting as a director. In our experience, forensic labs have technical leaders in the different sections and an overall director. In addition, forensic DNA labs typically deal with unusual cases, complex relationships, and testing of remains rather than just maternity and paternity cases. Because of this, their training in calculations would need to be extensive. Forensics labs deal with far fewer relationship cases than a Relationship Testing lab. Their TLs typically have far less practical experience in family relatedness testing than an RT lab supervisor. Because AABB does not dictate exactly what needs to be included in the training of a director, who is to say that the training has been adequate? In addition, Directors, as defined by AABB standards, have responsibility for all policies, processes and procedures. A forensic lab TL does not have these responsibilities in terms of the procedures and policies that govern an entire laboratory. How would the Laboratory Director of the entire forensic laboratory feel about this individual having the authorities normally given to a lab director?</p> <p>How will a forensics lab meet standards 1.2.1 and 1.2.1.1? Will they be issued variances when others with a Masters degree don’t get the same</p>	NO	<p>The committee reviewed this comment but did not feel that editing the standard would be appropriate at this time.</p> <p>The Technical Leader assuming the role of a RT laboratory director would need to be able to provide evidence of that they had the expertise required to be in this position. As a technical leader under the FBI DNA QAS is required to have at least a master’s degree and such an individual is under this new standard is waived from the doctoral degree requirement. This is open to any technical leader who is currently approved under the FBI DNA Quality Assurance Standards and is in a laboratory accredited to the FBI DNA Quality Assurance Standards. When a facility is assessed by AABB, the assessment will focus solely for the activity being performed that falls under the assessment umbrella, and a technical leader could not serve</p>

	<p>consideration? Why would a technical leader in a forensics lab be any more fit to be a RT lab director than a supervisor in a RT lab? Even if a forensic lab terms its' technical leader as a lab director, why couldn't an RT lab do the same? A TL is required to have a Masters degree but RT lab supervisors may also have a Masters or equivalent experience and they can never become a RT Director.</p> <p>Why would a forensics lab even want to be accredited by AABB? Most forensics labs are overloaded as it is. They do not need accreditation other than their forensics' accreditation to report out relationship type tests. Is the purpose of allowing TLs to become lab directors only so that they can assist large labs that are already accredited in forensics and RT to report RT tests, likely at a lower salary than a relationship testing lab Director or Director Designee?</p>		<p>in a role for which they are not qualified by training and experience.</p>
2.2 (New)	<p>The thought of a single laboratory director effectively overseeing even five accredited labs/facilities is daunting. In our view, a laboratory director who ultimately has responsibility and authority for all policies, processes, and procedures should interact extensively with the lab/facility on a daily basis. This is particularly true for your so-called "Collection /Verification Facilities" / third party administrators ("DNA test resellers") since only one of a total of thirteen of these facilities has an on-site laboratory director, and nine of these facilities were independently-owned third party administrators prior to their accreditation (i.e.: they were never labs to begin with)*. These Collection/Verification sites should be monitored even more closely than an actual lab by an off-site laboratory director.</p> <p>Allowing a single laboratory director to oversee more than five facilities is severely overburdening that individual and is effectively having the individual act as a laboratory director in name only (as noted in your guidance). Therefore, we believe that the number should not exceed five facilities. We would also propose that there be some minimal daily requirements for directing a facility such as a daily discussion and summary from each facility with the laboratory director. This idea does not seem unreasonable if one considers that the laboratory director is ultimately responsible for the day-to-day operations of a lab/facility.</p>	NO	<p>The committee reviewed this comment but did not feel that a change was needed at this time. The decision to cap the ability to oversee no more than 5 laboratories was based on CLIA requirements.</p> <p>It should be noted that the standard does not require a laboratory director to oversee 10 laboratories, merely that this the maximum once can oversee.</p>
2.2 (New)	<p>A laboratory director shall oversee a maximum of 10 accredited facilities, no more than 5 of those shall be testing laboratories and the remaining may be collection/verification facilities.</p> <p>Replace "<u>A</u> laboratory director" for "<u>The</u> Laboratory Director". Make clear that this standard is directed to "<u>The</u>" Lab Director and not "<u>A</u>" Lab Director Designee. See my comments on Standard 1.2.</p>	YES	<p>The committee agreed with this comment, and as the changes were made to standard 1.2.1, the changes to change "a" to "the" were made.</p>
4.3.3, #6	<p>Unless AABB accredited, third party administrators are prohibited from</p>	NO	<p>The committee reviewed this comment but did</p>

(New)	<p>initiating cases for immigration, visa, passport, and citizenship testing. Modify this statement as (notice the new sentence—underlined): “Unless AABB accredited, third party administrators are prohibited from initiating cases for immigration, visa, passport, and citizenship testing. <u>As this is prohibited, AABB-accredited laboratories may not pay commissions or delegate prospecting to third parties.</u>”</p> <p>The State Department was contacted for interpretation of the rules and regulations regarding the choice by petitioners by laboratories their DNA relationship testing. Their response: “As mentioned in the FAM and on travel.state.gov, petitioners are required to contact an AABB-accredited laboratory directly and “under no circumstances should a third party be involved in the process of selecting a lab, scheduling the appointment, or any other process outlined”. As this is prohibited, AABB-accredited laboratories may not delegate prospecting to third parties.”</p> <p>Prohibition of Non-accredited TPAs receiving commissions for referrals of immigration/visa/passport/citizenship DNA testing will inhibit them from prospecting (e.g. by running search engine ads) on behalf of an Accredited Facility. Such ads are expressly prohibited by Standards 6.4.4 and 6.4.5.</p>		<p>not feel that the change was appropriate and that it could be considered guidance and was overly prescriptive. The committee will expand on this standard in guidance to assist users in the requirement’s implementation.</p>
4.3.3, #6 (New)	<p>Recommend that the language specify USCIS/DOS so as to not appear to interfere with testing performed for immigration to non-USA locations. Same with 5.2.3.5, 5.2.4.8.</p> <p>I believe that the definition of suppliers should not include TPA's as they are more properly classified as wholesale customers. Specimens are not supplies in the usual sense of the word. No more than urine sent for analysis is a supply.</p> <p>Regarding 4.3.3 [6]: With all due respect, this appears to be a non-issue. Laboratories already maintain records that definitively establish the source of a case and are required to refuse USCIS cases initiated by a 3rd party. Laboratories that do not follow DOS rules can be reprimanded by both DOS and the AABB (under 1.1.1). That is more than sufficient to deter the practice.</p>	YES	<p>The committee noted this comment and updated the standard from the proposed version to include the “United States of America” for clarity. This will allow users to understand that in other countries, other regulations may apply.</p>
4.3.3, #6 (New)	<p>This standard seems to allow large laboratories to set up accredited collection sites, have them initiate and deal with the collection process, and then send the samples to that large lab for testing. Is that the meaning? That seems like AABB is creating a means for the large labs who can afford to “sponsor” collection sites and become even bigger and take away testing from the small labs who cannot afford to pay for collection sites. This standard appears to encourage the formation of monopolies in the RT business.</p>	YES	<p>The committee noted this comment and understands the potential confusion. As a result, the committee removed the term “facility” from the proposed edition in the final version of the 14th edition. Please note that third party administrators are not permitted to become accredited.</p>
4.3.3, #6 (New)	<p>We might consider some basic assessment of TPAs and I would be happy to assist with a program. The result would be a template the laboratories could</p>	YES	<p>The committee noted this comment and understands the potential confusion. As a result,</p>

	<p>administer to their TPAs. Assessment could be administered online with video confirmation of the participant to reduce fraud. Basic concepts (many found in the Glossary), understanding of laboratory workflow, why relationship indices for non-excludes cannot be stated with absolute certainty, and similar fundamentals would demonstrate reasonable competency. The cost of administering would be more than offset by reduced support costs and redraws so likely the laboratories would be an easy sell.</p>		<p>the committee removed the term “facility” from the proposed edition in the final version of the 14th edition.</p>
4.3.3, #6 (New)	<p>What does the change regarding “3rd party administrators” mean for testing for immigration purposes, and does 3rd party administrators refers to 3rd party collections. I saw that in the glossary, “Third Party Administrators” is defined as: Businesses that are not laboratories themselves, but market relationship tests and then send the client or client’s samples to a laboratory for the relationship testing. Also referred to as brokers or resellers. I could also see various comments around that change.</p>	YES	<p>The committee noted this comment and understands the potential confusion. As a result, the committee removed the term “facility” from the proposed edition in the final version of the 14th edition. This does not refer to third party collection sites as these are chosen and vetted by the AABB laboratory performing the testing. Standard 5.2.3.5 applies.</p>
4.3.3, #6 (New)	<p>There is also the question as to whether the RTS, a document that is revised bi-annually, is an appropriate place to state regulations that are entirely under the control of a government agency that can revise them at any time. The DOS covers the matter quite well on their website and provides written instructions to applicants. One can rely on those to be up-to-date. Why introduce a less authoritative source? The marketplace effectively curtails errant TPAs via chargebacks and bad reviews for incompetently delaying cases. Repeat offenders are terminated by their upstream laboratory for wasting their time and providing poor service. Same as if they repeatedly provided mislabeled specimens or incomplete chain docs. Why is USCIS testing a special case? Better to focus our efforts on improving TPA education overall. In my experience, on-boarding by AABB accredited laboratories leaves much to be desired. I would therefore recommend that the AABB use their resources to tackle TPA education, and possibly TPA assessment, in a more comprehensive, holistic matter. On the other hand, there does appear to be a longstanding problem where AABB accredited laboratories incorporate unaccredited entities in far-off lands that then advertise the accreditations of their American cousins. I don't believe this is a deliberate violation as much as a misguided belief that they are all part of the same family. When in fact these entities are no more than TPAs. Not sure this rises to the level of the RT Standards. However, it may cast the AABB in a poor light when they nuke micro-enterprises with C&D letters while giving the big guys a pass. Not to mention providing a hell-of-a defense</p>	NO	<p>The committee reviewed this comment but did not feel that a change was appropriate at this time. The Standards as written are comprehensive and various government agencies asked AABB to assist in their regulations. By working together there has been a reduction in fraudulent activity. If the government changes a regulation, AABB has the ability to issue interim standards to accommodate the change.</p>

	in the courtroom.		
5.2.3.1	We recommend that the term "sample" be defined in the glossary so it is clear as to whether each buccal swab is required to be individually labeled.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that the Guidance document covers this issue and describes that in fact buccal swabs would be considered a sample.
5.3.3, #4 (New)	Autosomal markers certainly can be informative for hypothesized relationships beyond second order. I just confirmed a case with first cousins based on autosomal loci.	NO	The committee noted this comment, and agreed that this statement is true, and that the standards do not prohibit this.
5.3.3, #4 (New)	4) The proposed standard states that autosomal loci shall be used unless those markers are not informative. This proposed statement suggests that a laboratory doesn't have to test autosomal loci at all. Moreover, is the standard saying that you don't have to report all loci tested? If autosomal loci don't have to be tested, wouldn't this preclude you from finding that the second order relationship claimed and subjected to testing is actually first order? You might not discover this fact if you did not test autosomal loci. Guidance that is listed after 5.3.11.2 does not apply to that standard. It refers to 5.3.3	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes this standard does not say that a laboratory "doesn't have to test autosomal loci at all". The standard is pointing out when autosomal markers must be tested and exceptions where non-autosomal markers can be used alone. This standard does not imply or state that a laboratories "don't have to report all loci tested."
5.3.11.2 (New)	It is well defined which samples in a typical parentage test must be retested to confirm an exclusion (5.3.11.1). Is the standard saying that only the individual alleged to be part of a pedigree needs to be retested or is it saying that all of the samples in a non-parentage exclusion case /a kinship case in which the genetic evidence does not support the relationship (LR <0.1 in 2 party comparison) should be re-tested? Many LIMS can match the C's sample against the other alleged parents in the system but that would be difficult with non-parentage or a case where genetic evidence does not support the alleged relationship of participants, so perhaps all samples should be re-tested. The stated standard is not clear on which samples need to be confirmed.	NO	The committee noted this comment but did not feel that a change was needed at this time. The committee will however add guidance that directly relates to multi-family relationship testing.
5.4.2	I am interpreting that a DNA profile from a Closed System can be used on an AABB Accredited Relationship Testing report. I am unclear how can one justify that a Positive Control (PC) is run only once per lot #. If the lot lasts six months, this means that the PC control is run once only in the 6-month period. The Closed Systems use a large library of Allelic Ladders and the data processing software automatically selects the best ladder. What are the quality checks that would give the reassurance that the profile reported by a Closed System is 100% accurate? Our laboratory is interested in this technology for Legal DNA Testing, but, the results have to be legally defensible, and I don't know how to address this issue with the positive control with the limited guidance provided in the standard.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee has included guidance to ensure that what is required of closed systems is understood.

5.5	For non-parentage cases, the report with test results should indicate clearly what hypothesis was used in the calculations. For Sibling cases, the lab should indicate if the scenario was setup as: i) full vs unrelated; ii) half vs unrelated; or iii) full vs half (or vice versa). For Avuncular cases, the lab should indicate if the formulae used are for: i) full sibling of the alleged parent; or ii) half sibling of the alleged parent. This knowledge can assist the Officially Interested Third-Party (e.g. Requesting Agencies such as Courts, USCIS, US Embassies, etc) in their proper interpretation of complex cases.	NO	The committee reviewed this comment and did not feel that a change was needed. This is a requirement under the reporting of results. See Reference Standard 6.3A Requirements for test reports. Section B.c & g that require stating the appropriate relationship. Also see 6.3.4.1
5.5.1 (5.5)	We may need to distinguish between linkage (which is accounted for via transmission probabilities) and linkage disequilibrium (which is accounted for by using haplotype frequencies). LD is generally not a problem for autosomal loci. In fact, I have not been able to find any published research demonstrating significant linkage disequilibrium for any of the standard autosomal STRs (except for O'Connor et al 2011, which was later corrected). For X-chromosome markers, within a linkage group, this certainly applies. Although LD probably should not be assumed even for these, but tested for and addressed when found.	NO	Standard 5.5.1 is new to this edition and previously appeared as the second sentence in standard 5.5. The previous version of this standard only referred to linked loci, when more appropriately one is looking for linkage disequilibrium. Guidance will be expanded to ensure that users can implement the standard.
5.5.1 (5.5)	Need to define significant. Will guidance include the loci that are currently considered to be linked?	NO	The committee reviewed this comment and noted that this would be covered in the guidance.
6.3.2	Y-STR markers can help solve difficult kinship cases. I agree that it is better to put a combined LR in a single report that allows an overall likelihood of the tested biological relationship. However, the standards provide limited guidance. The calculations are not just the simple formulae of the inverse of the profile's frequency. There is more than that. The complexity of this topic justifies a new chapter in the Appendix Section.	NO	The committee noted this comment but did not feel that a change would be appropriate at this time. The committee will expand on the requirements contained in the standard in guidance.
6.3.2	Could report loci that are not linked but others would be grouped into a haplotype?	NO	The committee reviewed this comment but did not feel a change was needed at this time. Loci that are not linked or in linkage equilibrium should be reported independently. Loci in linkage disequilibrium should be reported with a single likelihood ratio and could be grouped for that purpose.
6.4.4, 6.4.5 (New)	Define what is an "Accredited facility's official website." Some facilities advertise with URLs that point to websites with content that is undistinguishable from a non-accredited TPA. With modern technology, it might not be possible to confirm whether or not the website is the lab's or the non-accredited facilities. Please elaborate on this issue.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. AABB's lead assessor for relationship testing routinely reviews websites that could be considered against the requirements in these standards, and action is taken by AABB's Legal Department when these transgressions are

			discovered.
6.4.4, 6.4.5 (New)	Anti-cybersquatting seems out of place in the standard itself. Dare I say, it reduces the dignity of the standard and therefore is at odds with the intention of protecting AABB's IP and good name. Cybersquatting would seem to be prohibited under 1.1.1 and, if Attorney Killion believes it prudent to address that particular offense head-on, then I would recommend that it be part of an overarching contract to which the standard is attached. The explanation for the anti-cybersquatting language provided in the summary deserves its own Rule as I believe it applies to far more than domain names.	NO	The committee reviewed this comment but does not feel that a change is needed at this time. The committee feels that these standards are appropriate and are in line with the promotional materials and claims standards that exist in this edition.
6.4.4, 6.4.5 (New)	Not sure how this standard addresses the issue of using AABB for non-accredited activities. If you type in AABB, you are directed to, for example, dnacenter.com/AABB-DNA. Is this acceptable since the page focuses on accredited tests? (As an aside, this page advertises DDC as the premier lab for AABB immigration testing which is false advertising. Aren't all AABB accredited labs to be treated the same rather than one being better than another?) What does the last sentence mean?	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that these standards apply only if the information on the site purports that they are an actual website advertising an accredited activity for an accredited site, if not, it would not apply.
6.3A, #3, subletter c	Needs guidance as to precision and rounding for "The probability of relationship expressed as a percentage" so that the results are reported consistently among AABB accredited laboratories. In addition, as the standard references reporting in scientific literature elsewhere (e.g. 5.3.6 and the glossary), it would seem appropriate that these calculations be performed in a manner consistent with scientific literature. That is, calculations should be rounded to the same precision as the least precise operand.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee has created new guidance, with specific mention of rounding requirements that should provide further clarity about what is required for compliance with this standard.
9.1.6, 9.2.1 (New)	So, a preventive action must include an assessment of the risk of how something may affect continuity of operations? There is no similar standard for corrective action?	YES	The committee agreed with this comment and created new standard 9.1.6 to parallel new standard 9.2.1 to ensure that an assessment of risk takes place as a part of both corrective and preventive action.
Glossary - Laboratory	<u>Glossary</u> Define precisely "Facility", "Laboratory", and "Collection and Verification/Reporting Facility". The current definition of "Facility" and "Collection and Verification/Reporting Facility" are correct, but the one for "Laboratory" is unacceptable. Currently, the term "Laboratory" is defined as: <i>"See facility. The terms facility and laboratory are used interchangeable in these RT Standards."</i> Using those two terms interchangeably is creating a great deal of confusion	YES	The committee reviewed this comment and agreed with the sentiment that having one definition lead back to another could lead to confusion. As such the committee has augmented the previous definition to read as such: Laboratory: A location where testing is performed. Unless a standard specifically indicates otherwise the terms facility and

<p>on the interpretation of the Standards and has also resulted in misleading language. One example is in the context surrounding the “Laboratory Director”. There is only one “Laboratory Director” and he/she is the Laboratory Director of the Testing Laboratory as well as of any Collection/Verification/Reporting facility. Other lab directors, including those associated with the Collection/Verification/Reporting facilities, are Lab Director Designees. Thus, a Lab Director Designee at a Collection/Verification/Reporting facility cannot claim that he/she is the Lab Director if his/her facility lacks the infrastructure and the complexity that is consistent with a place where the actual DNA testing takes place. Using facility and laboratory interchangeably is making this ambiguous.</p> <p>Another example is the incorrect claims of the activities for which a facility has been accredited for. The AABB listing includes Collection/Verification/Reporting facilities located in home offices whose physical addresses are not even registered with the Secretary of State. While those businesses provide limited services, they certainly cannot be called laboratories. The interchangeable use of facility and laboratory implies that those home-based offices are laboratories—and they are not.</p> <p>In the context of a reputable AABB Accredited Relationship (DNA) Testing program, “Laboratory” can only have one meaning and that is: “Laboratory is a location: (1) employing at least one employee who is AABB-qualified Relationship Testing Laboratory Director and Supervisor and one employee who serves as second casework reviewer; and (2) that is assessed and accredited by the AABB for the specific activities of actual sample preparation and DNA testing of relationship testing casework”.</p> <p>With this definition, it is clear that a laboratory is the location that provides controlled conditions in which it receives the samples, extracts the DNA, amplifies it and generates the DNA profiles using instrumented methods and stringent quality-controlled processes.</p> <p>The AABB RT Standards were originally written for laboratories. If the intent is to justify co-listing a collection/verification/reporting site and the laboratories, using the terms “facility” and “laboratory” interchangeably is not serving well. A better approach is:</p>		<p>laboratory are used interchangeably in these <i>RT Standards</i>. See facility.</p>
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	<p>a) Define “laboratory” as suggested above—a definition of its own.</p> <p>b) Highlight the standards that apply for collection/verification/reporting sites.</p> <p>c) Highlight the standards that apply for home-based offices.</p> <p>d) Indicate clearly on the certificate of facility accreditation and in the AABB listing what activities a business was accredited for.</p>		
Glossary – Technical Leader	<p>Rather than as written, you should use “may be qualified to serve as a laboratory director (with appropriate training as described)” since it requires training under an accredited lab director for 3 years.</p>	YES	<p>The committee agreed with this suggestion and the change was made so that the definition now reads as follows:</p> <p>Technical Leader: An individual identified in a forensic laboratory that is responsible for the technical operations of the laboratory may be qualified to serve as a laboratory director under these <i>RT Standards</i>. This individual must meet and have been audited to all FBI quality assurance standards for forensic DNA testing laboratory technical leaders in addition to being the technical leader in an FBI quality assurance standards audited DNA testing laboratory. See standard 1.2.4.</p>