Response to Comments Received to the 12th edition of Standards for Relationship Testing Laboratories

Please note that public comments that were submitted address the proposed 12th edition of IRT 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 12th edition of RT Standards. Guidance that appears with the 12th 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?	Outcomes
1.1.7	This seems like overkill. Many directors and supervisors have been in their role for a long time, does it really matter how well they did in college or would just a "formal diploma" not a copy, with a seal work? Perhaps we could grandfather in current personnel.	NO	The committee noted this comment but felt that the addition was needed for the 12th edition. The standard is written to ensure that the individual in question has an actual diploma in the appropriate field. With regard to current personnel and the need to grandfather them, the committee did not feel this was relevant as those individuals hired would have to meet all the requirements of continued competence and meet the initial standards on the day of their hire. It should be noted that this standard requires that executive management be responsible for this;it is not the responsibility of the laboratory to submit this documentation to AABB for review prior to their assessment.
1.1.7	What is meant by 'official transcript'? Is this a CV? Training records? Or actually a transcript from undergrad or grad school?	NO	The committee noted this comment, and has added guidance to the Standards Portal to assist users with interpretation of this requirement. However, it should be noted that the standard requires that executive management obtain the "official transcripts" for these individuals, which means the document received from the academic

			institution an individual attended. The official transcripts should be related to the level of education required for the position.
3.2	The RT SPU might want to consider adding certain elements from standard 3.2 in the *Standards for Blood Banks and Transfusion Services*, which expands this standard to include re-qualification of equipment after repairs or upgrades. Also standard 3.5.2 in the *Standards for Blood Banks and Transfusion Services* is important for investigation and follow-up to equipment malfunctions and may want to be considered.	YES	The committee noted this comment and agreed with the suggestion to expand the standard. As such, the committee elected to add the second sentence in standard 3.2 which reads as follows: ***"Equipment repairs and upgrades shall be evaluated and equipment requalified, as appropriate, based on the facility's policies and manufacturer recommendations."*** With respect to the proposed elements in standard 3.5.2 from the *BBTS Standards*, the RT SPU felt that such a change would not be appropriate at this time. These elements will appear in the guidance with an eye towards adding investigation and follow-up of malfunctions in the 13th edition.
4.7.1 (NEW)	Please clarify what this standard refers to. Any and all documents? Documents provided by outside sources? Or will this be clarified in the guidance document?	NO	The committee noted this comment and noted that this is expanded upon in the Guidance to the 12th edition, available in the Standards Portal. However this would include all documents that are deemed critical to the operations of the laboratory.
4.7.1 (NEW)	Does this mean that they need to investigate reports that been altered from within their own laboratory? Or does the laboratory have to investigate any altered report presented to them? Does the laboratory have to now also become an investigative body as well as a testing body?	NO	The response to each question posed by the commenter is "yes." The goal of this standard is to ensure that laboratories pay attention to any reports that come into their facility to ensure they are not fraudulent. While the laboratory does not have to become an "investigative body," there should be measures that reduce the likelihood of documents issued by the laboratory being fraudulently altered, such

			as the use of unique watermarks or other identifying features.
5.1.3.2	When the RT SPU submitted the 12th edition for comment, standard 5.1.3.2 appeared as follows, with new elements presented in bold: **5.1.3.2** Quality control results shall be reviewed and evaluated against acceptance criteria. Quality control failures shall be investigated, **the root cause determined, and corrective action taken** before release of test results, products, or services. The following comments were received: • It may take some time to determine root cause and corrective action and therefore not feasible to hold test release of test results, products or services, especially for corrective action. It might be more appropriate to simply indicate that Standard 9.1 applies. As written a facility would not be able to perform testing until the investigation is completed, even if subsequent quality control testing results were acceptable. • Maybe the new bold items should include something like, "…the preliminary root cause determined, and any immediate corrective action taken…". It is true that you often would not have an RCA or CAPA complete for weeks or even months. And even then, a true root cause may not be identified.	YES	Based on the comments received the RT SPU elected to simplify the content of standard 5.1.3.2 to end the second sentence to read, "Quality control failures shall be investigated." and a reference to chapter 9 included as well.
5.2.4.6	How is the language "If a blood sample is collected" redundant? Suggested language: Replace "if a blood sample is collected by "When applicable" or "When relevant…"?	NO	The committee noted this comment but did not feel that a change was needed and felt that the removal of the clause was appropriate.
5.2.4.8	What does "receipt shipment" mean? Do they mean 'shipment receipt" or "receipt of shipment"? Please clarify.	YES	The committee agreed with this comment and changed "receipt shipment" to "shipment receipt."
5.3.2.2	Congenital chimerism caused by fusion of two separately fertilized ovum in early gestation ("tetragametic chimerism") is being detected at increasing frequency as more paternity and ancestry tests are ordered. This phenomenon may lead to false negative paternity and maternity results when the offspring was conceived with the genome present in the gametic cell line, and that genome differs from the other genome present in the sample taken from the parent for the relationship testing. Because chimerism is being detected at increasing frequency, and may be on the rise with the use of artificial reproductive technologies, we would advise discussions by the AABB to consider addressing the possibility of chimerism when the pattern of loci between purported parent and tested offspring suggests a second degree relationship (aunt/uncle to the	NO	The committee noted this comment but did not feel that an additional standard would be appropriate at this time. The committee feels that this situation is best addressed as an element of guidance and not a standard. Currently, this is not a frequent occurrence and in most cases this issues is determined through sample testing, resulting in the tester in question to determine if this was a case of a chimera.

	tested child). For laboratories who are unable to detect second degree relationships, we advise they partner with laboratories that have validated this testing and reflexively test negative results with high COI (coefficient of inbreeding) values in a second facility to ensure against false negative reporting. We would advise consideration of adding a section below 5.4.2.2 which encourages labs to test a second tissue type to investigate the possibility of chimerism as an explanation for an avuncular finding. Please consider adding the following wording: 5.4.2.3 When the null hypothesis is that the tested alleged parent may be a chimeric biological parent and the alternative hypothesis is that an untested person related to the tested alleged parent as a sibling is the biological parent, and there is a failure to exclude, the laboratory shall request a repeat sample of the tested alleged parent using a different tissue type, gametic cells are preferable (i.e. semen sample or cervical swab). A cervical sample for females can be considered as an approximation of gametic cells. The secondary cell line shall be tested for eight or more independent autosomal loci. "		
6.1.5	"Out of date documents shall be removed from work stations when updated ones are placed in service." This seems redundant with the first sentence: "Use of only current and valid documents." If you have outdated documents at workstations, you are not complying with the first sentence in 6.1.5.	NO	The committee noted this comment but felt that it was the new language added clarity, even if it seems redundant.
7.1	"Upon discovery, the root causes of nonconforming materials, samples, and services shall be investigated and their disposition determined." It appears that the user is required to investigate the root cause of nonconforming materials and samples and determine "their" disposition. I think "their" is intended to refer to the nonconforming material, but as written refers now to the root cause. The intent is really to <u>evaluate</u> the nonconforming material and determine the disposition of the nonconforming material, – can it be used or not? I would suggest not adding "root causes" or adding a reference to 9.1.	YES	The committee agreed with the intent of this comment and added the following clause to the end of the standard, "…disposition of **these nonconforming materials, samples and services shall be determined**." The committee felt that this addition along with the addition made that was proposed during the comment period clarified the intent of the standard and the requirement for the users of these *RT Standards*.