

14-Oct-19  
ANSI/ASB Std 038  
Standard for Internal Validation of Forensic DNA Analysis Methods

Note: a specific Proposed Resolution must accompany each comment or it cannot be considered.

#	Section	Type of Comment (E-)	Comments	Proposed Resolution	Final Resolution
1	3.5	E	definition was revised to reflect QAS definition, but "quantitation" instead of "quantification" was left from the original definition	change "quantitation" to 'quantification"	Accept
5	4.3.2	T	It appears that this section would allow internal validation to exceed developmental validation as long as there was documentation? Internal validation should not exceed the scope of developmental validation without being subjected to a new developmental validation (at least for those aspects falling outside of the original developmental validation); I believe this is stated explicitly in one of the other standards the group has worked on.	Add requirement that the limits of developmental validation shall not be exceeded in internal validation; should the lab wish to expand a method past the limitations established during developmental validation, they must perform a developmental validation (or perhaps, studies which meet the requirements for developmental validation shall be performed such that the requirements for developmental validation be met.)	Reject: There was an extensive discussion on this and the CB decided that it is important to be able to go outside of the scope of development validation for DNA methods as long as it is documented with an explanation. No additional changes or clarifications were made.
2	5 (numbered as 1 but at end of document after section 4?)	T	This entire section was removed, however a conformance section remains in STD 077.	Consistency between standards relating to similar topic areas (in this case validation) would be desirable. We like having the conformance section which clearly states the expectations for documentation required to demonstrate compliance to the standard.	Accepted with Modification: Section 5- Conformance was added back to this document and was modified accordingly.
3	5 (numbered as 1 but at end of document after section 4?)	T	STD 038 states the following: 1.2 Documented internal validation studies and modifications to forensic DNA analysis methodologies intended for forensic casework or database applications prior to implementation. 1.3 Quality assurance parameters, interpretation guidelines, and analytical procedures derived from internal validation studies. 1.4 Documented approval by the DNA Technical Leader or other appropriate personnel prior to implementation. STD 077 states the following: a) documentation of the developmental validation which can be internal, external, or documented in the peer reviewed literature; b) documentation of all internal validation; studies, data, and outcomes; c) documentation of any modification to the procedures, if applicable; and d) documentation of performance checks, if applicable.	Preference would be to modify the conformance sections to pull from each standard in the following order: STD 077 a, STD 038 1.2, 1.3, 1.4. STD 077 b, c, and d are not needed- b and c are absorbed in 1.2, and d is more applicable to equipment maintenance than a validation standard.	Accepted with Modification: Section 5- Conformance is included in this document and was modified, however Section 5-a from Std 077 is not applicable for Std 038.
4	5	E	Numbered as section 1	If retained, renumber as section 5.	Accepted with Modification: Section 5- Conformance was added back to this document and was modified accordingly.