

14-Oct-19
ANSI/ASB Std 077
Standard for the Developmental and Internal Validation of Forensic Serological Methods

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

#	Section	Type of Comment	Comments	Proposed Resolution	Final Resolution
9	3.7	E	Re 3.7 developmental validation: remove "typically" regarding internal validation studies. Internal validation studies should always follow developmental validation studies (wherever they are formulated) in a laboratory; I cannot think of an exception.		Accept
1	3.11	E	Material modification was struck from the definitions. The validation section of the Guidelines for a Quality Assurance Program for DNA Analysis by the Technical Working Group on DNA Analysis Methods defines material modifications as follows: : A material modification is a substantial and/or consequential alteration of a physical or analytical component in an integrated procedure. The modified procedure must be validated as concomitant with the nature of the alteration. 4.2 Modified procedures must be performance evaluated by comparison with the original procedure using similar DNA samples.	Define material modification consistently with previous SWGDAM guidelines, and retain the aspect of validation by comparison with the original procedure.	Reject: The term "material modification" is not used in this document. Refer to section 4.1.5. which requires any changes to a validated procedure to be evaluated.
6	4.1.3	E	This standard needs additional clarity when describing validation. Is the standard supposed to apply to internal validation studies only? By definition, internal validation studies are the studies where SOPs are established.	Consider editing the sentence to "...used in each of the internal validation studies..." if the standard applies to internal validation only. If the standard is going to cover the possibility for inhouse developmental validation, the sentence must be restructured since assay development steps can differ from standard operating procedures.	Partial Accept: This section was clarified. "To establish a standard operating procedure" was replaced with "to validate the method".
2	4.1.4	T	STD 038 contains a similar standard, but has different requirements. This standard requires additional developmental validation for samples outside of the scope of the original developmental validation. STD 038 requires a statement of explanation. Consistency between the standards would be ideal.	Consider adapting STD 038 4.3.2 to both documents in lieu of requiring additional developmental validation.	Reject: Section 4.1.4 is more appropriate for serology.
3	4.1.5	E	The standard was revised and addresses modification to validated procedures. In addition to suggestion above to retain material modification as defined, there is as similar standard in STD 038 for validation of DNA Analysis methods. These standards would ideally be consistent between the documents.	Consider adapting the much more succinct language from STD 038 for consistency between the documents. STD 038 4.2 "The laboratory shall conduct additional internal validation studies if there is an alteration to the previously validated procedure, reagents, software, or instrumentation that has an impact on the efficacy or the reliability of the analysis."	Reject: Section 4.1.5 is more appropriate for serology.
8	4.4.2	E	This standard must also apply to internal validations as well. Especially since 4.4.7 requires a retention policy for the summary and data correlating to internal validations.	Edit the sentence to include internal validation.	Reject: 4.4.2 was clarified to state a summary of data is acceptable for external developmental validation. See section 4.4.7 for internal validation requirements.
7	4.4.3	E		The section needs a standard to address internal validation documentation requirements specifically. Consider editing 4.4.3 to include what needs to be documented in an internal validation.	Reject: Please refer to section 4.4.7 and 5-b) for documentation requirements.
4	5	T	The conformance section was removed from STD 038, but remains in this document.	Retain the conformance section in both documents.	Reject: Not applicable for this document.
5	5	T	<p>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.</p> <p>1.3 Quality assurance parameters, interpretation guidelines, and analytical procedures derived from internal validation studies.</p> <p>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;</p> <p>b) documentation of all internal validation; studies, data, and outcomes;</p> <p>c) documentation of any modification to the procedures, if applicable; and</p> <p>d) documentation of performance checks, if applicable.</p>	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.	Partial Accept: Added 5-e) documentation of approval by the technical designee prior to implementation.