

Public Commenting Period Close Date 25-Oct-21

Document Title ASB BPR 114, Best Practice Recommendation for Validation of Forensic DNA Software

#	Section	Type of Comment (E-Editorial, T-Technical)	Comments	Proposed Resolution	Final Resolution
5	General	T	Read together, Standards 114 and 018 fail to create an appropriate standard for the validation of software, which may or may not be subject to appropriate testing by manufacturers. It should not be up to laboratories, not in the business of routinely validating and verifying software, to evaluate software that has no practical application outside the forensic world and which has not been ruggedly evaluated to ensure accurate performance and to fully identify edge cases.	Add requirements for laboratories to conduct software engineering validation and verification, i.e. IEEE 1012-2016, on software that has not been subjected to those standards.	Reject. The scope of testing recommended for laboratories has been clearly articulated within this BPR. Software engineering is outside of that scope.
7			This standard should require laboratories to perform independent validation and verification of the software. This comment was moved to the comments' spreadsheet.		Reject: Regardless of who participates in the validation process, the laboratory itself is still ultimately responsible for the validation results.
8			This standard should include a requirement that the laboratory conduct software engineering validation and verification. This standard even if read in conjunction with 018 is inadequate to assure that the software used produces valid and reproducible results. This comment was moved to the comments' spreadsheet.		Reject. The scope of testing recommended for laboratories has been clearly articulated within this BPR. Software engineering is outside of that scope.
2	General	T	I drafted the two comments below in response to the second round of balloting for 114 and repeat them here because I believe their inclusion is essential to meaningful recommendations for the internal validation of software in forensic laboratories. This document contains many quality recommendations and is an important start in recognizing the importance of software engineering concepts and their application to software used in forensic DNA labs. However, forensic DNA labs should adhere to software validation <i>standards</i> which adopt or match the rigor of the verification and validation requirements of IEEE--specifically, independent verification & validation.	See below. ASB NOTE: Comments highlighted in yellow are from the same commenter.	Reject. The scope of testing recommended for laboratories has been clearly articulated within this BPR. Software engineering is outside of that scope.
3	4	T	Independence is critical for establishing reliability of software	Add recommendation that there should be <i>independent</i> third party validation of software in addition to any internal validation or hired third party validation	Reject: Regardless of who participates in the validation process, the laboratory itself is still ultimately responsible for the validation results.
1	4.1	E	It is unclear if the edited versions of the 2nd paragraph and the added 3rd paragraph are redundant or is needed (reason unclear)	remove the third paragraph, or clarify its need	Accept: deleted second instance
6	4.1		Under 4.1, there is a duplicate comment that needs to be corrected by deleting one of the statements. This comment was moved to the comments' spreadsheet.		Accept: deleted second instance
4	4.8.6.1.2	T	All validation data should be kept, not just a summary, and be made available to the public	Add recommendation that 1) all validation data be kept and that 2) the validation data be made available for public review.	Accept with modification: 1) The original recommendation requires the preservation of validation. We have added some commas to emphasize. 2) Reject: This is up to the laboratory and applicable state/federal laws.