26-Nov-20

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
1		E	There are comments that Jessica has submitted with this document that I agree with. I don't know how future software will align with this standard (i.e. Pace) or how std. 18 will address software that will work in tandem with PG software. I do think there are differences between PG software and other software used in the lab that warrants separate documents. There should be requirements, and not a BPR, for software that is not tied to instruments that are part of a validation process (i.e. quant, automated extraction, etc.). Documentation of any validation should not be optional. I think the problem that exists is that the BPR does not provide specific examples of software that are meant to be covered by the document. There are many things I like in this document, but the purpose is weakened if there isn't a document mandating minimum validation standards of these other systems.		Reject: No proposed resolution has been provided. These concerns are noted and extensively discussed at the ASB DNA Consensus Body prior to the release of this document for public comment.
11	General	T	This document begins to address a critical need in the forensic community to adopt best practices of the software engineering community and is an important contribution. However,the forensic DNA community needs software validation standards and not simply recommendations. IEEE is the best practices of the software engineering community. These recommendations should at least match the rigor of the verification and validation requirements of IEEE (for instance, independent verification & validation). Also, i think it would have been beneficial to have had software engineers guide the ASB DNA Consensus body through the document before the vote.		Reject: No proposed resolution has been provided. These concerns are noted and extensively discussed at the ASB DNA Consensus Body prior to the release of this document for public comment.
3	Foreword		1) 3rd line of Foreword - change "standard" to "document"		Accept: Second paragraph, second sentence was edited as suggested.
4	3.2		2) Definition 3.2 - is there a word missing in the last sentence? It does not read smoothly.		Accept: Updated by adding "of".
6	4	T	My understanding from group discussions is this BPR is not intended to apply to internal validation of prob geno software and the language was modified (although it is unclear with the current wording whether it actually applies or doesnt). While the BPR in 114 are no substitute for the requirements set forth in ASB Std. 018 Validation of Probabilistic Genotyping, it doesnt follow that labs shouldn't ALSO follow these recommendations when conducting an internal validation for prob geno. Why shouldn't prob geno also adhere to a set of best practice recommendations regarding internal validation of software? Is there a reason why they shouldnt? Is there a more stringent set of recommendations/requirements that will be issued for prob geno?	Amend current comment re: prob geno to include an explanation of why BPR 114 does not apply to prob geno software (if in fact that is a correct interpretation of the document).	Accept with modification: BPR 114 contains guidelines and Standard 018 contains requirements. These are standalone documents. First paragraph was updated for clarity.

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7	4	T	While this document may be sufficient for the internal validation of some software used routinely in the lab, it's questionable whether it is sufficient for more complex software such as those based on machine learning--for example, PACE (program for estimating the number of contributors). (I'm assuming for purpose of this comment that this document also doesn't apply to prob geno; I think that this doc is also insufficiently rigorous to be applied to prob geno as it currently stands).	At the very least, note that these recommendations are insufficient for machine learning algorithms	Reject: Many software's exist and this document aims to provide guidelines to develop a validation plan. However it is not intended to be specific to any one software type. The ultimate responsibility to ensure the sufficiency of the validation study rest with the laboratory.
8	4	T	Independence is critical for establishing reliability of software	Add recommendation that there should be *independent* third party validation of software in addition to any internal validation or hired third party validation	Reject: This comment is not on a specifically redlined portion of the document and is therefore out of scope of this round of comments.
5	4.1 (now 4.2)		3) 4.1, 2nd paragraph - this sentence has some grammatical issues.	Suggest editing to: There may be examples of commercial software for which the DNA section has no autonomous control and thus may not be able to conduct internal validation on all of the modules (e.g., chain of custody software).	Accept
9	4.8.6 (now 4.9.6)	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.	1) Accept with modification: Added suggestion #1 to section 4.9.6.1.2. 2) Reject: This is up to the laboratory.
10	Annex A	T	IEEE should be referenced (it is in Std. 18).	Include in Bibliography: Institute of Electrical and Electronics Engineers. IEEE Std 1012-2012 - IEEE standard for system and software verification and validation, 2012;209; http://ieeexplore.ieee.org/document/6204026/.	Accept
2	Annex A		In Annex A (Informative) - Bibliography, reference #6 to SWGDAM Validation Guidelines should be updated from 2012 to 2016. The footnote link goes to the current 2016 version of the document.		Accept