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

	Section	Type of Comment	Comments	Proposed Resolution	Final Resolution
1	1.2	E	Updated (current) wording: "Laboratories should review validation for compliance with these standards, ..." Improper grammar - "… should review validation …"	"Laboratories should review their validation for compliance with these standards, …"	Accept: See edit made.
6	1.2	T	This revision is an improvement from the prior version as it is a stronger statement addressed at labs which have already validated prob geno systems. However, it doesn't go far enough; it still doesn't make the standard retroactive. Considering the enormous number of labs which have already brought probabilistic genotyping online or are currently validating them, making this standard mandatory is critical to ensuring a minimal requirement for producing quality, reliable results--that a thorough, well-designed validation was conducted.	Change "should" to "shall"	Reject: This standard is not meant to be a retroactive requirement. This is the same language used for Standard 20.
2	3.3	E	Spacing between sentences is inconstent. Document uses one space; however between 2nd and 3rd sentences appear to be two spaces.	Adjust spacing	Accept: edit made.
3	3.5	T	If a performance check is "A first step in the continuum of the validation process", this appears to be the first step before any developmental or internal validation. However, the definition goes on to discuss a performance check being done after a minor change. If a minor change is being implemented, clearly the software has already undergone develpmental and internal validations prior to this minor change - therefore this performance check cannot be "a first step... of the validation process." This sentence introduces a Catch-22.	Remove new sentence "A first step in the continuum of the validation process."	Accept: Edit made.
7	4	T	This revision is unsupportable. If a lab is going to use a probabilistic genotyping system, then the lab personnel designing the validation study must know how to calculate and explain likelihood ratios. How else are they competent to design and conduct a validation for a method that produces likelihood ratios?	Revert to the original language: Change "should" to "shall."	Reject. Sentence stands without deletion or modification. Consensus body discussed during 1/17/2019 meeting and decided "should" is the appropriate term in this sentence.
12	4	T	This standard, while improved, continues to fall short of providing basic requirements of quality. The revisions to the requirements still do not adequately address transparency of methods; separate verification of software; and the largely unanswered question of how and when probabilistic genotyping systems differ from one another, recognised as essential in the PCAST report (President's Council of Advisors on Science and Technology, "Report to the President: Forensic Science in Criminal Courts: Ensuring Scientific Validity of Feature Comparison Models").	Add requirement that the source code and copies of program for each version of the program be made available for inspection; that validation cannot replace or substitute for separate validation/verification of software; that validation include comparison with other prob geno programs (many of these are open source).	Reject: Source code is not necessary to complete an internal validation. This is outside of the scope of the document. A validation is designed to evaluate the suitability of a particular method. Comparison among methods are beyond the scope of any single validation.
4	4.1.4	E	Spacing between sentences is inconstent. Document uses one space; however between 1st and 2nd sentences appear to be two spaces.	Adjust spacing	Accept: edit made.
8	4.1.5	T	Since the true number of contributors to a forensic DNA mixture is still unknowable and to date determined by a human analyst, and since changing the number of contributors in a run of the software affects the LR, a lab shoud be required to test a range of # of contributors.	Change "should" to "shall"	Accept: edit made.
9	4.1.5	T	Requiring the evaluation of multiple propositions is a critical addition but may require a definition for proposition and some more explanation.	Add definition for proposition in Definitions section and/or further context/explanation either in the requirements section in a paranthetical or in the Annex (i.e. the testing of effect of assumed contributors on the LR; evaulating 2 persons of interest together as opposed to each separately; etc)	Reject: Standard 041 will provide greater guidance on propositions (when published).

14	4.3	T	We have noticed in casework from our local lab that locus LRs can be anti-conservative and either negate or overwhelm the use of the highest posterior density in moving an LR down. For example, in a recent case where the lab called a three-person mixture, an LR of 4.01 was reported for locus Penta E, where only a 9 allele at 70 rfu was called in one replicate, and no alleles appeared in the second replicate (50 rfu analytical threshold). The lab's probabilistic program gave the highest component interpretation weighting for Contributor 1 as a 9,9. The criminal defendant's profile at Penta E is a 9,17. The program assigned the highest LR to the defendant at Contributor 2. The weightings assigned to Contributor 2 were 9, 9 (.37) 9,Q (.34) and Q,Q (28.65). The weights for Contributor were the same genotypes as Contributor 2, with roughly the same weightings. The LR of 4.01 is extremely anti-conservative and countermands the definition of proof beyond a reasonable doubt in any American jurisdiction. In the validation study for the amplification kit, peak heights fluctuated dramatically for 125 pg of DNA down to 25 pg of DNA (it dropped off steeply after that). When the 9 can be explained as Contributor 1, a likelihood ratio of 4 goes against the legal standard of proof beyond a reasonable doubt. Labs should probably figure out when probabilistic genotyping can be used for investigative purposes or for commencing a criminal action against an individual, and when it should be modified or not used at trial.	Comment 4.3 should read follows: 4.3 Quality assurance parameters, analytical procedures, and interpretation protocols shall be derived from internal validation studies. Developmental and manufacturer recommendations may be used in addition to internal validation studies but shall not replace internal validation. The legal definition of probable cause and proof beyond a reasonable doubt should be taken into account when developing protocols that address reporting locus likelihood ratios that have potentially biased, anti-conservative likelihood ratios against suspects and criminal defendants	Reject - Since this sample is a casework sample and not ground truth, it is impossible to tell if the weightings and LRs are reasonable or not and the legal definitions are out of the scope of this scientific document.
5	4.3.1	T	The addition to standard 4.3.1 requiring a lab to perform additional developmental validation for samples that fall outside of the initial validation communicates something missing from standard 4.1.1, i.e., that developmental validation cannot substitute for internal validation first and foremost. In circumstances where labs are performing developmental validation, the experiments performed cannot serve a dual role as developmental and internal validation, and additional testing on different data needs to be performed for internal validation.	A sentence can be added to standard 4.1.1 stating that developmental validation is not a replacement for internal validation in situations in which labs are engaged in developmental validation. If the statement cannot be added to 4.1.1, a similar statement can be added to the end of 4.3.1 requiring that labs performing additional developmental validation must perform internal validation on different data sets. If this cannot be added to 4.3.1 directly, the statement can be added to the annex. If standard 4.7 is meant to address this circumstance, the use of the terms internal validation and developmental validation within the explanation given in the annex would provide additional clarity.	Accept. Put statement in 4.1.1 "Developmental validation shall not replace internal validation."
10	4.4	T	This section still does not provide necessary clarity of when a software change requires validation or a performance check. There may be some contradiction in the examples provided in 4.4 (a change in the visual display may not require a performance check) with the example provided in the definition of performance check (reformatting output reports). Also, at a minimum a performance check (functional testing) should always be required.	Provide greater clarity and delete sentence "If neither….".	Reject: The Working Group is of the opinion that there is enough clarity in sections 4.4 and no change should be made.
11	4.5	T	Lab should also be required to obtain/retain a copy of the developmental validation studies (essential to understanding the limitations methodology; for the lab to determine whether it is exceeding its bounds as per 4.1.3, etc.)	Add requirement: "The laboratory shall retain a copy of the developmental validation of the probabilistic genotyping system."	Partial Accept: See Annex A Requirement 4.5 includes the following information: Laboratory should have a summary statement of the sample types for which the product has been validated in development by the manufacturer.
13	Annex B Bibliography	T	A presidential scientific commission (PCAST) undertook a review of the scientific foundations of DNA mixture analysis, including concrete recommendations regarding probabilistic genotyping. The PCAST report should be added to the bibliography.	Add the PCAST report (President's Council of Advisors on Science and Technology, "Report to the President: Forensic Science in Criminal Courts: Ensuring Scientific Validity of Feature Comparison Models," September 2016, and its Addendum.	Reject: This is not a peer reviewed scientific article or a standard.