<table>
<thead>
<tr>
<th>#</th>
<th>Section</th>
<th>Type of Comment</th>
<th>Comment</th>
<th>Proposed Resolution</th>
<th>Final Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>39</td>
<td>Forward</td>
<td>T</td>
<td>“of” is missing between “current as” and “the publication” on last line of Foreword</td>
<td>Add “of” between “current as” and “the publication” on last line of Foreword</td>
<td>Accept</td>
</tr>
<tr>
<td>40</td>
<td>Forward</td>
<td>E</td>
<td>“of” is missing between “current as” and “the publication” on last line of Foreword</td>
<td>Add “of” between “current as” and “the publication” on last line of Foreword</td>
<td>Accept</td>
</tr>
<tr>
<td>41</td>
<td>Keywords</td>
<td>E</td>
<td>DNA should be listed</td>
<td>Add “DNA”</td>
<td>Partial accept: added DNA Standards</td>
</tr>
<tr>
<td>42</td>
<td>Abstract</td>
<td>E</td>
<td>“The interpretation of autosomal DNA short tandem repeat” or “short tandem repeat DNA analysis”</td>
<td>Accept</td>
<td></td>
</tr>
<tr>
<td>52</td>
<td>L</td>
<td>T</td>
<td>The standards should be made to apply to all laboratories, and should apply retroactively. To do otherwise would lead to inconsistent validation levels of software systems between laboratories, where one lab’s version of the software was validated properly according to the standards set forth, while another was not, merely based on the date the software system was acquired by the lab. This poses issues of fundamental fairness to criminal defendants, whose right to have reliable evidence presented against them is a part of the purpose of these standards in the first place. There is no countervailing reason for not requiring retroactive validation.</td>
<td>Make the standards retroactive</td>
<td>Accept with revision: Revise 1.2 to read: Laboratories are advised to review validation for compliance with these standards, supplement validation where necessary, and modify existing protocols accordingly.</td>
</tr>
<tr>
<td>53</td>
<td>1.2</td>
<td>T/T</td>
<td>By reading this section, it seems like the standard is not meant retroactively. The ASB standard 020 for validation of mixture interpretation protocols sounds like it is retroactive. This contract is a bit confusing. The standards should take the same stance on whether the documents are retroactive or not. Make wording under between documents to increase clarity of intent.</td>
<td>See #3</td>
<td></td>
</tr>
<tr>
<td>55</td>
<td>1.2</td>
<td>T</td>
<td>The statement “These standards are not meant to be applied to probabilistic genotyping systems which have been previously validated. However, laboratories are advised to review their previous validation relative to these standards” will allow substandard validation to stand for the significant percentage of developers and laboratories which have already purported to validate these programs. The standard should be retroactive.</td>
<td>Make the standards retroactive</td>
<td>Accept with revision: Revise 1.2 to read: Laboratories are advised to review validation for compliance with these standards, supplement validation where necessary, and modify existing protocols accordingly.</td>
</tr>
<tr>
<td>60</td>
<td>1.2</td>
<td>T</td>
<td>Technical reference to retrospective actions may stray from scientific arena to legal one. There is no scientific reason why validation studies used to report past data should not be reviewed and compliant impact assessed. Validation of continued process should not be attributed to previous.</td>
<td>Remove first sentence in this section. Commence with “Labs are advised to review...”</td>
<td>See #3</td>
</tr>
<tr>
<td>66</td>
<td>2.2</td>
<td>T</td>
<td>The statement should be restricted. Many labs have begun and some have completed validations of probabilistic genotyping systems already. A lack of retroactivity will mean that thousands of cases will be interpreted and reported without assurance of properly validated probabilistic genotyping systems. Add requirement that the standards apply retroactively.</td>
<td>Add requirement that the standards apply retroactively</td>
<td>See #3</td>
</tr>
<tr>
<td>70</td>
<td>1.2</td>
<td>I</td>
<td>Not necessary or appropriate</td>
<td>delete 1.2; accrediting bodies can determine how and when these standards should be applied; could move last sentence to Annex, but it seems that this statement is implied without additional relevant discussion</td>
<td>Partial accept. This section has been modified. See #3</td>
</tr>
<tr>
<td>81</td>
<td>1.2</td>
<td>T</td>
<td>No software standards or practices are included in the references.</td>
<td>Clarify software standards and requirements.</td>
<td>Accept: Included one reference (#7) to software standards in Annex B Bibliography.</td>
</tr>
<tr>
<td>82</td>
<td>1.2</td>
<td>E</td>
<td>Software standards doesn’t hold water. Break up fig. There are no informative reference documents. Annex C Bibliography contains informative commentary.</td>
<td>Accept with revision: Staff to review.</td>
<td></td>
</tr>
<tr>
<td>89</td>
<td>1.2</td>
<td>E</td>
<td>Should be two sentences</td>
<td>Update commentary after “documents” with a period</td>
<td>Add if applicable to section 2 of Section A</td>
</tr>
<tr>
<td>93</td>
<td>1</td>
<td>T</td>
<td>Should be two sentences</td>
<td>Update punctuation</td>
<td>Add to Table based on ASB Style Guidelines</td>
</tr>
</tbody>
</table>
SWGDAM has published clear and thorough definitions of all of the terms mentioned in this standard in the SWGDAM Guidelines for the Validation of Probabilistic Genotyping Systems. It seems very practical to use the definitions as stated in the SWGDAM Guidelines for the Validation of Probabilistic Genotyping Systems to avoid confusion for practitioners and non-practitioners alike. While the terms and definitions as stated in the SWGDAM Guidelines for the Validation of Probabilistic Genotyping Systems may not appear anywhere in the standards and therefore no definition is necessary, the consensus body feels that it is important that the definitions that are specific to this document be included.

27.3 T material modification is not defined (example or example given) Define material modification

Accept with revision: “material modification” removed and definition reworded for clarification.

28.3 E Suggest adding a comma within sentence

A statistical model and accompanying method that evaluates DNA profiles by assigning weights for the observed data assessing the presence or absence of allelic peaks for different contributor genotypes.* A statistical model and accompanying method that evaluates DNA profiles by assigning weights for the observed data assessing the presence or absence of allelic peaks for different contributor genotypes.* Accept. Modification made.

27.3 T SWGDAM: continuous models This term does not appear anywhere in the standards and therefore no definition is necessary. Delete 3.10

Accept. Definition deleted.

28.3 E “performed” is used twice in second sentence

Suggest saying “Profiles from mixtures of 3 or more contributors are not suitable for accuracy studies.” Revised: “However, profile results where the ground truth is not known are not suitable for accuracy studies.”

28.3 T Greater clarity is needed for the phrase “ambiguous mixture profiles” within the definition for accuracy studies. Provide a definition for “ambiguous mixture profile” or provide greater detail of the samples that should not be used in an accuracy study within the text. State the limitations of the accuracy studies, particularly with respect to generalizing beyond the specific types of samples and conditions tested. Reject. See #44.

3.1.2 Technical

This definition of “case-type profile” is different from “case-type samples” defined in ASB Standard 020. Since both standards reflect regulations on validations, definitions about the same concept should be the same. Combine or alter the definitions to be more consistent between the two standards. Reject. “Case-type profile” is the appropriate term in this document, and the definition is correct for the use within the text.

3.1 E modified specification that case-type profiles are generated from samples with known genotypes (e.g. known contributors with known genotypes, known number of contributors and mixture ratio). add necessary specification to the definition. Accept. The specifications are contained in 4.1.2 and 4.1.3.

3.1 T As written is that development validation is the accumulation of test data within the laboratory. However, the forward to the document states that “developmental validation may be conducted outside the laboratory planning to use it.” Also 4.1.1 states that developmental validation may be conducted by manufacturers.

Accept. Added some text from SWGDAM definition. See comment #66.10. SWGDAM test reference.

3.2 T The purpose of this standard appears to address internal validation so laboratories can use probabilistic genotyping software. In the event a laboratory creates its own software, developmental validation is mentioned in the standard to cover all bases. However, the term as defined and used in this document does not address all of the concerns and issues that must be addressed in developmental validation. For example is a developmental validation an evaluation of a novel technique/method? How is a laboratory accumulating test data if a developmental validation is performed by an outside manufacturer? The use of the phrase “expected values” in this definition also leads to numerous questions that are not answered in the standard. It would seem that developmental validation is where the expectation of performance (parameters and limitations) is established and an internal validation is where the performance is confirmed. Greater clarity is needed to explain the definition and the requirements is studies for developmental validation.

The definition for developmental validation from the SWGDAM Guidelines for the Validation of Probabilistic Genotyping Systems should be used.

Accept. Additional public comments have required clarification of definitions from OSAC version.

3.3 T The phrase “within the laboratory” suggests that the laboratory must do the work rather than the developers of the software. In this case, the definition should be modified to “external validation.”

Accept with modifications. See comment #47.

3.3 E Developmental validation refers to a “change in the input parameters such as the number of MCMC iterations above a default and validated minimum.” How is a laboratory to assess how well the software is working. Is it possible that the definition for developmental and internal validation were switched in this document? Using “a change in the input parameters such as the number of MCMC iterations” as an example of something that would require a performance check? Delete the text. Accepted. Additional public comments have required clarification of definitions from OSAC version.

3.3 T For consistency purposes “within the laboratory” should be added after “data” in the definition for internal validation. The standard mentions several times that laboratories must perform internal validation; this concept should be reflected in the term. The results of an internal validation should be measured against results of a developmental validation to assess how well the software is working. Is it possible that the definitions for developmental and internal validation were switched in this document?

Change the beginning of the first sentence of this definition to: “The acquisition of test data within the laboratory to verify the functionality of the system…”

Accept. As written “within the laboratory”.

3.3 T Misusing “In the laboratory” Add “In the laboratory” to all references for internal validation.

Accept. As written “within the laboratory”.

3.6 T Using “a change in the input parameters such as the number of MCMC iterations” as an example of something that would require a performance check. In the consensus group suggesting that every increase in the number of MCMC iterations above a default and validated minimum would require a performance check?

Delete the text. Accepted.

3.7 E If the probabilistic genotyping software may not necessarily produce the same statistical calculation from repeated analysis, the standard should provide some guidance on what precision studies should entail and how to present results.

The text in language deleted from prior draft “studies should demonstrate the range of values that can be expected from multiple analyses of the same data.”

Accept. Accepted. See #103.

3.7 T Commercial software… accounts for the effects of... not expected. Additional comments from the group have reworded this section.

Delete the text. Accepted.

3.7 T How much variation is okay? No concrete guidance is provided. The text in language deleted from prior draft “studies should demonstrate the range of values that can be expected from multiple analyses of the same data.”

Accept. Accepted. See #103.
Statement as written: “Studies performed to assess the ability of the probabilistic genotyping system to support or not to contribute.” Awkward phrasing in 1st sentence – 3.11 states how the ProbGen system supports the presence of a known contributor.

3.12 second sentence then states that true non-contributors would correctly indicate the absence. This is awkward phrasing. A small 0.8 might indicate the absence of a true non-contributing individual

Suggested rewrite: Studies performed to assess the ability of the probabilistic genotyping system to support the absence of true non-contributors. True non-contributors are those who are known not to contribute.

Accept with revision. Text modified to clarify definition.

3.13 E This definition of “validation” differs in punctuation from the one in ASB Standard 020. Since both standards reflect regulations on validations, definitions about the same concept should be the same. Combine or alter the definitions to be more consistent between the two standards.

Accept. Definition modified to match the one in Std 020. Semicolon added to match the definition in Std 20.

3.12 E This definition of “validation” differs in punctuation from the one in ASB Standard 020. Since both standards reflect regulations on validations, definitions about the same concept should be the same.

Add a comment requiring reference to Annex B.

Accepted. Include a note in Requirements/Section 4. (See note in Std 40 to ensure consistency between Std 18 and Std 40).

The standard relies heavily on the reader knowing all of the defined terms and what is meant by the defined terms in order to conduct a validation study. However, many of the terms’ definitions are vague and confusing. Additionally, there is limited information on the quality, quantity, and variety of the samples used to generate the data that will be put into the software. The requirements are not explicit in requiring the preparation of these samples to be stressful to the software in order to find the true limitations of the system. The samples used in a validation mixture interpretation, which probabilistic genotyping is designed to address, should include: (1) a variety of samples with multiple contributors based on the number of contributors the lab intends to interpret; (2) a pool of participants that demonstrate the diversity of the United States; (3) mixtures created from related individuals; (4) mixtures created from both individuals that are of different ethnicities and from individuals of the same ethnic; (5) a range of mixture ratios; and (5) degraded samples. All validation samples should be run in replicate to evaluate stochastic effects between amplifications and varied likelihood ratios calculated. The evaluation of multiple mixed samples from related individuals, degraded samples, and mixtures from the same and different ethnicities would well inform mixture interpretation protocol and understanding of the values generated by the software. Lastly, the standard provides little guidance on the interpretation protocol for parameters not tested during validation. For example, during validation if the lowest total amount of DNA for a three-person mixture is 1 ng, is the software capable of evaluating a three-person mixture with sample lower than 1 ng?

Prove greater detail and examples of the sample preparation process that results in the data entered into the software. The Standard for Validation of DNA Mixtures, and Development and Verification of a Laboratory’s Mixture Interpretation Protocol should be referenced in section 4 or a statement should be added to Annex B detailing the samples that should be used for developmental and internal validation studies. Additionally, more guidance should be provided about the interpretation of samples beyond the limitations tested during developmental and internal validation, (or, more specifically, cautiousing against the interpretation of these samples).

Partial Accept. Amended 4.1.4 and added 4.1.5, in relation to proportion between related individuals. 4.1.3 requires the range of actual case type samples intended for analysis, 4.1.5 requires that the lab demonstrate the limitation and reliability of the software. Further requirements on how to meet these points would be overly proscriptive.

4.1 T Reconsider spacing between sentences. Add a space before sentences here. Add extra space.

The President’s Council of Advisors on Science and Technology listed four fundamental questions to be answered by those validating probabilistic genotyping standards in “Report to the President: Forensic Science in Criminal Courts: Ensuring Scientific Validity of Forensic Comparison Methods” (Sept 2016). This proposed standard fails to sufficiently consider that a lab or developer performing a validation determine answers them.

These should be incorporated into the requirements of Standard 18. (1) How well does the method perform as a function of the number of contributors to the mixture? How well does it perform when the number of contributors to the mixture is unknown? (2) How does the method perform as a function of the number of alleles shared among individuals in the mixture? Relatedly, how does it perform when the mixtures include related individuals? (3) How well does the method perform--and how does accuracy degrade--as a function of the absolute and relative amounts of DNA from various contributors? (4) Under what circumstances—and why—does the method produce results (random inclusion probabilities) that differ substantially from those produced by other methods? PCAST Report, p.79-80.

Reject. This is outside of the scope of the document. It is not the place of a lab to provide proprietary source code, implement the models/algorithms intended? cannot be answered satisfactorily. Require that source code be disclosed to the defense in a criminal case.

Partial Accept. A comprehensive list cannot be fully specified, therefore, the last sentence in 4.1.3 has been modified to read: “The individuals designing and evaluating the validation studies should possess, at a minimum, the appropriate foundational knowledge in the calculation and explanation of likelihood ratios.”

4.1 E PCAST in its report stressed that a program’s results should be compared to other programs. This is obviously critical given actual courtroom examples where there is substantial variation among results generated by different programs. This should be part of the standard.

Provide a more comprehensive list of necessary skills and knowledge, for example, including study design methodology and quality assurance procedures.

Reject. See comment 57.

PCAST in its report stressed that a program’s results should be compared to other programs. This is obviously critical given actual courtroom examples where there is substantial variation among results generated by different programs. This should be part of the standard.

Include requirement that program must be compared with other probabilistic genotyping programs.

Reject. See comment 59.
Validation must be performed by an expert or lab that is fully independent of the developer and the requisitioning lab. This independent validation is consistent with the recommendations of the President’s Council of Advisors on Science and Technology (PCAST). In its 2016 Report to the President: Forensic Science in Criminal Courts: Ensuring Scientific Validity of Feature Comparison Models,” PCAST recommended that probabilistic genotyping systems be independently reviewed before being accepted as “scientifically valid” or “valid as applied,” see Report, at pp. 80-82. Internationally recognized software engineering groups, including the IEEE, also recommend independent review of software programs, particularly where, as here, the software performs critical functions. See IEEE Standard for System and Software Verification and Validation, IEEE Std 1012-2004, May 12, 2012. Appendix A and E. The International Society of Forensic Genetics, in 2016, recognized this IEEE standard as appropriate for use in validating probabilistic genotyping software systems. See Coble M.D., J. Buckleton, J.M. Butler, T. Egeland, R. Frenmen, P. Dug, et al., “DNA Commission of the International Society for Forensic Genetics: Recommendations on the validation of software programs performing biostatistical calculations for forensic genetics applications,” Forensic Sci. Int.: Genetics 25, 2016, n. 16. Hainan and Genetix propose another, also widely used, protocol for software codel Review. This procedure also calls for independent code review, along with compatibility with other similar software programs, and review of the “concept,” “operation,” and “software code itself” through “visual inspection and re-encoding.” See validation of probabilistic genotyping software for use in forensic DNA casework: Definitions and illustrations, Science & Justice, 56 (2016) 104-108.

The consensus group added the following test: “that represent (in terms of number of contributors, mixture ratios, and total DNA template quantities) the range of scenarios that would likely be encountered in casework. Studies shall not be limited to positive DNA samples but shall also include compromised DNA samples (e.g., low-template degraded, and unsubmitted samples).” It is my recollection that the OSAC committee specifically avoided using this language in the developmental validation studies section, because the range of sample types tested will vary considerably between different end users. For example, one laboratory may only test samples with up to three contributors using the multiple manufacturers’ standard settings, while another laboratory may test up to six-person mixtures using enhanced detection approaches. The consensus during the OSAC discussions was that the manufacturer of the probabilistic genotyping system should not have to validate all possible profile types at all laboratories may wish to test. This is why that language appears only in the internal validation studies section of the OSAC document.

The consensus group added the following test: “that represent (in terms of number of contributors, mixture ratios, and total DNA template quantities) the range of scenarios that would likely be encountered in casework. Studies shall not be limited to positive DNA samples but shall also include compromised DNA samples (e.g., low-template degraded, and unsubmitted samples).” It is my recollection that the OSAC committee specifically avoided using this language in the developmental validation studies section, because the range of sample types tested will vary considerably between different end users. For example, one laboratory may only test samples with up to three contributors using the multiple manufacturers’ standard settings, while another laboratory may test up to six-person mixtures using enhanced detection approaches. The consensus during the OSAC discussions was that the manufacturer of the probabilistic genotyping system should not have to validate all possible profile types at all laboratories may wish to test. This is why that language appears only in the internal validation studies section of the OSAC document.

The standard should provide guidance on the type of testing that warrants developmental validation. It is not necessary to have a specific procedure for a process that can be covered in a procedure manual. The consensus group added the following text: “Developmental validation may be conducted by the manufacturer/developer of the application or another laboratory/agency.” Developmental validation may be conducted by the manufacturer/developer of the application or another laboratory/agency, as long as it is also conducted by a different laboratory/institute/agency that has full independence from the developer and the requisitioning laboratory.

Effect of various degrees of allele sharing and accounting for relatedness is not specified as a requirement during both developmental and internal validation studies. Relatedness is simply a reality in casework. See PCAST at 79. There is no requirement concerning the # of samples to be used in developmental or internal validation. While this may vary among laboratories according to intended use, there should be a minimum standard. See PCAST at 81. For example, a laboratory wanting to evaluate 10 person mixtures with software already in use need to perform a developmental validation for such testing.

The field still has not figured out how to accurately determine the number of contributors to a mixture. The true number of contributors to a complex mixture in casework is unknown. Although there is a mention of “alternate hypotheses testing,” there should be an explicit requirement to test N+1 and N+2 contributors that the lab intends to interpret in casework. The effect of underestimation and overestimation of the number of contributors on the LR hypotheses. Assuming the number of contributors in a mixture is a known problem within the forensic DNA community and testing conditions where three persons may present like three persons mixtures or five person mixtures may present like three person mixtures should be a requirement explicitly stated. Alternate hypothesis testing can be defined in section 3 of the standard or text can be added 4.1.3 to explain what it means by alternate hypothesis testing. The expectation for mixtures with known numbers of contributors to be tested with alternate number of contributor hypotheses and testing with known contributor conditioning should be clearly communicated in the standard.
In addition to publishing the "mathematical basis" for the software program, the source code also should be either publicly available or freely open to inspection upon request with no restriction. Several experts, including Drs. Balding and Steele, recommend the probabilistic genotyping software be either "open source" or "open to scrutiny." Open source software is highly desirable in the court environment because openness to scrutiny by any interested party is an invaluable source of bug reports and suggestions for improvement. (Stokes, C.D. and Bolding, D.J., Statistical evaluation of forensic DNA profile evidence, *Annu. Rev. Res. Dev. In Appl.*, vol. 1, pp. 361–370, 2014).

4.1.5 T

Change: "The underlying scientific principle(s) of the probabilistic genotyping model and associated method and software including the mathematical basis and underlying algorithms shall be published for publication in peer-reviewed scientific journal(s)." To: "The underlying scientific principle(s) of the probabilistic genotyping model and associated method and software including the mathematical basis and underlying algorithms shall be published for publication in peer-reviewed scientific journal(s)."

4.2 T

There should be a requirement that the source code and a copy of the program must be made available to the defense upon request. The developer of the program should be required to provide its developmental validation studies as well.

4.3 T

Guidelines may not provide adequate specificity and necessity; whereas protocols do.

4.4 T

Check.

4.5 E

Add requirement that any change in laboratory testing/machinery/instrumentation/processes that could impact DNA interpretation requires re-validation. For instance, if the lab switches from 3130 CE machines to the more sensitive 3500s, there would need to be a new validation. It belongs in section 4.1.

4.6 T

Comma needed "It is impossible, for example, to base a requirement..." Accept.

4.7 E

Delete requirement 4.7. As written, it does not appear to apply to the validation process. If so, it should be moved under 4.1 and then would not appear in this annex.

4.8 T

Comma needed.

4.9 E

Delete this requirement, as written it does not appear to apply in the validation procedure. If so, it should be moved under 4.1 and then would not appear in this annex.

4.10 E

Italicize "as a requirement." A copy of the program shall be published for publication in peer-reviewed scientific journal(s).

23 4.6 E

This is written almost exclusively for one program, STRmix. Add standard concerning making the source code and copies of program available for inspection.

30 4.6 E

As these are potentially international standards, not every lab may have a "technical leader" Add "or other appropriate personnel" Partial Accept: Text revised to "... (or equivalent)."

4.8 E

Delete extra word in last line ("for publication") Delete "for publication" or state "...shall be published or accepted for publication in peer-reviewed..." Accept. See comment 11.

51 4.7 T

"a different data set" implies only one profile or limited set of profiles is sufficient make plural - "...utilizing different data sets than were originally used..." Accept.

57 4.9 E

"assessors seeking review" changes to whom is meant by assessors seeking review. Documentation demonstrating conformance with the standard should be made readily available to all parties requiring.

59 4.9 E

The standard should offer clarity as to whom is meant by assessors seeking review. Partial Accept. "By the assessor" has been removed.

61 4.9 E

"...as written..." Accept.

64 4.9 E

"4.9 This appears to be a requirement intended to be addressed with each use of the system in casework. As such, it goes beyond the scope of this document. It is meant to apply for each validation run, so it belongs in section 4.1. Other delete 4.6 or move it into the validation procedures in section 4.1."

25 4.8 E

This is written almost exclusively for one program, STRmix. Add standard concerning making the source code and copies of program available for inspection.

27 4.8 E

This is written almost exclusively for one program, STRmix. Add standard concerning making the source code and copies of program available for inspection.

28 4.8 E

This is written almost exclusively for one program, STRmix. Add standard concerning making the source code and copies of program available for inspection.

32 4.8 E

While this is important, as written it does not appear to apply in the validation procedure. If so, it should be moved under 4.1 and then would not appear in this annex.

33 4.8 E

Delete this paragraph. Delete: Setting the parameters is an important part of the validation process. Annex B is normative. It is a requirement.

34 4.8 E

Add: It is impossible, for example, to base a requirement... Accept.
<table>
<thead>
<tr>
<th>Annex, Requirement</th>
<th>Action</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>B, requirement 4.4</td>
<td>T</td>
<td>“It is impossible, for example to base a requirement on changes to software version numbers or build numbers.” A lab has a requirement that absolutely any change to software version number or build number will require a complete validation, I don’t see how this would be in violation of the intent of this document. It may not be the most time-effective policy, but it would meet the requirements of these standards. “It is not recommended to base a requirement simply on changes to software version numbers or build numbers. A requirement shall be based on the list of documented changes.” Accept with modification: A laboratory need not base a requirement for revalidation solely upon changes to software version numbers or build numbers.</td>
</tr>
<tr>
<td>E</td>
<td>E</td>
<td>Period needed at end of paragraph Add period at end of paragraph Accept</td>
</tr>
<tr>
<td>E</td>
<td>E</td>
<td>Period missing at the end of the section after “documented” Accept</td>
</tr>
<tr>
<td>C, Footnote</td>
<td></td>
<td>Reference to is properly listed as “latest version” of the QA Standards. However, footnote would lead the reader to a specific version of the Standards, which will be obsolete next year. Either remove footnote, or change the link to the FBI page which would list the most current version of the Standards, rather than the link to the 9-11 version only. Accept. New link used.</td>
</tr>
<tr>
<td>C</td>
<td></td>
<td>Any substantive changes to the operating system and software that result in changes to the probabilistic genotyping software functions should also be subject to validation. (Comment posted on ballot, no resolution recommended) Accept. Modifications made to include computing platform in 4.4</td>
</tr>
<tr>
<td>A, 4.4</td>
<td>E</td>
<td>Change the word “requirement” in last 2 sentences of requirement 4.4 to another word to avoid confusion. Change to “A laboratory does not need to perform additional validation based solely upon changes to software version numbers or build numbers. Additional validation or a performance check shall be based on the list of documented changes provided by the developer that accompany each updated version of the software installed in the laboratory.” Accept.</td>
</tr>
</tbody>
</table>