	Section	(E-Editorial, T-Technical)	Comments	Proposed Resolution	Final Resolution
12	Title	E	The term "Serological" doesn't accurately cover the types of screening and testing procedures that would likely fall under this standard	Use another word in the title and throughout the document that would more accurately reflect the range of screening and testing methods for which this standard would apply.	Partial Accept: The term forensic serology was clarified in the Foreword - see 3rd paragraph added to the Foreword. WG is of the opinion this is an editorial change.
13	Foreword	E	extra words can be deleted from first sentence of second paragraph	This standard provides requirements for the validation of methods that will be used…..	Accept: Edits made to the 2nd paragraph.
14	Foreword	T	It is unclear what is meant by "studies of performance characteristics"	Please provide clarification of the term "performance characteristics" that is used twice in the Foreword	Accept: Edits made to the 2nd paragraph.
37	3	T	Need definition for mock casework samples	Suggested definition: "samples that are representative of a range of casework conditions" (gives some examples of real life casework conditions?)	Accept: Definition 3.12 added.
15	3.1	T	It is unclear what the difference is between "procedure" and "method"	Please provide clarification of the meaning of the term "characterization of the test procedure"	Accept: See 3.1 clarified definition. A second sentence was added.
9	3.2	T	For the term "confirmatory", a clear distinction is necessary in order to differentiate whether the test confirms the presence of a biological molecule which can be present in more than one biological fluid/material versus "confirmatory" for a molecule that is unique to that particular bodily fluid. The word "material" should be defined further.	Suggest changing the definitiont of "confirmatory" to: *A test that is specific for the presence of a particular biological material. Confirmatory tests are specific for the body fluid, stain, or residue of interest, and reduce or eliminate false positive results.*	Partial Accept: Definition was modified and condensed.
16	3.2	E	1) term is plural, definition is singular; 2) the term being defined should not be used in the definition; 3) the second sentence is mostly redundant	1) term = confirmatory test; 2) An assay that is specific for the presence….; 3) delete redundant material and clarify the definition (maybe see SWGDAM)	Partial Accept: Definition was modified and condensed.
17	3.3	T	the definition seems to need more explanation since the unintended presence of many contaminants may be irrelevant	Suggested change to the definition: The unintentional introduction to a test sample of one or more exogenous materials or substances that may impact the test results (e.g., causing an incorrect assessment of a sample as positive or negative for a biological material due to the presence of the contaminant)	Reject: See 3.4 for further clarification.
18	3.4, 3.6, 3.10, 3.17 and many others	E	Change the beginning of the definition of all defined terms with "studies" to the same for consistency and clarity - suggest using "Experiments performed to …. "	For 3.4: Experiments performed to verify that the …..	Partial Accept: Instead of the word "verify" we used "assess".
19	3.4	T	Suggested modification to the definition that provides additional explanation	Experiments performed to assess the risk of the introduction of materials via the assay components, instrumentation, operator and testing procedure that may impact the test results.	Partial Accept: the definition was modified.
1	3.7	E	Punctuation issues in first sentence	Either keep the semicolon and make "This" lower case, or replace the semicolon with a period.	Accept: edits made.
2	3.7	E	The final sentence is not part of the definition of developmental validation, but provides procedural guidance	Delete last sentence	Reject: Definition was taken from OSAC's Lexicon.
3	3.8	E	In the last sentence, "current crime biology laboratory practices" sounds awkward	Replace "crime" with "forensic"	Accept: Edit made as suggested. The sentence that was edited has now been deleted as per comment 21 in line 16.
20	3.8	E	Clarify the meaning of "in general" since the term "serology" does not accurately reflect the majority of the tests used under this definition as typically defined outside of its use in crime laboratories	Suggestion: A broad term that covers the procedures typically used in Serology or Biology sections of crime laboratories for the detection, characterization….	Partial Accept: The words "in general" were deleted. See "Forward" section for a revised explanation of serology.
21	3.8	E	delete "current" since this is for the validation of new methods; reorganize the last section	Suggestion: Delete the last phrase and substitute "DNA testing of a sample of biological origin may follow one or more of these procedures."	Accept: Edit made as suggested (last phrases were completely deleted).
4	3.10	E	"effect" should be "affect"	Replace "effect" with "affect"	Accept in full.
22	3.11	E	suggested modification to the definition for additional clarity	Experiments performed to evaluate the performance of the test method when samples containing mixtures of similar or different body fluids and/or cell types are assayed.	Accept in full.
7	3.13/4.1.4	T	3.13 defines performance check as relating only to functionality of equipment and instruments. 4.1.4 appears to use performance checks in a broader sense-even for tests which may not utilize any instrumentation	Redefine performance check as a quality assurance measure to ensure that a particular test is providing the correct response when used on known samples, or something similar.	Reject: Definition was taken from OSAC's Lexicon. However, the word "reagent" was incuded in this definition.

23	3.14	T	It is unclear what is meant by this term. Is it referring to the possibility that samples from different individuals within the general population (possibly unrelated to ancestral or ethnic origin) may behave differently using the assay, or is this referring to the need to see that samples from different populations groups perform appropriately and to develop information regarding frequencies of various possible test results in the populations? The term "population" suggests the latter but the definition suggests the former meaning.	Please provide clarity regarding what is actually required for "population studies" in this standard. Experiments performed to determine ….. What studies need to be done? What data collected? For what purpose?	Partial Accept: WG edited defintion for population studies.
10	3.15	T	The definition states: "Presumptive tests are sensitive, but not specific." That definition is true for tests such as luminol and phenolphthalein (generally enzymatic/catalytic type reachtion), but not true for other presumptive tests that are based on antibodies. For instance, the antibody-based P30 test is confirmatory for P30, presumptive for semen, and not considered sensitive per se. Similarly, the antibody-based test for human salivary amylase is confirmatory for human amylase, presumptive for human saliva, and not considered sensitive per se.	Suggest either changing the definitiont to: *"A screening test which may be positive in the presence of a biological material of interest.* *Some presumptive tests are sensitive, but not specific. A positive result indicates that further testing* *could be informative* " or removing the sentence "*presumptive tests are sensitive, but not specific.* "	Accept.
24	3.15	E	Term is plural; definition is singular	Term = presumptive test	Accept- term was corrected to be singular.
25	3.15	E	minor suggested changes	A screening assay that may give a positive reading in the presence of one or more biological materials; a presumptive test should be sensitive, but is not specific for a particular biological material. ... Maybe add a statement that a confirmatory test is needed to verify the presence of a particular biological material.	Reject: See confirmatory test 3.2 definition.
26	3.16	E	suggested wording changes to provide more clarity	Experiments performed to assess the ability to generate the same test results or the range of acceptable test results when performed by the same person and using the same instrument.	Reject: The definition is succinct as is.
27	3.17	E	Minor wording suggestion	Experiments performed to assess the capability of obtaining the same test results...	Accept
28	3.18	T	It is unclear what the last part of the definition means and how this applies to the procedures for which this standard is intended to be used; robustness often refers to the ability of an assay to perform when a sample is compromised in some way and may also refer to some possible limitations of the assay (sensitivity, specificity, age, denaturation/degradation, etc.)	Please provide more clarity to what this means and what types of experiments would be required under this term	Accept with modification.
29	3.19	T	first statement is unnecessary in this document	Suggestion: Experiments performed to define the lower and upper limits or bounds of an assay to accurately detect an analyte, typically involving the use of serial dilutions (e.g., of a sample with a specified concentration).	Partial Accept: Definition was modified.
30	3.21	T	this definition is too broad	without additional specificity, this definition alone is too broad to provide individuals conducting validation studies or auditors clear guidance on what studies are actually needed to meet the requirements in this standard	Accept with modification: This comment is valid. Stability studies are included in robustness studies. Therefore, definition 3.21 has been deleted and the stability studies was removed from section 4.2.
38	4	T	Need to explain the difference in scope and purpose for developmental validation and internal validation. This could be done in an Annex.	Explain difference between two validations--different in scope and size; methods developed in developmental validation must be peer reviewed, etc.	Reject: Definitions for developmental and internal validations answer this comment.
47	4	T	If a lab develops a serological method inhouse, it needs to conduct both a developmental and internal validation. Should the data sets for each be, at least in part, different?	Consider adding requirement that if the lab conducts both developmental and internal validation to bring a method online for casework, the lab shall use, at a minimum, a different data set for internal validation than that used in developmental validation, but a lab may also use both."	Accept: Verbiage added under 4.1.2 indicating different samples shall be used for developmental validation studies
39	4.1	T	Standard does not clearly lay out role of internal validation or that a lab must use only methods that are both developmentally and internally validated.	Add "Validations shall include both developmental and internal validations." after first sentence of 4.1.1	Partial Accept: Addressed in comment # 5.
5	4.1.1	T	Internal validation should also precede the implementation of any tests in practice	Change second sentence to begin "Developmental and internal validation…"	Accept
32	4.1.1	T	This first statement seems misplaced and perhaps belongs in the foreword or scope as the general goal of this standard rather than a mandatory requirement since the whole point of this document is to provide requirements for acquiring validated methods.	Suggest deleting the first sentence (or moving elsewhere in the document). Also delete "new" from the second sentence.	Reject: The first sentence determines that this is a requirement, therefore it can not be deleted.
34	4.1.1	T	This section needs to include internal validation	Insert after Developmental: "and internal"	Accept
33	4.1.3	T	The types of samples to be tested seems to also be important	Suggested change: "...shall determine the number, types and range of sample types to be used in each of the validation studies to ensure the generation of sufficient data to establish a standard operating procedure.	Accept
35	4.1.5	T	This is not specific enough. The direction is if the modification of the procudure has the potential to affect the analytical results, the modified proceudre or instrumentation should be evaluated. What type of evaluation does this include? It seems like a very subjective process without set criteria.	Add more detail and specific requirements for each step in the process, such as conducting a small scale test or doing a search of supportive peer reviewed studies.	Accept: Paragraph 4.1.5 was modified.

40	4.1.4	T	This paragraph may be confusing; for instance, when is a performance check warranted?	Clarify when a new validation vs. performance check is needed. Suggestion:add to 4.1.3 "Any change to a validated procedure shall be evaluated to determine if it is material or minor. A material modification shall require validation. A minor modification shall require, at a minimum, a performance check. Both material modifications and performance checks made to validated procedures shall be documented. The evaluation of changes to validated procedures and further validation shall conform to requirements of this standard and shall include a comparison of the modified method to the original method which was modified. Material modification, performance check, and evaluation documentation shall be included with the validation."	Partial Accept: Section 4.14 and 4.15 were clarified to indicate when a development valication or a validation is needed.
6	4.1.6	E	Punctuation around the word "however" is incorrect	Should read "...shared; however, performance..."	Accept
31	General comment for Sections 4.2 and 4.3	T	No clarification or directed guidance is provided for the mandatory studies that must be performed under these sections. Given the lack of specificity and detail for some of the defined terms, there is a high risk that there may not be general agreement within the community of test users and auditors regarding what studies are needed, what the studies must address and what the required outcome of the studies must entail, which could easily lead to inconsistencies, and inappropriate and/or inadequte evaluations of studies performed	Strongly recommend that additional information be provided in the definitions, requirements and/or in a normative annex to provide clearer guidance and specific direction on what would be required to fulfill these requirements to be of the best benefit to the forensic testing community. Particular guidance as it applies to the various range of testing methods embraced by this standard per the definition of "forensic serology" at 3.8 should be detailed where ambiguities may exist (e.g., physical methods vs. biochemical assays vs. microscopy).	Reject: See definitions section which was modified to define each set of studies needed.
41	4.2	T	With respect to the last requirements for Developmental Validation (the analysis of mock or adjudicated cawework samples")--A lab/developer should be required to test on mock casework samples; with adjudicated samples you don't necessarily know the right answer.	change "or" to "and" OR "the analysis of mock or adjudicated casewwork samples: to "the analysis of mock casework samples" OR "the analysis of, at a minimum, mock casework samples, and if possible, adjudicated casework samples"	Accept: The words "or Adjudicated" was removed from sections 4.2 and 4.3 so now the standard indicates validations should use the analysis of mock casework samples.
42	4.2	T	Repeatability studies is not present in the requirements for developmental validation but should be (necessary component of determining accuracy).	Add "repeatability studies"	Reject: Repeatability studies are not normally evaluated within the scope of developmental validation. Such studies must be conducted as part of the internal validation.
43	4.3	T	robustness studies is absent from internal validation study requirements. Should it be?	Consider adding robustness studies to internal validation.	Reject: Robustness is tested during the developmental validation.
44	4.3	T	With respect to the last requirements for Internal Validation (the analysis of mock or adjudicated cawework samples")--A lab/developer should be required to test on mock casework samples in addition to adjudicated samples; with adjudicated samples you don't necessarily know the right answer.	change "or" to "and" ***OR*** "the analysis of, at a minimum, mock casework samples, and if possible, adjudicated casework samples"	See comment # 41
8	4.4.1	E	Suggest rewording first sentence to replace "list" with "document", OR state to maintain a list	The laboratory shall identify and document scientific literature...OR ...shall identify and maintain a list of scientific literature...	Partial Accept: Sentence was modified to address the concern.
11	4.4.1	T	While it is necessary that the the laboratory list the scientific literature describing the test and/or the scientific principles that serve as its foundation, it is also crucial that the lab recognizez the limitations of each test and remain current on literature publications that reveal such limitations.	Suggest adding a sentence to the guideline 4.4.1: *"The laboratory shall also identify and list the scientific literature that describes the limitations of the test* ."	Partial Accept: Sentence was modified to address the concern.
36	4.4.2	T	The lab should retain the orginal developmental studies including documentation of study design, data obtained from the study and a summary of the analysis of that data unless the developmental validation was done externally and published. Having a policy as in sec 4.4.6 is not adequate.	Add: If the developmental validation was done externally, the lab should maintain documentation of the study in the form of published peer reviewed articles. If the developmental validation study was done by the individual laboratory, the lab should maintain documentation of the design of the study, bench notes, data obtained and any analysis of the data including a summary.	Partial accept: see modified conformance section.
45	4.4.3	T	The lab should have more than just a summary and, similar to the prob geno validation standards, there should be a requirement that internal validation does not exceed the limits of developmental validation.	Require that a copy of the developmental validation be kept by the laboratory; add requirement that "The internal validation shall not exceed the scope of the conditions tested in the developmental validation. Case type profiles that fall outside the range of conditions explored in developmental validation shall require additional developmental validation studies."	Partial Accept: see section 4.1.3 (new numbering). This section is now 4.4.3.
46	4.4.5	T	Requiring the lab to simply have a policy rather than what that policy should be at a minimum is too weak and will fail to advance the goal of raising quality.	Replace 4.4.6 with "All validation, material modification evaluations, and performance check studies conducted by the laboratory shall be documented and retained by the laboratory and made available for review. This includes all raw data."	Partial Accept: See section 4.4.7 and section 5.