December 13, 2019

Via OSAC Open Comment Portal
Forensic Science Standards Board
Organization of Scientific Area Committees
For Forensic Science
National Institute of Standards and Technology
U.S. Department of Commerce
https://www.surveymonkey.com/r/2XKW9WR

Re: Request for Comment on Standard 020—Standard for Validation Studies of DNA Mixtures, and Development and Verification of a Laboratory's Mixture Interpretation Protocol.

Dear Forensic Science Standards Board:

Brooklyn Defender Services ("BDS") submits these comments in opposition to placing the Organization of Scientific Area Committees for Forensic Science's (OSAC) Biological Data Interpretation & Reporting Subcommittee's Proposed Standard for Validation Studies of DNA Mixtures, and Development and Verification of a Laboratory's Mixture Interpretation Protocol, ASB approved February 2018, ANSI approved September 2018 (hereinafter, "Standard 020"), ANSI/ASB Standard 020, 1st Edition 2018, on the OSAC Registry.

While BDS applauds the OSAC's commitment to developing uniform standards across forensic science fields, the proposed standard falls woefully short in a number of critical respects. Before this standard is included in the OSAC Registry, these shortcomings must be addressed.[1]

Defining validation. While the title of Standard 020 and the "terms and definitions section" both refer to "validation" generally, Standard 020 *only* substantively addresses internal validation. Standard 020 never references developmental validation, and never distinguishes the baseline requirement that methods be *developmentally* validated before being internally validated and used in the interpretation of DNA data. Similarly, Standard 020 includes no requirement that the underlying scientific principles of a technique be peer-reviewed, developmentally validated, or scientifically sound.[2]

[1] If, despite these serious shortcomings, Standard 020 *is* admitted to the Registry, these comments are offered for consideration in the drafting of future versions of this standard.
[2] In contrast, multiple standards currently passing through the standards development process appropriately define validation, and discuss the foundational importance of developmental

Either (A) the standard should be re-titled to include the restrictive adjective "Internal" and the definition of "validation" in the "terms and definitions section" should be removed *or* (B) the standard should specifically define "validation" as a process inclusive of *both* developmental and internal validation, state that this standard *only* addresses internal validation, and refer the reader to the additional standard(s) that cover developmental validation.[3]

Defining qualifications. Standard 020 does not mention or address the qualifications needed for the personnel conducting the validation and does not refer to any other standard that might define those qualifications. The only reference to the specific laboratory personnel who should be involved in the internal validation process comes in the Conformance section. There, Standard 020 states "Documented conformance to these requirements need to be: (1) approved by the laboratory's DNA Technical Leader or other appropriate personnel . . . ." In addition to being a poorly constructed sentence, this requirement alone cannot ensure that internal validation—the most critical phase of laboratory technique adoption—is conducted by qualified personnel or that its appropriate completion is actually approved by qualified personnel.

Standard 020 should either define the appropriate qualifications for the involved personnel or specifically reference the standard that controls those qualifications.

Defining the effective date. Standard 020 is not clearly retroactive and does not prescriptively define *when* internal validation is required. The standard only specifically requires the *verification* of existing protocols, *see* Requirements 4.4.3 ("Verification shall be performed on new, existing, and modified mixture interpretation protocols."), but merely *advises* that previous validation be reviewed without requiring retroactive review. *See* Scope 1.2 ("Laboratories are advised to review their previous

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validation. *See, e.g.,* ASB Standard 038, "Standard for Internal Validation of Forensic DNA Analysis Methods," (First Edition, 2019); ASB Standard 077, "Standard for Developmental and Internal Validation of Forensic Serological Methods," (First Edition, 2019); and ASB Standard 018, "Standard for Validation of Probabilistic Genotyping Systems," (First Edition, 2019). Additionally, the Federal Bureau of Investigation's *Quality Assurance Standards for Forensic DNA Testing Laboratories* requires "STANDARD 8.2 Developmental validation shall precede the use of a novel methodology for forensic DNA analysis."; defines developmental validation under 8.2.1; and states "8.2.2 Peer-reviewed publication of the underlying scientific principle(s) of a technology shall be required."

[3] *Compare, e.g.,* Standard 020 at 3.5 ("Validation" is defined as "The process of performing a set of experiments that establish the efficacy, reliability, and limitations of a method, procedure or modification thereof; establishing recorded documentation that provides a high degree of assurance that a specific process will consistently produce an outcome meeting its predetermined specifications and quality attributes.") *with* the Federal Bureau of Investigation's *Quality Assurance Standards for Forensic DNA Testing Laboratories* at 2 ("Validation" is defined as "[A] process by which a procedure is evaluated to determine its efficacy and reliability for forensic casework analysis and includes the following: (1) Developmental validation is the acquisition of test data and determination of conditions and limitations of a new or novel DNA methodology for use on forensic samples. (2) Internal validation is an accumulation of test data within the laboratory to demonstrate that established methods and procedures perform as expected in the laboratory.").

validation for compliance with this standard, supplement validation where necessary, and modify existing protocols accordingly.").

Standard 020 should be clear, and specifically prescribe retroactive review for conformity with its requirements.[4]

Defining a scientifically appropriate scope. Standard 020's Scope states: "This standard applies to any type of DNA testing technology and methodology used, including . . . rapid protocols." *Id.* at 1.2. By including "rapid protocols," Standard 020 clearly suggests that the OSAC is approving laboratory use of rapid systems on *mixture analysis*. This is contrary to the position of numerous oversight bodies, including SWGDAM, the FBI's Quality Assurance Standards, and the Texas Forensic Science Commission.[5] It is also scientifically unsupported. Scientific Working Group on DNA Analysis Methods, *Position Statement on Rapid DNA Analysis* at 1 ("Rapid DNA technology is not currently suitable for crime scene samples . . . .").

Standard 020's Scope should *not* include "rapid protocols."

Defining "unsuitable for comparison" and a complexity threshold. While Standard 020 states that "the data from the validation studies . . . shall provide guidance for the types of mixed DNA profiles that will be interpreted by the laboratory" and requires the studies to "aid in assessing and defining the [methodologies'] limitations," Standard 020 does *not* address the role of the internal validation in developing, as required by Standard 040, "criteria for defining what are interpretable data versus data that cannot be interpreted" and "suitable for comparison versus data that are unsuitable for comparison." Standard 040.4.2.5 and 4.2.6. Similarly, Standard 020 does not specifically address mixture complexity at all. Instead, Standard 020 gestures toward "defining the limitations," but includes no substantive discussion of methodological limitations or any requirement that validation actually incorporate a sufficient quantity of data to identify and define those methodological limitations.

Similarly, by limiting the mixture study requirements in Requirement 4.2, Standard 020 actively avoids an internal validation protocol that would "defin[e] the limitations" of the methodology. Standard 020 reads: "The mixture studies shall include, at a minimum, mixed DNA samples that: . . . Are representative of those **typically** encountered and interpreted by the testing laboratory." *Id.* at 4.2 and 4.2.1 (emphasis added). The limiting adjective "typically" should be removed, as the standard should require that mixture studies include all types of samples encountered by the laboratory which the laboratory intends to interpret and compare.

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[4] Annex A "Foundational Principles" states: "It is the intent that this standard be applied to any existing interpretation and comparison protocols and that the protocol be revised as needed." But Annex A is marked as "informative," not "normative."

[5] *See, e.g.,* Maura Dolan, *'Rapid DNA' promises breakthroughs in solving crimes. So why does it face a backlash?*, Los Angeles Times (September 25, 2019) at https://www.latimes.com/california/story/2019-09-24/rapid-dna-forensics-crime-police; *Rapid DNA*, Federal Bureau of Investigation at https://www.fbi.gov/services/laboratory/biometric-analysis/codis/rapid-dna.

Standard 020 should include a definition of "cannot be interpreted" and "unsuitable for comparison" that is consistent with Standard 040. Standard 020 should also address the role of internal validation in establishing and defining a complexity threshold for interpretation. Standard 020 should not limit internal validation to "typical" samples, but instead should require all sample types that will be tested, interpreted, and compared by the laboratory.

Defining "documented conformance" and "be[ing] made readily available for review." Standard 020's commitment that "documented conformance" be made "readily available for review" by "stakeholders who use reports generated by the DNA mixture test protocols and procedures" gestures toward an essential requirement for validation testing more broadly. Specifically, it signals the underlying necessity that validation testing be comprehensively documented, and that "all validation documentation be retained and available for review." *See* the Federal Bureau of Investigation's *Quality Assurance Standards for Forensic DNA Testing Laboratories* (effective July 1, 2020) at 8.9. However, Standard 020 is not explicit in the requirement that all portions of internal validation testing be comprehensively documented and does not specifically require that *all* validation documentation be retained and available for review.

Standard 020 should explicitly require that all validation data be documented, and that all validation documentation be retained and electronically available for review by stakeholders (including criminal defense attorneys) who use reports generated by the DNA mixture test protocols and procedures. *See* National Commission on Forensic Science, *Recommendation to the Attorney General Transparency of Quality Management System Documents* (Recommending that all quality management system documents be immediately made accessible to the public in an electronic format upon request and posted on the laboratory's website within one year of the recommendations adoption), https://www.justice.gov/archives/ncfs/page/file/839706/download.

Because Standard 020 fails to adequately define validation, required qualifications, its own effective date, a scientifically appropriate scope, a complexity threshold and documentation requirements, this standard should not be included in the OSAC Registry. Instead, these critical shortcomings should be addressed, and the standard should be improved prior to inclusion.

Sincerely,

/s/ *Elizabeth Daniel Vasquez*
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OSAC Registry Request Comment Adjudication Template

Document Title	ANSI/ASB Standard 020 Edition 1, 2018 -
Standard for Validation Studies of DNA Mixtures, and Development and Verification of a Laboratory's Mixture Interpretation Protocol	
Requesting Subcommittee	OSAC Biology/DNA Reporting & Interpretation

Subcommittee Chair		**Subcommittee Technical Contact**	
Name:	Beth Ordman	Name:	Charlotte Word
Affiliation:	Pinellas County Forensic Laboratory	Affiliation	consultant

Beginning Comment Period Date	11/13/19
End Comment Period Date	12/13/19
Comment Adjudication Meeting Dates	4-Feb-20
# of Members Present	20

Note: This template is intended for use by all subcommittees considering a new document for addition into OSAC Registry

Id	Person	Subject
1	Norah Rudin	
2	Norah Rudin	
3	Elizabeth Daniel Vasquez	
4	Christina Buettner	

5 Christina Buettner

6 Joanne B. Sgueglia

7 Bruce J. Heidebrecht

8 Angelo Bommarito

Elizabeth Daniel Vasquez - continuation
9 from #4 above

Elizabeth Daniel Vasquez - continuation
10 from #4 above

Elizabeth Daniel Vasquez - continuation
11 from #4 above

Elizabeth Daniel Vasquez - continuation
12 from #4 above

Elizabeth Daniel
Vasquez - continuation
13 from #4 above

Elizabeth Daniel
Vasquez - continuation
14 from #4 above

Comment/Proposals

The standard is an improvement on current guidelines. However it lacks discussion of the following two issues: 1) While the standard mentions that casework interpretation should not exceed the number of contributors in the validation studies, it fails to explicate that the number of contributors in casework samples could be underestimated, especially in complex samples. This issue needs to be explicitly addressed, both by requiring that validation samples exceed the casework limit by at least one contributor, preferably more, and by mentioning the risks of underestimating the number of contributors.

2) This standard, like others, continues to avoid the doughnut-hole of historical statistical approaches. The validation mentioned should apply not just to manual interpretation, but to any statistical approaches, including historical methods such as CPI, 2P, and "binary LRs." Laboratories continue to point to the lack of guidelines regarding these methods to continue using unvalidated statistics.

Because Standard 020 fails to adequately define validation, required qualifications, its own effective date, a scientifically appropriate scope, a complexity threshold and documentation requirements, this standard should *not* be included in the OSAC Registry. Instead, these critical shortcomings should be addressed, and the standard should be improved prior to inclusion. Please see attached complete comment.

4.3.3 - criteria for establishing minimum number of contributors to a mixture would not be applicable to all laboratories. I do not see the need for this criteria if a minimum number of contributors is not used in interpretation.

4.4.1 - Exclusion of all non-contributors will not be possible with every mixture interpretation system depending on the level of data the lab is analyzing. We know that known non-contributors may sometimes have LRs above 1 based on genetic similarities.

Yes--the document clearly outlines the procedures needed for a laboratory to properly conduct mixture validation studies. I have 2 comments: 1. Section 4.3.1 states the validation summary shall describe how the studies led to the parameters used in the interpretation protocol. My question is can it be another supporting document and need not be the validation summary itself. For example, a separate document that details the criteria established from the validation studies to be used in the interpretation guidelines (attached as an appendix to the interpretation guidelines). 2. Later in the document it is stated that the lab shall define the acceptable range of variability in the interpretation of DNA mixtures for use in the evaluation of consistency within the lab. My question is regarding the "acceptable range of variability". How would one define such a range--how is it to be measured? Would it be based on the final statistical outcome? Would one calculate some sort of relative standard deviation? I think this should be expanded upon to better define or assist readers how to evaluate such variance.

"If the laboratory has not performed any validation studies using five- or more-person mixtures, the mixture interpretation protocol shall state that only DNA samples assumed to contain four or fewer contributors and no mixed DNA data assumed to contain five or more contributors may be interpreted." I do not fully agree with this stated requirement. Imagine a lab analyzing two different samples: 1) Mixture of apparently four contributors at 97:1:1:1 ratio. 2) Mixture of apparently five contributors at 96:1:1:1:1 ratio. It is clear that there will be no significant difference in the interpretation of the major profile regardless of the addition of one more contributor in the second mixture. Forcing a lab to discard the analysis of the major profile from the second mixture simply because they did not validate five-person mixtures would be inane. This is not simply a hypothetical. This very situation (albeit not quite as dramatic ratios) came up on a discussion board recently.

This document is acceptable. It is a clear, and understandable guide. My only concern is that item 4 in the bibliography references the ISO 17025:2005(E) guide, whereas I could not find a specific reference in the document to this standard, the current version is ISO17025:2017. Thanks,

Topic #1 - Defining Validation (see letter dated December 13, 2019)

Topic #2 - Defining qualifications (see letter dated December 13, 2019)

Topic #3 - Defining the effective date (see letter dated December 13, 2019)

Topic #4 - Defining a scientifically appropriate scope (see letter dated December 13, 2019)

Topic #5 - Defining "unsuitable for comparison" and a complexity threshold (see letter dated December 13, 2019)

Topic #6 - Defining "documented conformance" and "be[ing] made readity available for review (see letter dated December 13, 2019)

Response	Status	Resolution	Disposition
The wording of this requirement was carefully considered and discussed at both the OSAC and ASB during development of the standard; the issue presented in this comment was a significant part of those discussions. This requirement was written as a minimum requirement equivalent to the previously released ASCDL/LAB requirement; however, this standard encourages the laboratory to do studies beyond the number of contributors it intends to interpret and report as stated in the normative Annex B. This suggestion will be passed to the ASB committee for re-consideration when this document is revised.	Resolved	Previously considered	Resolved
The validation and use of statistical methods is outside the scope of this document except where their use is directly tied to the interpretation covered by this standard, in which case, the validation studies must include validation of the associated statistical methods. An additional standard specifically for the validation of probabilistic genotyping software has been developed and is in its final stages for publishing by ANSI/ASB (Standard 18 – Validation Standards for Probabilistic Genotyping Systems). Additional standards are under development at OSAC regarding statistical methods.	Resolved	Not persuasive	Resolved
The comments provided are beyond the scope of this document. Responses to specific comments detailed in the accompanying letter from this commenter are provided below individually.	Resolved	Not persuasive	Resolved
The laboratory must have some criteria for establishing the number(s) of contributors for evaluation and interpretation of the DNA data. If the laboratory uses the minimum number of contributors in its interpretation, this portion of the requirement would apply and need to be fulfilled. Any criteria (or portions thereof) that do not apply to a laboratory would be considered “not applicable.”	Resolved	Not persuasive	Resolved

The wording of this requirement was carefully considered and discussed at both the OSAC and ASB during development of the standard; the issue presented in this comment was a significant part of those discussions. It is critical to have validation studies demonstrating the accuracy of the laboratory's interpretation protocol and use by the analysts as well as defining the limitations of the DNA testing procedures and the interpretation protocol. This and other requirements in the standard ensure that each statement in the interpretation protocol is supported by sufficient validation studies and any limitations are addressed and defined by the studies and the protocol.	Resolved	Previously considered	Resolved
The commenter confirmed during a phone conversation that the document should be accepted for the registry and that the comments were simply questions regarding the specific application and intent of the document. The following responses address the questions provided. #1 - 4.3.1 – The requirement and normative annex state the documentation will be included in the validation summary for the laboratory. Documentation elsewhere that is not included as part of the validation summary would likely not meet the intent of this requirement. #2 – The acceptable range of variability would need to be defined within the laboratory based on the validation studies performed for the particular assays used in the laboratory, the types of data generated and the interpretation methods employed. Providing a list of the variables and methods for addressing the variability are outside the scope of this standard.	Resolved	Not persuasive	Resolved

This response was discussed at length with the OSAC subcommittee that wrote the original standard. The group feels strongly that testing appropriate known constructs of mixtures for all numbers of contributors that the laboratory is planning to interpret and does ultimately interpret for casework is a mandatory minimum requirement. This requirement does not preclude the laboratory from specifying criteria in its protocol for the interpretation of all mixture ratios up to a defined maximum number of contributors, and specifying separate criteria for a single interpretable major contributor profile with multiple uninterpretable minor contributor profiles even if it exceeds the maximum defined number of contributors allowed for general interpretation. Any criteria used for interpretation must be supported by appropriate validation and verification testing and include an upper bound on the	Resolved	Not persuasive	Resolved
An email was sent to the commenter 1/14/2020 to inform him that this modification had been emailed to ASB, and that because it was a minor administrative change, the update can be made to the published document. Teresa Ambrosius confirmed that she will make the change. Persuasive change accepted but review is not required.	resolved	Persuasive - review requir	Resolved
The Scope specifies this document is intended only for internal validation within the laboratory. The FBI Quality Assurance Standards and other documents address developmental validation.	see #4 above		
Qualifications for Technical Leaders and other relevant personnal are addressed by other existing standards (e.g., FBI Quality Assurance Standards, ISO 17025).	see #4 above		
This standard was published in 2018, and has been available for laboratories to adopt since that time. No accrediting body or other agency to date is requiring conformity to this standard at this time as far as we know.	see #4 above		
This is a standard with requirements for laboratories doing any type of DNA mixture interpretaton regardless of the method, instrumentation or technologies employed to develop the mixed data. It is not a postion statement regarding the use of any method, instrumentation or technology.	see #4 above		

This standard and Standard 40 (Standard for Forensic DNA Interpretation and Comparison Protocols) are intended to be used together to address validation studies, protocol development and verification of the protocol. The studies conducted, the numbers and types of samples tested, the limitations explored, etc. must be determined by the laboratory performing the validation studies for the technologies and methods employed in the laboratory. Additional information is available in the FBI Quality Assurance Standards and from SWGDAM, and others. see #4 above

Documented conformance to this standard is required in Section 5 along with the requirement that the documentation is readily available for review. Retention of validation studies and other documents are addressed by other relevant standards (e.g., FBI Quality Assurance Standards, ISO 17025). see #4 above

No response needed

Resolution Date and Vote Outcome	Company Name	Interest Category

2/4/2020; 20 out of 20

2/4/2020; 20 out of 20

2/4/2020; 20 out of 20

2/4/2020; 20 out of 20

2/4/2020; 20 out of 20

2/4/2020; 20 out of 20

2/4/2020; 20 out of 20

2/4/2020; 20 out of 20

Submission Date	Group Name	Document Name

Revision Number	Document Description	History