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/B9K8QM6

Re: Request for Comment on Standard 040—Standard for Forensic DNA Interpretation and Comparison Protocols.

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 Forensic DNA Interpretation and Comparison Protocols, ASB approved February 2019, ANSI approved September 2019 (hereinafter, "Standard 040"), ANSI/ASB Standard 040, 1st Edition 2019, on the OSAC Registry.

While BDS applauds the OSAC's commitment to developing uniform standards across forensic science fields, as with companion Standard 020, the proposed Standard 040 falls woefully short in several critical respects. Before this standard is included in the OSAC Registry, these shortcomings must be addressed.[1]

Defining validation. Standard 040 contains only a single reference to developmental validation, and that reference appears in passing in Annex B.[2] Like Standard 020, Standard 040 never distinguishes the baseline requirement that methods be *developmentally* validated before being internally validated and used in the interpretation of DNA data. Similarly, Standard 040 includes no requirement that the

[1] If, despite these serious shortcomings, Standard 040 *is* admitted to the Registry, these comments are offered for consideration in the drafting of future versions of this standard.
[2] "First, DNA data interpretation and comparison protocols are derived from developmental and internal validation data (Section 4.1), after which the interpretation protocols will be assessed in accordance with the limitations defined in the protocol to determine whether the data (either in part or as a whole) are suitable or unsuitable for interpretation and comparison (Section 4.2)." Annex B at 5.

underlying scientific principles of a technique be peer-reviewed, developmentally validated, or scientifically sound.[3]

Standard 040 at 4.1 should read "The laboratory interpretation protocols and comparison protocols, including criteria for drawing conclusions from comparisons between evidentiary data and reference (or other evidentiary data), shall be based on, developed from, and supported by **developmental validation studies** and internal validation studies."

Defining qualifications. Standard 040 does not mention or address the qualifications needed for the personnel responsible for the interpretation and comparison protocols and does not refer to any other standard that might define those qualifications.

Standard 040 should either define the appropriate qualifications for the involved personnel or specifically reference the standard that controls those qualifications.

Defining the effective date. Standard 040 is not clearly retroactive and does not prescriptively define *when* new, updated, or expanded protocols are required. Annex B, which is only informative, begins: "It is the intent of this document that any DNA data: 1) that fall outside the acceptable range of the interpretation and/or comparison method employed; 2) for which no suitable/appropriate documented protocol exists; or 3) for which no suitable internal validation studies exist to support the method, will not be interpreted or compared by the laboratory until the standards are sufficiently met and approved by the appropriate authority(ies) within the laboratory." This compound sentence gestures at an effective date and triggering events for the creation of protocols. But the sentence is muddled and is buried in an informative annex.

Standard 040 should be clear, specifically define a retroactive effective date, and include required triggering events for the creation, updating, or editing of protocols.

Defining a scientifically appropriate scope. Standard 040's Annex A Foundational Principles state: "This document applies to any type of DNA testing technology and methodology used, including . . . rapid protocols, etc., where mixtures of DNA may be encountered, analyzed, interpreted and compared." *Id.* at 1.2. By including "rapid protocols," Standard 040 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.[4] It is also scientifically unsupported. Scientific

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[3] In contrast, 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."

[4] *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.

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 040's Annex A should *not* include "rapid protocols."

Addressing contamination. Standard 040 does not contain a single requirement that interpretation and comparison protocols include a review of appropriate data from either standards or controls. Tellingly, the only discussion of contamination comes in Requirement 4.2.4, where Standard 040 opaquely states that interpretation protocols need to address the "limitations of the interpretation methods such as characterizing and defining . . . issues associated with . . . potential contamination events." Given that the threat of contamination is an ever-present specter, particularly as techniques continue to become ever more sensitive, this omission is both startling and inexcusable.

Standard 040 should directly define contamination and include clear requirements for documented protocols governing both the use of standards and controls and the detection of contamination.

Addressing non-conformity events. Standard 040 does not address the need for a protocol covering instances of non-conformity uncovered by the technical or administrative review. Additionally, the Standard does not address the need for a protocol regulating analyst requests to deviate from the established protocols.

Standard 040 should directly address the need for documented protocols regulating instances of non-conformity with the interpretation and comparison protocols uncovered during the review process and/or instances of analyst requests to deviate from established interpretation and comparison protocols. Standard 040 should, at a minimum, include a requirement that non-conformity events be documented and that any ensuing corrective action, or similar review, be documented and included in the case file.

Defining "data that cannot be interpreted" and "data that are unsuitable for comparison". Standard 040 requires that interpretation protocols address both "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. Furthermore, Standard 040 defines "unsuitable for comparison" as "data that cannot be used for comparisons for reasons including, but not limited to, poor or limited data quality, mixture complexity, or a failure to meet quality assurance requirements." *Id.* at 3.7. However, Standard 040 never defines "cannot be interpreted." The Standard fails to connect either data that cannot be interpreted and/or data that are unsuitable for comparison to "the limitations of the interpretation methods used," and instead separates the limitations discussed in 4.2.4 from the criteria required in 4.2.5 and 4.2.6.

Standard 040 should include a definition of *both* "cannot be interpreted" and "unsuitable for comparison." Standard 040 should also connect the limitations identified

by internal validation to the establishment and definition of both data that cannot be interpreted and data that is unsuitable for comparison.

Addressing statistical calculations. Standard 040 does not include any requirement for comparison protocols to address the appropriate calculation of statistical significance for any inclusionary result. This is such a fundamental step in the comparison process that the Standard's failure to address it is glaring.

Standard 040 should include a requirement that comparison protocols address statistical calculations.

Addressing the availability of interpretation and comparison protocols for review. Both Standard 020 gestures to "documented conformance" being made "readily available for review" by "stakeholders who use reports generated by the DNA mixture test protocols and procedures" and the updated QAS requires "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 040 does not include any requirement that the laboratory's documented interpretation and comparison protocols be made readily available for review.

Standard 040 should explicitly require that the laboratory's documented interpretation and comparison protocols 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 040 fails to adequately define validation, required qualifications, its own effective date, a scientifically appropriate scope, contamination, complexity thresholds, statistical calculations, 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*
Elizabeth Daniel Vasquez
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OSAC Biology Scientific Area Committee Intent/Clarification Update
September 2, 2020

Intent of ANSI/ASB Standard 040 *Standard for Forensic DNA Interpretation and Comparison Protocols* Requirement 4.3

Requirement 4.3 from ANSI/ASB Standard 040 as proposed by the Organization of Scientific Area Committees (OSAC) for Forensic Science's Biology Scientific Area Committee is intended to ensure that evidentiary data are interpreted prior to performing comparisons. The standard defines interpretation as *the process of evaluating DNA data for purposes including, but not limited to, defining assumptions related to mixtures and single source profiles, distinguishing between alleles and artifacts, assessing the possibility of degradation, inhibition, and stochastic effects, and determining whether the data are suitable for comparison* (Definition 3.4). See below for clarification.

Alleles versus artifacts in any samples are to be determined prior to comparison. Reference profiles will not be used during interpretation of evidence sample data to determine if a peak in the evidence sample is, or is not, an artifact.

For evidence samples with a reasonably expected contributor (assumed donor), the reference profile of the assumed contributor may be used as part of the evidentiary profile deconvolution process as long as the assumption (and assumed contributor profile) are documented in the case record (See Requirement 4.3.3). If changes are needed to the interpretation based on comparisons of reference profile(s) to the evidence sample, Requirement 4.4.2 may be consulted.

Samples that qualify per laboratory protocol for the use of an assumed contributor, in general, require the following steps to be performed and documented prior to comparison to assumed contributor reference profiles:

1. Data interpretation (as defined above) completed
2. Determination of whether data are suitable for interpretation and comparison
3. Determination of assumptions that MAY be used per laboratory protocol (such as number of contributors, presence of an assumed contributor, etc.)

For samples where no contributors may be reasonably assumed, a reference profile will not be used to determine if low-level data (i.e., in the stochastic range) is suitable for comparison. Additionally, if using binary methods, acceptable contributor genotypes must be resolved prior to comparison to reference profiles. If changes are needed to the interpretation based on comparisons of reference profile(s), Requirement 4.4.2 may be consulted.

The use of one fraction of a differential extraction to assist in the interpretation of the data from the other fraction of the same sample is appropriate and does not involve the use of a reference profile.

Note: This standard does not conflict with the 2017 SWGDAM Interpretation Guidelines for Autosomal STR Typing by Forensic DNA Laboratories.

OSAC Registry Request Comment Adjudication Template

Document Title	ANSI/ASB Standard 40 Edition 1 - Standard for Forensic DNA Interpretation and Comparison Protocols, 2019
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	Assigned To	Person Email
	Elizabeth Daniel Vasquez		evasquez@bds.org
	Elizabeth Daniel Vasquez - continuation from #2 above		
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(718) 254-0700 x 413

Comment/Proposals	Response	Status	Resolution
Because Standard 040 fails to adequately define validation, required qualifications, its own effective date, a scientifically appropriate scope, contamination, complexity thresholds, statistical calculations, 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.	The comments provided are beyond the scope of this document. Many are already addressed by other standards required for DNA laboratory accreditation. Responses to specific comments detailed in the accompanying letter from this commenter are provided below individually.	resolved	Not persuasive
Topic #1 - Defining Validation (see letter dated December 13, 2019)	Requirement 4.1 states that the protocol shall be based on internal validation studies. However the note to 4.1 indicates that published literature and other appropriate resources may provide supplemental support for the protocol; this could include relevant developmental validation studies. It is the intent that internal validation studies provide the primary support for a laboratory's interpretation and comparison protocol. The FBI Quality Assurance Standards and other documents address developmental validation studies.	See #2 above	
Topic #2 - Defining Qualifications (see letter dated December 13, 2019)	Qualifications for Technical Leaders and other relevant personnal are addressed by other existing standards (e.g., FBI Quality Assurance Standards, ISO 17025).	See #2 above	
Topic #3 - Defining the Effective Date (see letter dated December 13, 2019)	This standard was published in 2019, 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 #2 above	

Topic #4 - Defining a Scientifically Appropriate Scope (see letter dated December 13, 2019)	This is a standard with requirements for laboratories doing any type of DNA interpretaton and comparison regardless of the method, instrumentation or technologies employed to develop the DNA data. It is not a postion statement regarding the use of any method, instrumentation or technology.	See #2 above
Topic #5 - Addressing Contamination (see letter dated December 13, 2019)	Current accreditation requirements for DNA testing laboratories include existing standards for monitoring for contamination during DNA testing and for the laboratory to have procedures for handling contamination and other situations that may require assessments and corrective actions. Procedures for addressing contaminaton and DNA profile interpretation and comparison should be defined in the laboratory protocol. Additional documents regarding contamination in the laboratory and the interpretation of data are currently under development by OSAC and ASB.	See #2 above
Topic #6 - Addressing Non-confomity Events (see letter dated December 13, 2019)	If a properly constructed laboratory interpretation and comparison protocol based on sound validation studies is used by both the analyst and technical reviewer, it is unlikely that there would be significant non-conformity events. Other existing standards require laboratories to have protocols for addressing non-conformities.	See #2 above
Topic #7 - Defining "data that cannot be interpreted" and "data that are unsuitable for comparison" (see letter dated December 13, 2019)	It is incumbent upon the laboratory to define the specific conditions under which it is permitted and not permitted to interpret a DNA profile based on the laboratory methodology and technical procedures, the validation studies performed and the limitations observed. Since those conditions may vary from laboratory to laboratory depending on the methods employed, the definition is simply any situation that precludes the data from being interpreted.	See #2 above

Topic #8 - Addressing Statistical Calculations (see letter dated December 13, 2019)	This document only includes protocols for interpretation and comparison. Additional existing standards and standards under development by OSAC and ASB further address statistical calculations. Several are listed in the Bibliography and mentioned in the Foreword and Annex.	See #2 above
Topic #9 - Addressing the Availability of Interpretation and Comparison Protocols for Review (see letter dated December 13, 2019)	A laboratory's protocols are already required to be available for review for DNA laboratory accreditation, and thus it was not repeated in this document. Production of the protocols for discovery is a legal matter and beyond the scientific parameters outlined in this document.	See #2 above

No response needed

Disposition	esolution Date and Vote Outcom	Company Name	Interest Category
resolved	2/4/2020; 20 out of 20		

Submission Date	Group Name	Document Name

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