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,

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