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,

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