Scientific & Technical Review Panel Final Report for 2021-S-0003 Standards for Determining Analytical and Stochastic Thresholds for Application to Forensic DNA Casework Using Electrophoresis Platforms

Organization of Scientific Area Committees (OSAC) for Forensic Science

STRP Final Report
2021-S-0003
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Scientific & Technical Review Panel Members

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- Dan Krane, Wright State University
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Report Summary:

The Scientific and Technical Review Panel (STRP) for "Standards for Determining Analytical and Stochastic Thresholds for Application to Forensic DNA Casework Using Electrophoresis Platforms" is an independent panel appointed by the National Institute of Standards and Technology (NIST). A STRP is established with a range of experts to consider how well a standard meets the needs of the forensic science, law enforcement, and legal communities, and to recommend improvements to the standards under review. The STRP appreciates the efforts of Christian Westring, Human Forensic Biology Subcommittee member, while serving as the subcommittee liaison to this STRP during the review process.

The STRP began its review process with a kickoff meeting on December 15, 2020 and concluded with this STRP final report. The panel reviewed the draft standard and prepared comments for the OSAC Human Forensic Biology Subcommittee.

Report Components:

The STRP reviewed this draft standard against OSAC's *STRP Instructions for Review* which include the following content areas: scientific and technical merit, human factors, quality assurance, scope and purpose, terminology, method description and reporting results. The details below contain a brief description of each reviewed content area and the STRP's assessment of how that content was addressed in the draft OSAC Proposed Standard.

1. **Scientific and Technical Merit:** OSAC-approved standards must have strong scientific foundations so that the methods practitioners employ are scientifically valid, and the resulting claims are trustworthy. In addition, standards for methods or interpretation of

results must include the expression and communication of the uncertainties in measurements or other results.

1.1. Consensus View – The STRP believes that this standard is sufficient, well grounded in theory, complete, and capable of producing accurate, repeatable and reproducible results.

It was the consensus view of the STRP that the Human Forensic Biology Subcommittee sufficiently addressed their comments, so the standard is not overly prescriptive or overly generalized.

With the addition of suggested statistical parameters such as probability, standard deviation, and one-way analysis of variance (ANOVA) included in the notes of 4.1.1 and 4.1.6, the standard is not only strengthened, but provides more substantive guidance to the laboratory.

1.2. Minority View – None

2. **Human Factors:** All forensic science methods rely on human performance in acquiring, examining, reporting, and testifying to the results. In the examination phase, some standards rely heavily on human judgment, whereas others rely more on properly maintained and calibrated instruments and statistical analysis of data.

2.1. Consensus View – The STRP believes this standard sufficiently articulates the basis for determining analytical and stochastic thresholds. By standardizing the nature and extent of the data that labs should collect to provide a foundation for their thresholds, and the way in which labs should use the empirical data to determine and the nature of the statistical analyses required to assess the appropriateness of the lab's thresholds, the standard mitigates contextual bias and improves human objectivity. Furthermore, by prescribing predetermined specifications and quality attributes in a validation summary, a reviewer can independently conclude whether the validation met its predetermined specification.

2.2. Minority View – None

3. **Quality Assurance:** Quality assurance covers a broad range of topics. For example, a method must include quality assurance procedures to ensure that sufficiently similar results will be obtained when the methodology is properly followed by different users in different facilities.

3.1. Consensus View – There was a split view that method modification should require re-evaluation of both analytical and stochastic thresholds, and that the parenthetical language from the respective sections (4.1.4-analytical, 4.2.4-stochastic) may be combined for both thresholds. While the STRP appreciates

the distinction for assessment of expected baseline noise from an instrument independently of the method applied to a sample prior to electrophoresis, the panel also recognizes enhanced sensitivity methods may reduce the ability to distinguish resulting allelic data from baseline noise, thus potentially impacting the analytical threshold.

3.2. Minority View – The minority view of the STRP was that 4.1.4 states specifically that the analytical threshold shall be reevaluated when modifications to the methods are made and including the language from 4.2.4 would only serve in making the standard more prescriptive.

A second suggestion was to change the word "when" to "whenever".

4. **Scope and Purpose:** Standards should have a short statement of their scope and purpose. They should list the topics that they address and the related topics that they do not address. Requirements, recommendations, or statements of what is permitted or prohibited do not belong in this section.

4.1. Consensus View – The STRP finds the standard contains an appropriate scope and purpose. Additionally, the forward sufficiently introduces the reader to the subject of the standard and the questions it is intended to address.

4.2. Minority View – None

5. **Terminology:** Standards should define terms that have specialized meanings. Only rarely should they give a highly restricted or specialized meaning to a term in common use among the general public.

5.1. Consensus View – The STRP believes most definitions and terms used throughout this standard are well defined, and use common language and ordinary meaning. Upon final review, a few exceptions were noted.

There is no formal definition for the use of the statistical term K or a contextual reference.

Definition 3.8 Locus (loci) should state "Unique physical location(s)..." for consistency.

The STRP recommends including a statement in the terminology report section to detail that variations from the FBI Quality Assurance Standards (QAS) definitions are to ensure consistency of the OSAC Lexicon across OSAC disciplines, but do not contradict or otherwise negate the QAS definitions. Furthermore, the STRP recommends including references to QAS and

SWGDAM to not only underscore the aforementioned point, but also emphasize that labs are accountable for compliance of their validations to those standards.

5.2. Minority View – None

6. **Method Description:** There is no rule as to the necessary level of detail in the description of the method. Some parts of the method may be performed in alternative ways without affecting the quality and consistency of the results. Standards should focus on standardizing steps that must be performed consistently across organizations to ensure equivalent results. Alternatively, standards can define specific performance criteria that are required to be demonstrated and met rather than specifying the exact way a task must be done. For example, it may be enough to specify the lower limit for detecting a substance without specifying the equipment or method for achieving this limit of detection.

6.1. Consensus View – The STRP believes this document standardizes a portion of a method, but more specifically is demonstrative of how to more appropriately conduct method validation. It sufficiently standardizes how validations must be performed consistently across laboratories such that results are repeatable and reproduceable.

6.2. Minority View – None

7. **Reporting Results:** Methods must not only be well described, scientifically sound, and comprehensive but also lead to reported results that are within the scope of the standard, appropriately caveated, and not overreaching.

7.1. Consensus View – The STRP believes this standard makes clear what should be included in a validation summary report, that the results must be approved by the appropriate official, and that the results shall be trained and available for review.

7.2. Minority View – The minority view of the STRP was that validation reports and data be made readily available to the public (e.g., accessible through a website and not overtly subject to Sunshine or Freedom of Information Act requests). STRP members from public laboratories understand and tacitly support the spirit of this minority view; however, data practice decisions fall outside the scope of this standard. Moreover, proprietary information and intellectual property may be a barrier to commercial entities making documents public, and if legislated to do so, such documents may require significant redaction.