Priority Action Report

Biology Data Interpretation and Reporting Subcommittee

Biology/DNA

Robyn Ragsdale, Ph.D.

February 13, 2017

NIST
National Institute of Standards and Technology
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Subcommittee Leadership

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Executive Secretary	Catherine Grgicak, Ph.D.	Boston University School of Medicine	3	cgrgicak@bu.edu

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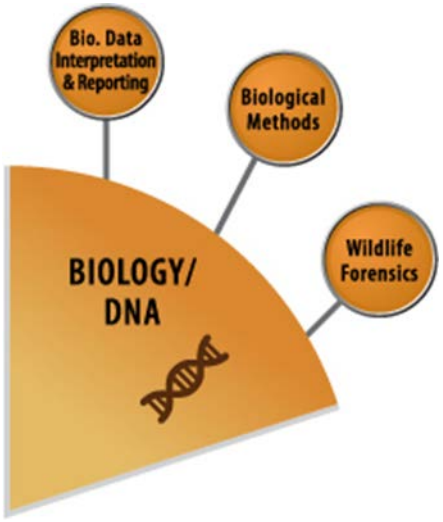
Biological Data Interpretation and Reporting Subcommittee



This Subcommittee (formerly called DNA Analysis 2) focuses on standards and guidelines related to forensic DNA laboratory interpretation.

The Biological Data Interpretation and Reporting Subcommittee focuses on establishing best practices, guidelines, and standards for inclusion in the OSAC Registry. The goal is to foster quality and consistency within the forensic community through the standardization of scientifically valid methods of interpretation, statistical analysis and reporting of biological results.

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Additional Items of Interest

The following documents have been submitted to the Academy Standards Board:

- **Standards for Validation Studies of DNA Mixtures and Development and Verification of a Laboratory Mixture Interpretation Protocol**
- **Validation Standards for Probabilistic Genotyping Systems**

The following document has been submitted to the Biology/DNA SAC for final review:

- **Best Practice Recommendations for Validation of Forensic DNA Software**

Summary of Priority Projects

Priority	OSAC Process	Working Title of Document
1	SDO	Standards for Forensic DNA Interpretation and Comparison Protocols
2	SDO	Interpretation Protocol Self-Evaluation
3	SDO	Formulating Propositions for Likelihood Ratios
4	SDO	Standards for Reporting DNA Conclusions

Summary of Priority Projects

Priority	OSAC Process	Working Title of Document
5	SDO100	Standards for Reporting DNA Results Containing a Contaminant or Associated with a Failed Control
6	SDO100	Training Standards for DNA Data Interpretation (autosomal and Y; includes testimony and CODIS training)
7	SDO100	Statistical Interpretation
8	SDO100	Standards for Determining Analytical and Stochastic Thresholds

Standards/Guidelines Development Priority 1 Document

Document Title: Standards for Forensic DNA Interpretation and Comparison Protocols

Scope: This document describes requirements for a laboratory's DNA interpretation protocol. These standards were designed to provide direction to laboratories for the development of DNA mixture interpretation protocols. The goal is for the laboratory to consistently produce reliable and reproducible interpretations and conclusions that are supported by internal validation data.

Objective/rationale: Detailed and comprehensive DNA interpretation protocols are needed to ensure reliable and consistent interpretation and comparison of DNA profiles from single source and mixed DNA samples regardless of the possible variables affecting the profile.

Issues/Concerns: Additional standards are needed for the development and use of laboratory protocols specifically for the interpretation and the comparison of DNA data for all areas of forensic DNA testing.

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Task Group Name: Mixture Interpretation
Task Group Chair Name: Rebekah Kay
Task Group Chair Contact Information:
cjword@comcast.net **or rkay@utah.gov**
Date of Last Task Group Meeting: December 2016

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Standards/Guidelines Development Priority 1 Document

Key Components of Standard:

Specific requirements for a laboratory's protocol for the interpretation and comparison of DNA profiles are provided. These requirements include defining assumptions that may be used, limitations of the interpretation methods and when profiles are unsuitable for interpretation based on the laboratory's validation studies. Requirements for establishing a workflow to ensure data from evidence samples are interpreted prior to comparison to known reference data along with relevant documentation are also provided.

Task Group/Subcommittee Action Plan

Planned Actions	OSAC Process Stage (e.g., SDO 100)	Assignee	Estimated Completion Date
Complete adjudication of comments received	SDO 200	Task Group	February 15, 2017
Provide final document in ABS format and Technical Merit Worksheet to SAC for final vote	SDO 300	Rebekah Kay	March 15, 2017
Forward final document to ABS SDO	SDO 300	Robyn Ragsdale	April 15, 2017

Standards/Guidelines Development Priority 2 Document

Document Title: Interpretation Protocol Self-Evaluation

Scope: These guidelines will focus on the requirement to periodically (annually or after a significant change in the protocols) evaluate the effectiveness of interpretation protocols. This includes monitoring of proper utilization of the lab's DNA interpretation protocol as well as consistency in data interpretation between analysts and/or between laboratories (multi-system labs).

Objective/rationale: This will allow a laboratory to identify the effectiveness of its SOP, assess analyst drift as well as fill the gap in what the current proficiency tests do not provide relative to data interpretation.

Issues/Concerns: Current assessment processes such as proficiency tests do not address the effectiveness of an lab's interpretation SOP and may not detect issues with inconsistent application or analyst drift.

Task Group Name: Interpretation Protocol Self-Evaluation
Task Group Chair Name: Carl Sobieralski
Task Group Chair Contact Information:
csobieralski@isp.in.gov
Date of Last Task Group Meeting: January 13,2017

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Standards/Guidelines Development Priority 2 Document

Key Components of Standard:

- Monitoring lab for consistency with lab protocols and between analysts
- - To fill the gap for what the proficiency tests doesn't cover
- - Identifies effectiveness of procedures
- - Detects protocol drift
- - Monitor consistency between analysts
- - Would be from a data set (not from a sample starting from extraction)

Priority 2: Interpretation Protocol Self-Evaluation

Task Group/Subcommittee Action Plan

Planned Actions	OSAC Process Stage (e.g., SDO 100)	Assignee	Estimated Completion Date
Finalize draft document	SDO 200	Task Group	June 2017
Provide draft document to all relevant parties	SDO 200	Carl Sobieralski	July 2017
Adjudicate comments received from all relevant parties	SDO 200	Task Group	September 2017
Provide final document in ABS format to SAC for final vote	SDO 300	Carl Sobieralski	November 2017
Forward final document to ABS SDO	SDO 300	Robyn Ragsdale	December 2017

Standards/Guidelines Development Priority 3 Document

Document Title: Formulating Propositions for Likelihood Ratios

Scope: This standard will focus on establishing techniques for formulating the competing propositions required for the assignment of likelihood ratios for the evaluation of DNA typing results. It will include requirements and considerations that need to be addressed as part of the proposition selection process as well as address possible pitfalls for contextual bias.

Objective/rationale: This standard will give guidance to laboratories on the proper formulation of likelihood propositions

Issues/Concerns: With the current trend to probabilistic genotyping, laboratories are switching to utilizing LRs and there is a need for guidance/education

Task Group Name: Formulating Propositions for Likelihood Ratios

Task Group Chair Name: Steven Myers

Task Group Chair Contact Information:

steven.myers@doj.ca.gov

Date of Last Task Group Meeting: January 13,2017

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Standards/Guidelines Development Priority 3 Document

Key Components of Standard:

- The assumption of contributors (use of knowns)
- Protocol for running more than one hypothesis
- Establish criteria for when to reassess data
- Policy for additional calculations requests
- Policy on which calculations to report
- Hypothesis for multiple defendants
- Safeguard against bias
- Hypothesis needs to be based on the data

Currently the TG is comparing work practices and the theoretical basis for those approaches, and identifying possible standards including those in the literature as well as *de novo* suggestions.

Task Group/Subcommittee Action Plan

Planned Actions	OSAC Process Stage (e.g., SDO 100)	Assignee	Estimated Completion Date
Finalize draft document	SDO 200	Task Group	April 2017
Provide draft document to all relevant parties	SDO 200	Steven Myers	June 2017
Adjudicate comments received from all relevant parties	SDO 200	Task Group	August 2017
Provide final document in ABS format to SAC for final vote	SDO 300	Steven Myers	October 2017
Forward final document to ABS SDO	SDO 300	Robyn Ragsdale	November 2017

Standards/Guidelines Development Priority 4 Document

Document Title: Standards for Reporting DNA Conclusions

Scope: This standard or guidance document will focus on the proper terminology to be utilized in the report when addressing single source and mixture samples. The document will also address the need to report assumptions as well as the methods and detail required when reporting these assumptions. Commentary will also include the proper reporting of samples evaluated utilizing probabilistic genotyping.

Objective/rationale: To provide standards for reporting DNA conclusions in an attempt to unify the information provided by laboratories reporting DNA conclusions

Issues/Concerns: There exists a wide variety in terminology and content for how laboratories report DNA conclusions. This document seeks to provide a common framework for laboratories to report DNA conclusions.

Task Group Name: Reporting DNA Conclusions
Task Group Chair Name: Shawn Monpetit
Task Group Chair Contact Information:
smontpetit@pd.sandiego.gov
Date of Last Task Group Meeting: January 27, 2017

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Standards/Guidelines Development Priority 4 Document

Key Components of Standard:

Utilizing the foundation documents listed below, this standard or guidance document should help in standardizing reporting formats.

FBI Director's *Quality Assurance Standards for DNA Testing Laboratories*, ENSFI Reporting Guidelines, SWGDAM Interpretation Guidelines 2011/2017, and the Report Wording Suggestions document (available on STRBase) created by members of SWGDAM's autosomal interpretations guidelines subcommittee.

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Task Group/Subcommittee Action Plan

Planned Actions	OSAC Process Stage (e.g., SDO 100)	Assignee	Estimated Completion Date
Review foundation documents	SDO 100	Task Group	January 27, 2017
Complete draft document	SDO 100	Task Group	June 2017
Provide draft document to all relevant parties	SDO 200	Shawn Monpetit	July 2017
Adjudicate comments received from all relevant parties	SDO 200	Task Group	September 2017
Provide final document in ABS format to SAC for final vote	SDO 300	Shawn Monpetit	November 2017
Forward final document to ABS SDO	SDO 300	Robyn Ragsdale	December 2017

Standards/Guidelines Development Priority 5 Document

Document Title: Standards for Reporting DNA Results Containing a Contaminant or Associated with a Failed Control

Scope: These standards are to be used by laboratories when the need arises to report a result from a sample that contains a contaminant or is associated with a failed control.

Objective/rationale: If a laboratory is required to report a sample with an issue, there needs to be a consistent way to address such samples. Currently there is no guidance on how to report samples if an issue of contamination or failed controls arises.

Issues/Concerns:. A DNA profile associated with a contaminant or a failed control may be reliable and exclude an individual, but this information is not being conveyed to the investigator or court. This raises concerns about proper Brady disclosure.

Task Group Name: Reporting DNA Results with Issues
Task Group Chair Name: Todd Bille
Task Group Chair Contact Information: todd.bille@atf.gov
Date of Last Task Group Meeting: January 2017

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Standards/Guidelines Development Priority 5 Document

Key Components of Standard:

In many laboratories, if an evidence sample is associated with a failed control, the DNA profile and any comparisons to the profile are not made/reported. In addition, if the evidence profile is associated with contamination, the profile and any comparison to the profile may not be made/reported. For example, an analyst has obtained a two person mixture from a swab of a knife handle. After a search of the staff elimination database, the evidence technician that collected the knife cannot be eliminated as the minor contributor to the mixture. Based on laboratory policy, the analyst then reports that the staff hit and no further comparisons can be conducted. However, a reliable profile may have been developed from the evidence, but was not used for comparison purposes or reported. This standard will give guidance so that the unknown profile may be reported and comparisons made following the laboratory's normal procedure, but with a caveat explaining the issue and that the evidence should be interpreted with caution.

Task Group/Subcommittee Action Plan

Planned Actions	OSAC Process Stage (e.g., SDO 100)	Assignee	Estimated Completion Date
Work on draft document	SDO 100	Task Group	March 2017
Provide draft document to all relevant parties	SDO 200	Todd Bille	April 2017
Adjudicate comments received from all relevant parties	SDO 200	Task Group	June 2017
Provide final document in ABS format to SAC for final vote	SDO 300	Todd Bille	August 2017
Forward final document to ABS SDO	SDO 300	Robyn Ragsdale	September 2017

Standards/Guidelines Development Priority 6 Document

Document Title: Training Standards for DNA Data Interpretation (Autosomal and Y)

Scope: To provide requirements in the form of several documents that ensure proper and consistent training in DNA Interpretation used within the forensic DNA community.

Objective/rationale: The purpose of these documents is to provide consistent training guidelines within the forensic DNA community

Task Group Name: STR Interpretation Training
Task Group Chair Name: Beth Ordeman
Task Group Chair Contact Information:
bordeman@co.pinellas.fl.us
Date of Last Task Group Meeting: December 16, 2016

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Standards/Guidelines Development Priority 6 Document

Key Components of Standard:

This standard will consist of individual documents covering training in the following areas –

- Autosomal STR Interpretation
- Autosomal Statistics
- Y-STR Interpretation and Statistics
- Report Writing
- Courtroom testimony
- CODIS

The documents will not address how to specifically perform the training but rather the minimal topics that need to be addressed within each of the above areas as well as provide a comprehensive list of resources to utilize in the training process.

Task Group/Subcommittee Action Plan

Planned Actions	OSAC Process Stage (e.g., SDO 100)	Assignee	Estimated Completion Date
Work on initial drafts of all documents	SDO 100	Task Group Members Individually	February 1, 2017
Evaluate all draft documents	SDO 200	Task group	March 17, 2017
Provide draft documents to all relevant parties	SDO 200	Beth Ordeman	April 2017
Adjudicate comments received from all relevant parties	SDO 200	Task Group	June 2017
Provide final document in ABS format and Technical Merit Worksheet to SAC for final vote	SDO 300	Beth Ordeman	August-October 2017
Forward final document to ABS SDO	SDO 300	Robyn Ragsdale	September-November 2017

Standards/Guidelines Development Priority 7 Document

Document Title: Statistical Interpretation

Scope: Description of existing methods and delineating appropriate areas of application

Objective/rationale: State generally accepted methods and limitations for statistical analysis of single source and mixed DNA profiles

Issues/Concerns: Statistical calculations in the case of mixtures. Concerns have raised about the correction application of different statistical approaches for mixtures. Forensic science community is in transition regarding which approach to adopt and how to properly use it.

Task Group Name: Statistical Interpretation
Task Group Chair Name: Sandy Zabell
Task Group Chair Contact Information:
zabell@math.northwestern.edu
Date of Last Task Group Meeting: January 2016

Standards/Guidelines Development Priority 7 Document

Key Components of Standard:

Description of existing methods, and guidance on appropriate areas of application

Note: SWGDAM recently approved updated Interpretation Guidelines (January 2017). The task group has two documents in progress: Standards for Statistical Analysis and Standards for Statistical Formulae.

Task Group/Subcommittee Action Plan

Planned Actions	OSAC Process Stage (e.g., SDO 100)	Assignee	Estimated Completion Date
Work on initial drafts of all documents	SDO 100	Task Group Members	April 2017
Provide draft documents to all relevant parties	SDO 200	Sandy Zabell	May 2017
Adjudicate comments received from all relevant parties	SDO 200	Task Group Members	July 2017
Provide final document in ABS format and Technical Merit Worksheet to SAC for final vote	SDO 300	Sandy Zabell	September 2017
Forward final document to ABS SDO	SDO 300	Robyn Ragsdale	October 2017

Standards/Guidelines Development Priority 8 Document

Document Title: Standards for Determining Analytical and Stochastic Thresholds

Scope: To provide requirements for establishing appropriate methods for determining empirically derived analytical an stochastic thresholds in DNA interpretation. The standard will describe a variety of methods for determining thresholds, including guidelines for validation and performance testing threshold values.

Objective/rationale: The purpose of this document it to provide a robust foundation for DNA interpretation in the forensic DNA community.

Issues/Concerns: Currently, threshold vary greatly from one laboratory to the next for the same chemistries and instrumentation. This leads to differences in allele calling, and ultimately, in the profile detected.

Task Group Name: DNA Thresholds group
Task Group Chair Name: Christian G. Westring, Ph.D
Task Group Chair Contact Information:
christian.westring@NMSlabs.com
Date of Last Task Group Meeting: January, 2017

Standards/Guidelines Development Priority 8 Document

Key Components of Standard:

This standard will cover a number of analytical methods by which laboratories can evaluate thresholds. These methods will consider the following aspects of determining thresholds:

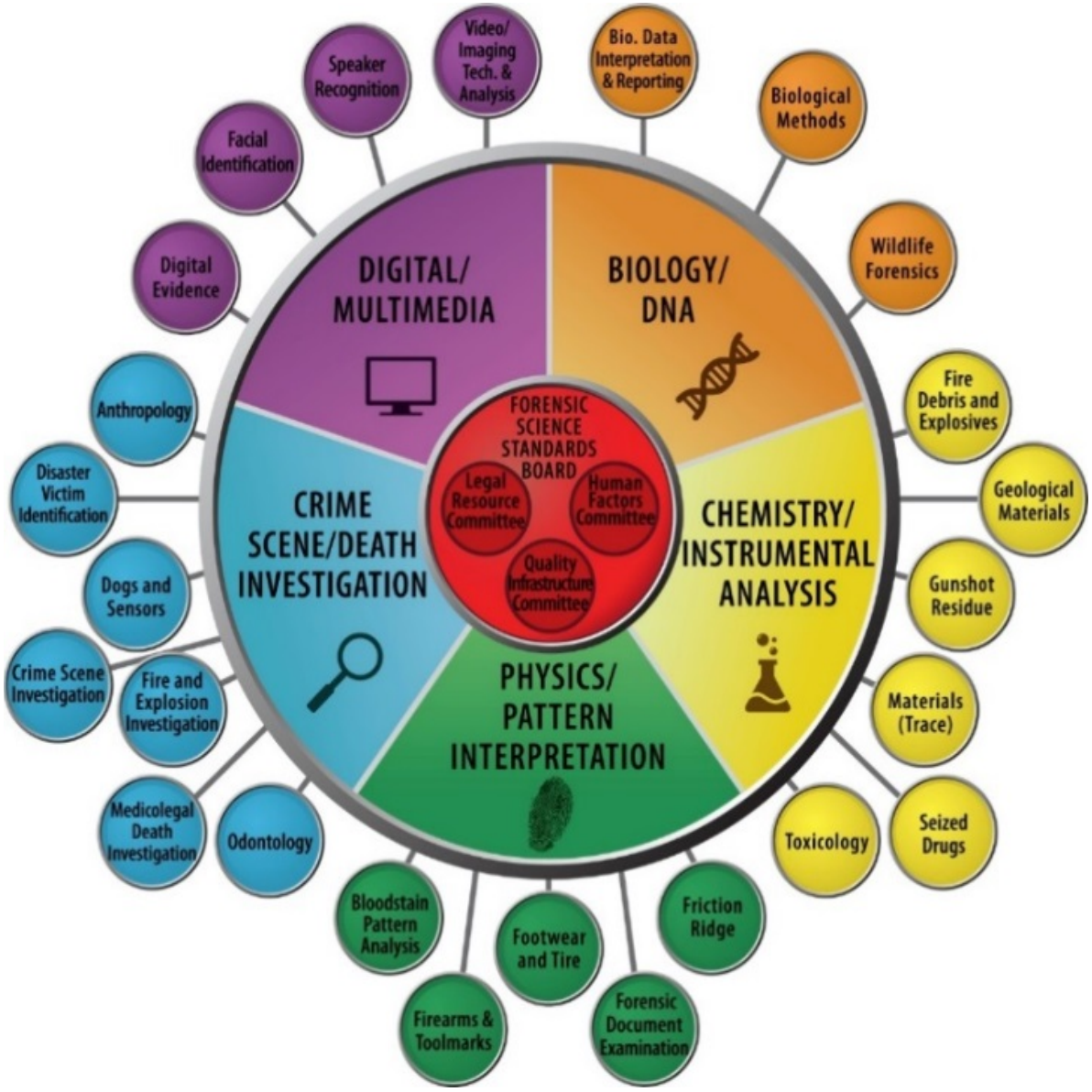
- Definition of instrument noise (industry standard)
- Definition of artifact and classes of artifacts
- Approaches to validation (sample types, reagents, etc.)
- Statistical approaches to determining thresholds
- Thresholds as binaries vs continuums
- How to handle signal below threshold
- How to isolate the variable of interest (e.g. stochastic variability in PCR)
- Statistical tools for evaluating data distribution patterns and empirical data sets
- Range of applicability (number of contributors, allele stacking, etc.)

Task Group/Subcommittee Action Plan

Planned Actions	OSAC Process Stage (e.g., SDO 100)	Assignee	Estimated Completion Date
Develop initial draft(s) of standard document	SDO 100	Task Group Members Individually	March 1st, 2017
Evaluate all draft document(s)	SDO 100	Task group	April 1st, 2017
Provide draft document(s) to all relevant parties	SDO 200	Christian G. Westring	April 15th, 2017
Adjudicate comments received from all relevant parties	SDO 200	Task Group	June 15th, 2017
Provide final document in ABS format and Technical Merit Worksheet to SAC for final vote	SDO 300	Christian G. Westring	August 1st, 2017
Forward final document to ABS SDO	SDO 300	Robyn Ragsdale	September 1st, 2017

Research & Development Needs Identified

- Assessment of Specific Classes of Evidence Types to Determine the Necessity to Quantify DNA Before Amplification of Human Autosomal STR Loci
- Characterizing, Designing and Constructing Integrated DNA Mixture Interpretation Solutions
- Proficiency Testing for Complex Data Interpretation and Biostatistical Evaluations
- Software Solutions for Y-STR Mixture Deconvolution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