Green Mountain DNA Conference

THE EXPANDING SCOPE OF STANDARDS & BEST PRACTICE RECOMMENDATIONS FOR FORENSIC TESTING LABORATORIES USING HUMAN SEROLOGICAL AND DNA TESTING METHODS

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Burlington, VT

July 25, 2023

AAFS AMERICAN ACADEMY OF FORENSIC SCIENCES EST. 1948

OSAC Organization of Scientific Area Committees for Forensic Science

ASB ACADEMY STANDARDS BOARD

STANDARD DEVELOPMENT PROCESS

Draft Documents

Standard Development

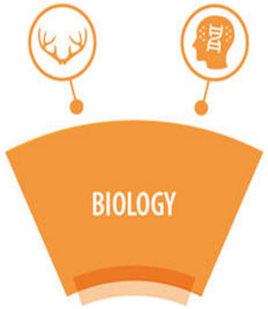
OSAC
Organization of Scientific Area Committees for Forensic Science

ASB
ACADEMY
STANDARDS BOARD

OSAC
REGISTRY

Biology/DNA SAC
- Methodology
- Biology Data Interpretation and Reporting

Human Forensic Biology (now combined)
- Wildlife (sequencing)



AAFS ASB DNA Consensus Body for Standard Development as American National Standards

OSAC Proposed Standards

STANDARDS AND BEST PRACTICE RECOMMENDATIONS

Standard = Lists *Requirements* with "shall"
Best Practice Recommendations (BPR) = Lists *Recommendations* with "should"

Approved by ANSI and published by the ASB:
https://www.aafs.org/academy-standards-board

OSAC Registry https://www.nist.gov/organization-scientific-area-committees-forensic-science/osac-registry

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STANDARD DEVELOPMENT PROCESS

OSAC
Organization of Scientific Area Committees for Forensic Science

35 Drafted
9 Being Drafted

BIOLOGY

ASB
ACADEMY
STANDARDS BOARD

14 Published
3 Very Soon

OSAC
REGISTRY

5 OSAC Proposed Standards
(at ASB for development)
1 To be Published very soon

2 in OSAC Registry Process

STANDARDS AND BEST PRACTICE RECOMMENDATIONS USE IN LABORATORIES

Written to be used in conjunction with other documents

- FBI Quality Assurance Standards
- ISO 17025
- Accreditation Requirements (e.g., ANAB)
- SWGDAM Guidelines

ASB ACADEMY STANDARDS BOARD

OSAC REGISTRY

AVAILABLE FOR IMPLEMENTATION IN LABORATORIES

SEROLOGY/BIOLOGY

Validation Studies and Protocols

1) ANSI/ASB Standard 077, *Standard for the Development and Internal Validation of Forensic Serological Methods*, First Edition, 2020

2) OSAC 2021-S-0028, *Standard for Use of Serological Testing Methods Associated with Forensic Investigations* (currently under development with ASB DNA Consensus Body)

Training

1) ANSI/ASB Standard 110, *Standard for Training in Forensic Serological Methods*, First Edition, 2020

AVAILABLE FOR IMPLEMENTATION IN LABORATORIES

DNA

Validation Studies and Protocols

1) ANSI/ASB Standard 018, *Standard for Validation of Probabilistic Genotyping Systems,* First Edition, 2020*
2) ANSI/ASB Standard 020, *Standard for Validation Studies of DNA Mixtures, and Development and Verification of a Laboratory's Mixture Interpretation Protocol*, First Edition, 2018* (5 year anniversary)
3) ANSI/ASB Standard 040, *Standard for Forensic DNA Interpretation and Comparison Protocols*, First Edition, 2019*
4) ANSI/ASB Best Practice Recommendation 114, *Best Practice Recommendations for Internal Validation of Software Used in Forensic DNA Laboratories, First Edition, 2022 (in OSAC Registry approval process)*
5) ANSI/ASB Standard 038, ***Standard for Internal Validation of Forensic DNA Analysis Methods***, First Edition, 2020

AVAILABLE FOR IMPLEMENTATION IN LABORATORIES

DNA

Validation Studies and Protocols

1) OSAC 2020-N-0007, *Best Practice Recommendations for the Management and Use of Quality Assurance DNA Elimination Databases in Forensic DNA Analysis* (Best Practice Recommendation 171 with ASB) (in final stages for publication as an ANSI/ASB BPR)

2) OSAC 2020-S-0004, *Standard for Interpreting, Comparing and Reporting DNA Test Results Associated with Failed Controls and Contamination Events* (Standard 175 with ASB) (currently under development with ASB DNA Consensus Body)

3) OSAC 2021-S-0029, *Standard for Familial DNA Searching* (currently under development with ASB DNA Consensus Body)

ASB ACADEMY STANDARDS BOARD

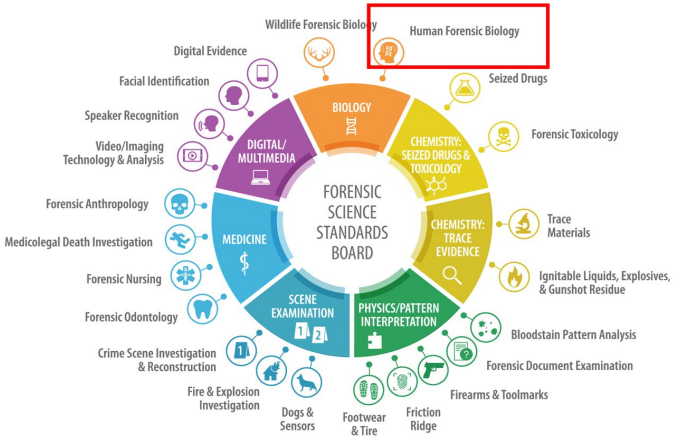
STANDARDS AND BEST PRACTICE RECOMMENDATIONS UNDER DEVELOPMENT BY ASB

DNA

Validation Studies

1) Standard 039, *Standard for Internal Validation of Human Short Tandem Repeat Profiling on Capillary Electrophoresis Platforms*

2) Best Practice Recommendation 129, *Best Practice Recommendations for Internal Validation of Human Short Tandem Repeat Profiling on Capillary Electrophoresis Platforms*



ASB ACADEMY STANDARDS BOARD

AVAILABLE FOR IMPLEMENTATION IN LABORATORIES

DNA

Training - General & STRs

1) ANSI/ASB Standard 022, ***Standard for Forensic DNA Analysis Training Programs***, First Edition, 2019
2) ANSI/ASB Standard 023, *Standard for Training in Forensic DNA Isolation and Purification Methods*, First Edition, 2020
3) ANSI/ASB Standard 116, *Standard for Training in Forensic DNA Quantification Methods*, First Edition, 2020
4) ANSI/ASB Standard 115, *Standard for Training in Forensic Short Tandem Repeat Typing Methods using Amplification, DNA Separation, and Allele Detection*, First Edition, 2020

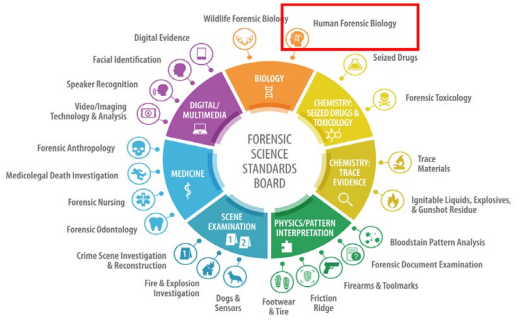
ASB ACADEMY STANDARDS BOARD

STANDARDS AND BEST PRACTICE RECOMMENDATIONS UNDER DEVELOPMENT BY ASB

DNA

Training – General and STRs

1) Standard 154, *Standard for Training on Testimony for Forensic Biology* (soon to be published, will need to be submitted to OSAC Registry)
2) Standard 091, *Standard for Training in Analysis of Forensic Short Tandem Repeat (STR) Data*
3) Standard 078, *Standard for Training in Forensic Autosomal Short Tandem Repeat (STR) and Y-STR Data Interpretation and Comparison*
4) Standard 081, *Standard for Training in the Use of Statistics in Interpretation of Forensic DNA Evidence*
5) Standard 080, *Standard for Training in Forensic DNA Reporting and Review*
6) Standard 079, *Standard for Training in the Use of Combined DNA Index System (CODIS)*



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AVAILABLE FOR IMPLEMENTATION IN LABORATORIES

DNA

Training – Sequencing Methods

1) ANSI/ASB Standard 130, *Standard for Training in Forensic Amplification Methods for Subsequent Capillary Electrophoresis Sequencing*, First Edition, 2021

2) ANSI/ASB Standard 131, *Standard for Training in Forensic DNA Sequencing Using Capillary Electrophoresis*, First Edition, 2021

3) ANSI/ASB Standard 140, *Standard for Training in Forensic Human Mitochondrial DNA Analysis, Interpretation, Comparison, Statistical Evaluation, and Reporting*, First Edition, 2021

STANDARDS AND BEST PRACTICE RECOMMENDATIONS UNDER DEVELOPMENT BY ASB

DNA

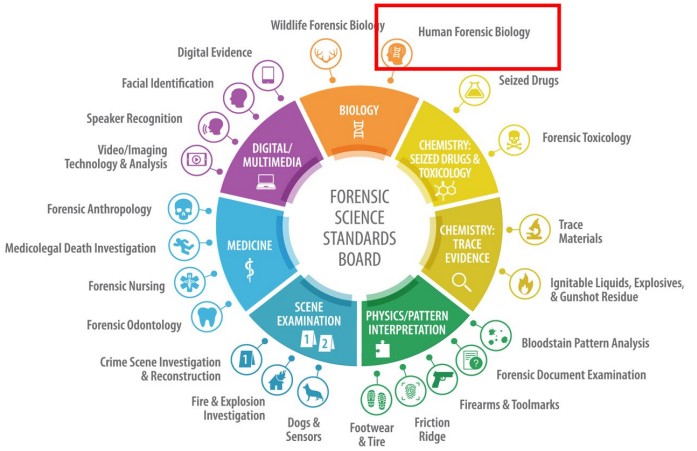
Contamination, Statistics, Quality Control

1) Standard 041, *Formulating Propositions for Likelihood Ratios in Forensic DNA Interpretations*

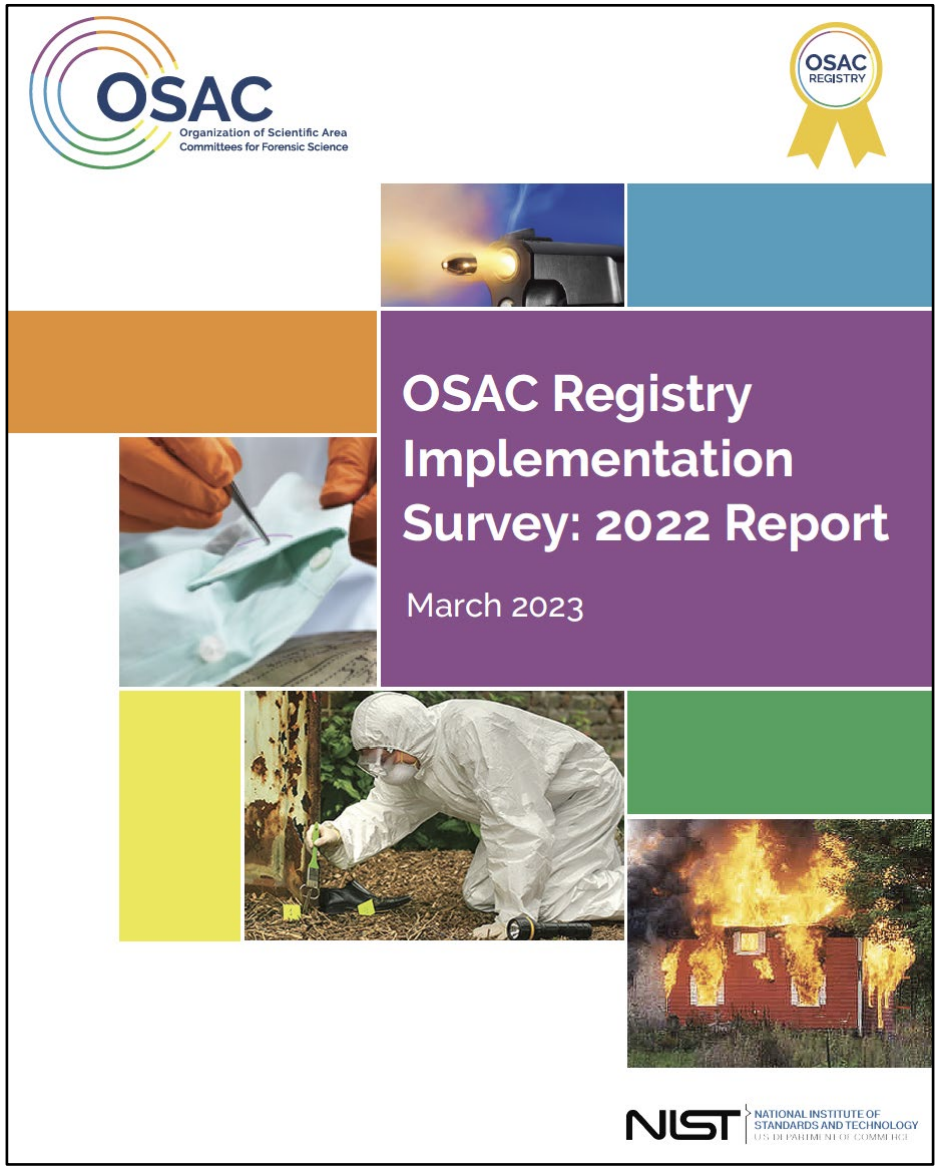
2) Standard 123, *Standard for Routine Internal Evaluation of a Laboratory's DNA Interpretation and Comparison Protocol* (soon to be published, will need to be submitted to OSAC Registry)

3) Standard 136, *Forensic Laboratory Standard for Prevention, Monitoring, and Mitigation of Human DNA Contamination*

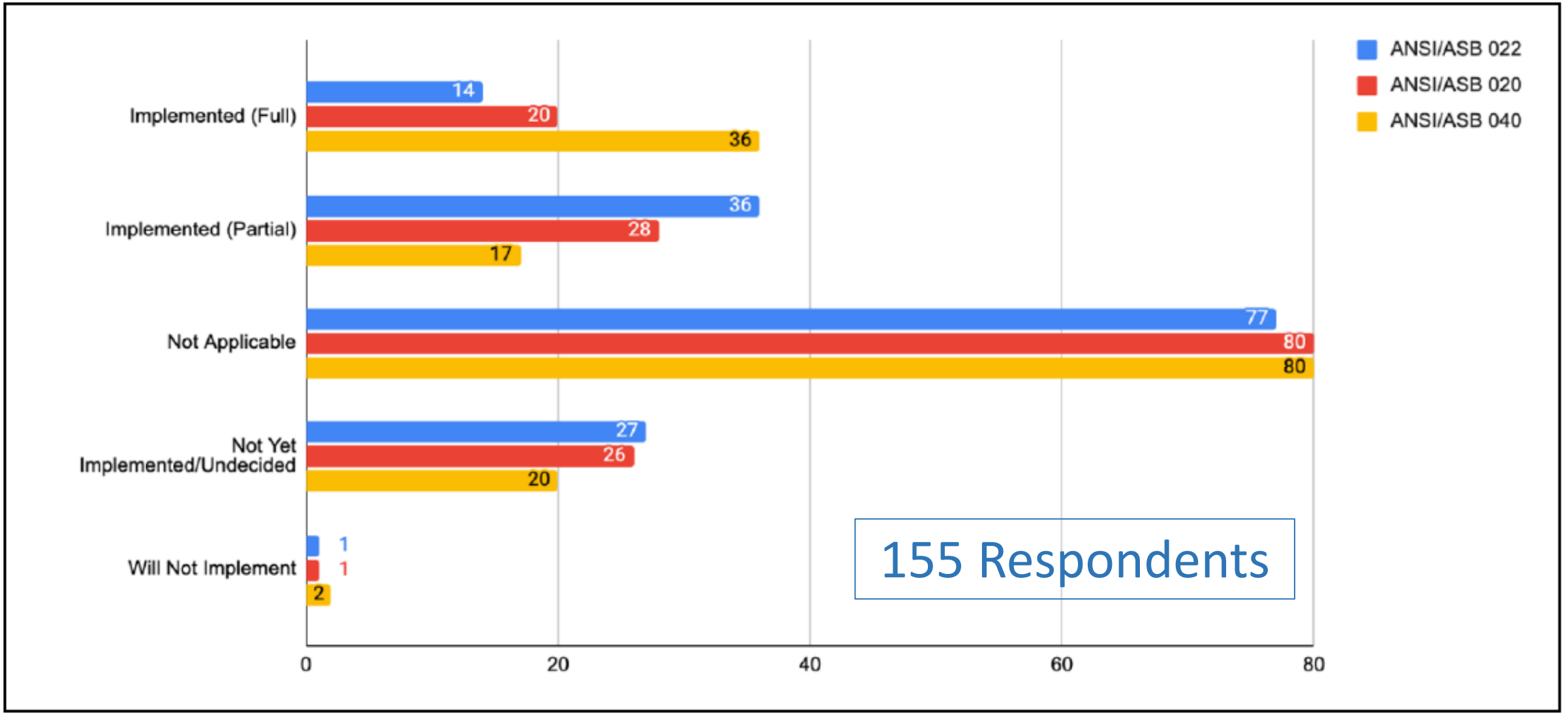
4) Standard 139, *Reporting DNA Conclusions* (very close to being published)



IMPLEMENTATION IN LABORATORIES

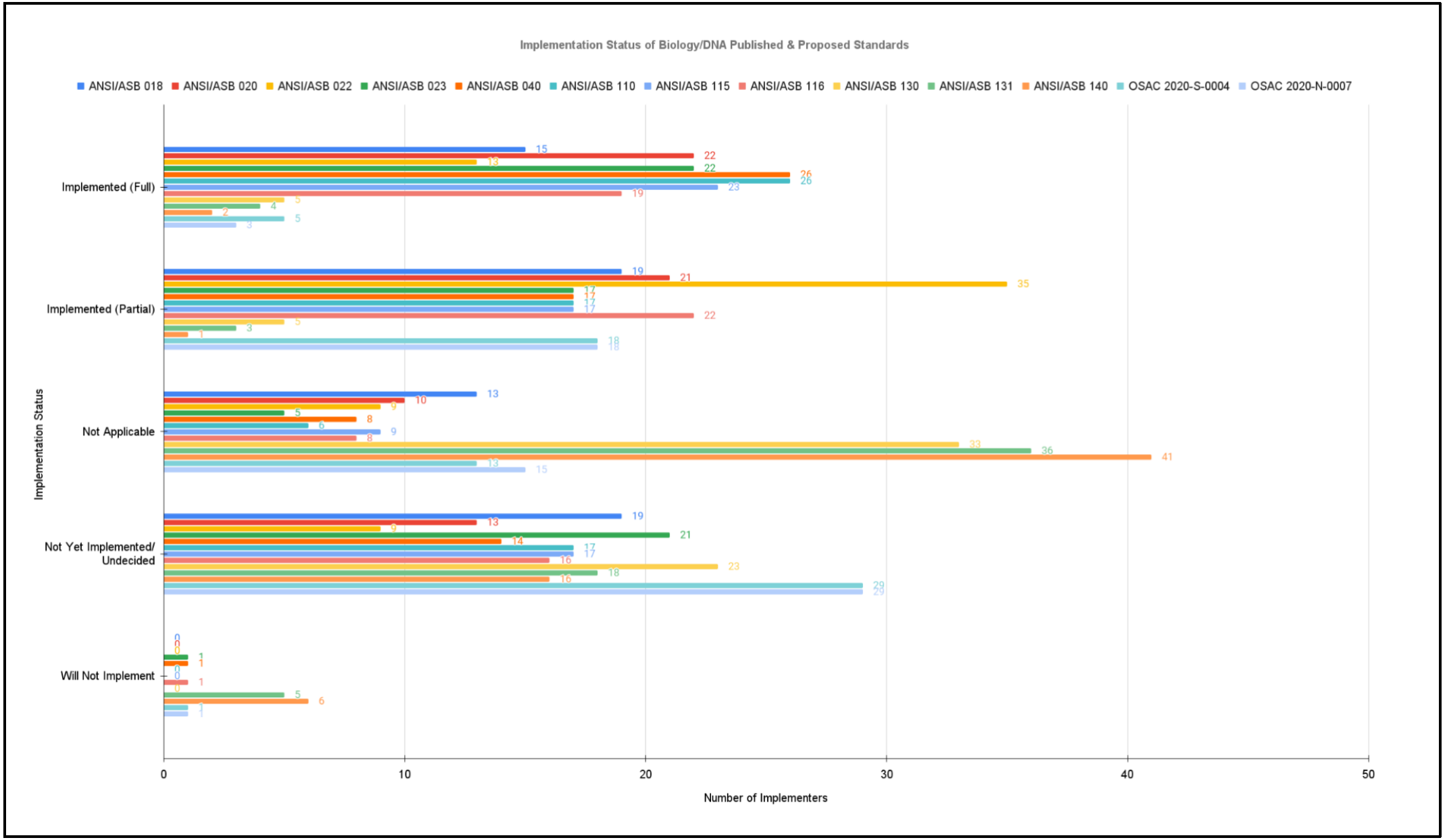


IMPLEMENTATION OF STANDARDS 22, 20 & 40
AUGUST 2021



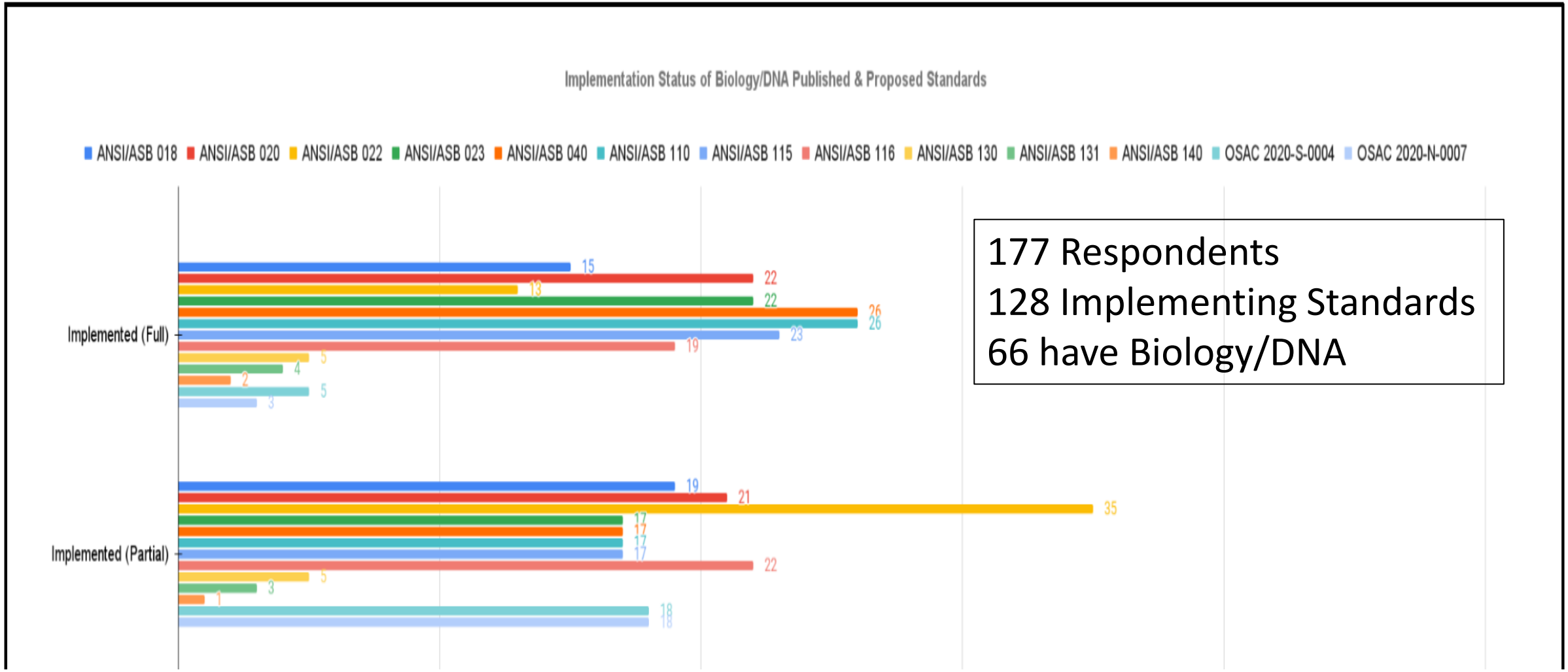
IMPLEMENTATION IN LABORATORIES 2022

Implementation Status by Standard:



IMPLEMENTATION IN LABORATORIES 2022

Implementation Status by Standard:

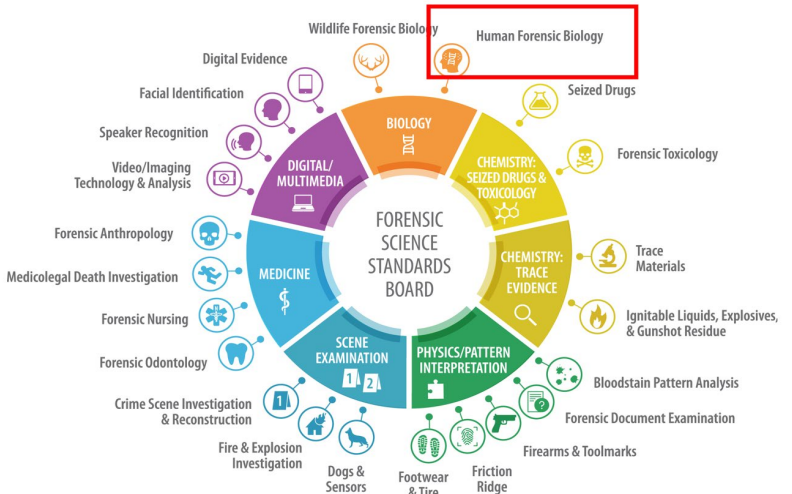


177 Respondents
128 Implementing Standards
66 have Biology/DNA

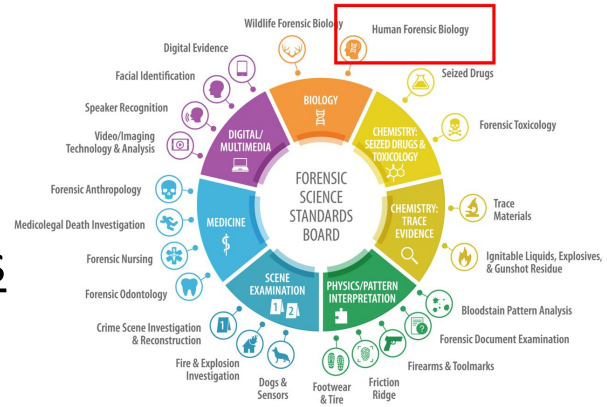
STANDARDS AND BEST PRACTICE RECOMMENDATIONS UNDER REVIEW FOR LISTING ON THE OSAC REGISTRY AS PROPOSED STANDARDS

1) OSAC 2021-S-0003, *Standards for Setting Analytical and Stochastic Thresholds for Applications to Forensic DNA Casework Using Electrophoresis Platforms*

2) OSAC 2022-S-0024, *Best Practice Recommendations for Evaluative Forensic DNA Testimony*



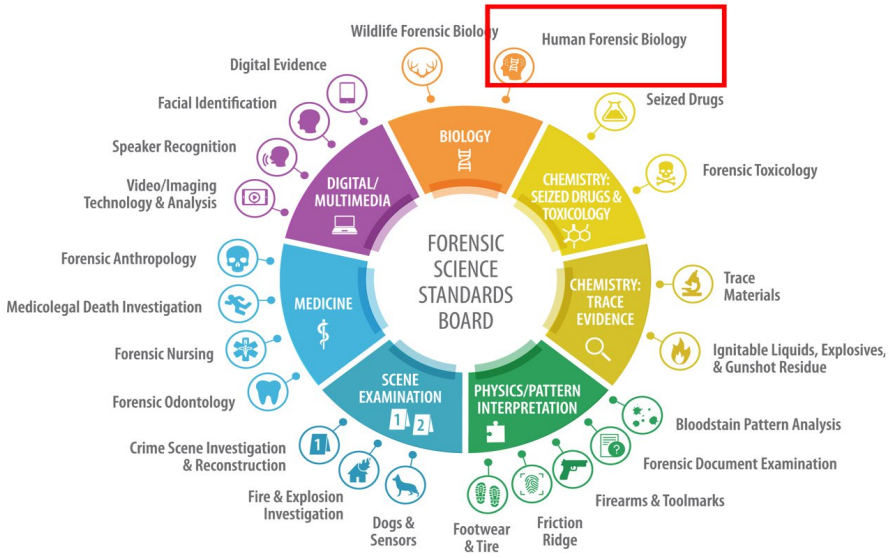
DOCUMENTS CURRENTLY BEING DRAFTED AT OSAC



Validation

- Standard for Internal Validation of Genetic Analysis on NGS/MPS Platforms
- Standard for the Internal Validation of DNA Extraction Methods
  - Best Practice Recommendations for the Internal Validation of DNA Extraction Methods
- Standard for the Internal Validation of Human DNA Quantification
  - Best Practice Recommendations for the Internal Validation of Human DNA Quantification
- Standard for the Internal Validation of Automated Platforms
  - Best Practice Recommendations for the Internal Validation of Automated Platforms
- Best Practice Workflows for Efficient Sampling and Direct to DNA of Sexual Assault Kits
- Appendix Exemplar for Reports

RESOURCES AVAILABLE



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STANDARDS CHECKLISTS

Checklists provide a tool to allow a forensic science service provider to evaluate the level of standard implementation and/or audit conformance to a standard. Each checklist, provided in Excel, uses a standardized format that also allows flexibility when used.

https://www.aafs.org/research-insights-featured-standards-resources-and-training/checklists

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STANDARDS BOARD

STANDARD 040 ASSESSMENT GUIDE

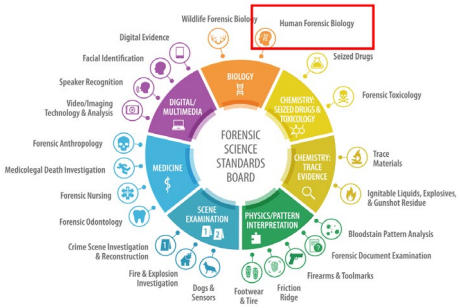
Assessment Guide for ANSI/ASB Standard 040,
Standard for Forensic DNA Interpretation and Comparison Protocols, First Edition, 2019

INTRODUCTION

This Assessment Guide is to be used by laboratory staff for self-assessment or by an assessment team for evaluating whether the laboratory has met the Requirements listed in Section 4 of the ANSB/ASB Standard 040, Standard for Forensic DNA Interpretation and Comparison Protocols, First Edition, 2019.

Provides Detailed Instructions and an Excel Worksheet for Documenting the Assessment Process

https://www.nist.gov/system/files/documents/2022/07/19/ASB%2040%20Assessment%20Guide%20032222.pdf



FACTSHEETS

The AAFS Standards Factsheets provide a concise summary of each standard and facilitate broader understanding.
They also highlight the purpose of a standard, why it is needed, and the benefits of adoption.

https://www.aafs.org/research-insights-featured/search?_page=1&keywords=factsheets&_limit=7&topic=66

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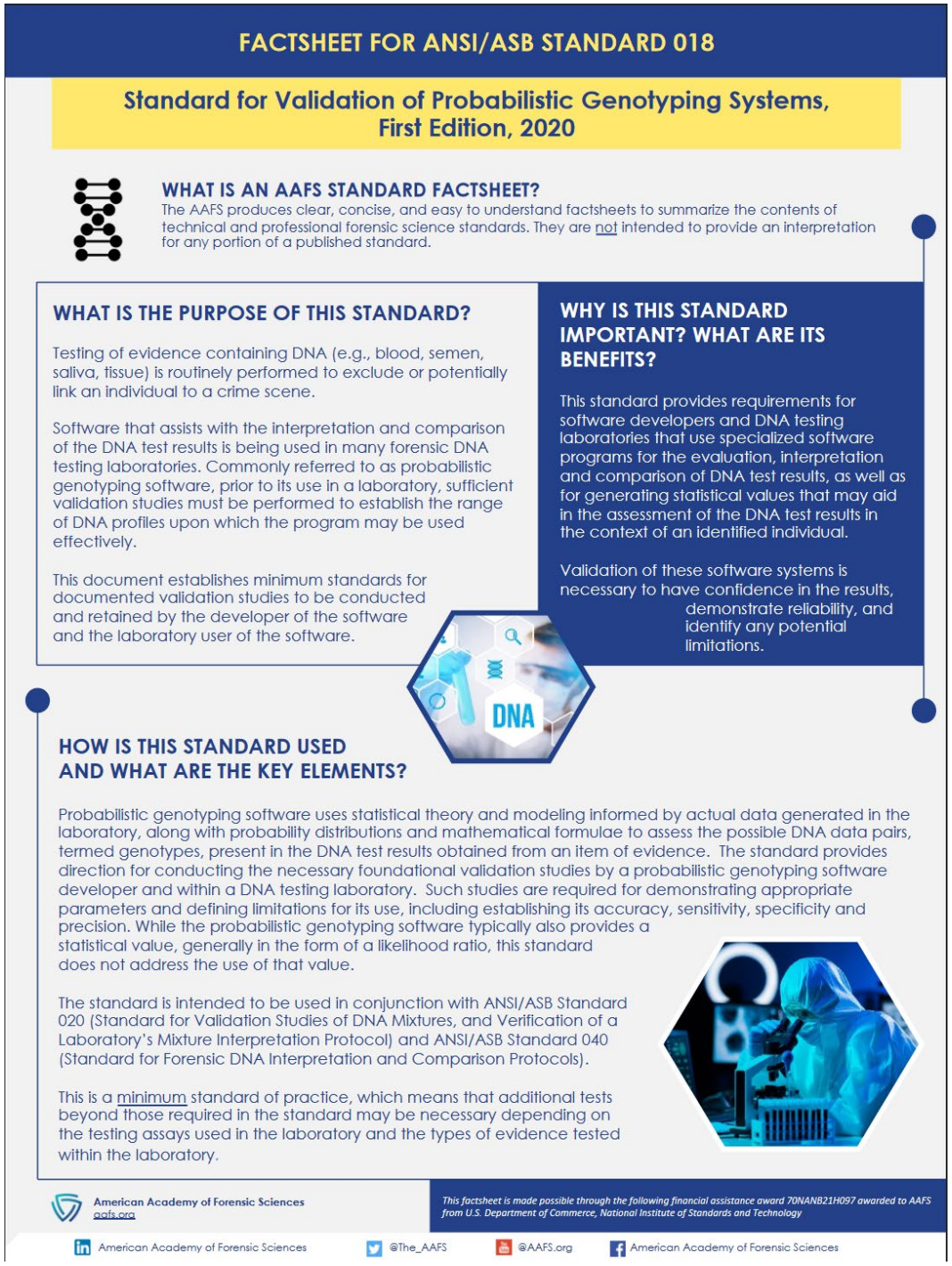

FACTSHEET FOR ANSI/ASB STANDARD 018

Standard for Validation of Probabilistic Genotyping Systems, First Edition, 2020

WHAT IS AN AAFS STANDARD FACTSHEET?

The AAFS produces clear, concise, and easy to understand factsheets to summarize the contents of technical and professional forensic science standards. They are not intended to provide an interpretation for any portion of a published standard.

WHAT IS THE PURPOSE OF THIS STANDARD?

Testing of evidence containing DNA (e.g., blood, semen, saliva, tissue) is routinely performed to exclude or potentially link an individual to a crime scene.

Software that assists with the interpretation and comparison of the DNA test results is being used in many forensic DNA testing laboratories. Commonly referred to as probabilistic genotyping software, prior to its use in a laboratory, sufficient validation studies must be performed to establish the range of DNA profiles upon which the program may be used effectively.

This document establishes minimum standards for documented validation studies to be conducted and retained by the developer of the software and the laboratory user of the software.

WHY IS THIS STANDARD IMPORTANT? WHAT ARE ITS BENEFITS?

This standard provides requirements for software developers and DNA testing laboratories that use specialized software programs for the evaluation, interpretation and comparison of DNA test results, as well as for generating statistical values that may aid in the assessment of the DNA test results in the context of an identified individual.

Validation of these software systems is necessary to have confidence in the results, demonstrate reliability, and identify any potential limitations.

HOW IS THIS STANDARD USED AND WHAT ARE THE KEY ELEMENTS?

Probabilistic genotyping software uses statistical theory and modeling informed by actual data generated in the laboratory, along with probability distributions and mathematical formulae to assess the possible DNA data pairs, termed genotypes, present in the DNA test results obtained from an item of evidence. The standard provides direction for conducting the necessary foundational validation studies by a probabilistic genotyping software developer and within a DNA testing laboratory. Such studies are required for demonstrating appropriate parameters and defining limitations for its use, including establishing its accuracy, sensitivity, specificity and precision. While the probabilistic genotyping software typically also provides a statistical value, generally in the form of a likelihood ratio, this standard does not address the use of that value.

The standard is intended to be used in conjunction with ANSI/ASB Standard 020 (Standard for Validation Studies of DNA Mixtures, and Verification of a Laboratory's Mixture Interpretation Protocol) and ANSI/ASB Standard 040 (Standard for Forensic DNA Interpretation and Comparison Protocols).

This is a minimum standard of practice, which means that additional tests beyond those required in the standard may be necessary depending on the testing assays used in the laboratory and the types of evidence tested within the laboratory.

American Academy of Forensic Sciences
aafs.org

This factsheet is made possible through the following financial assistance award 70NANB21H097 awarded to AAFS from U.S. Department of Commerce, National Institute of Standards and Technology

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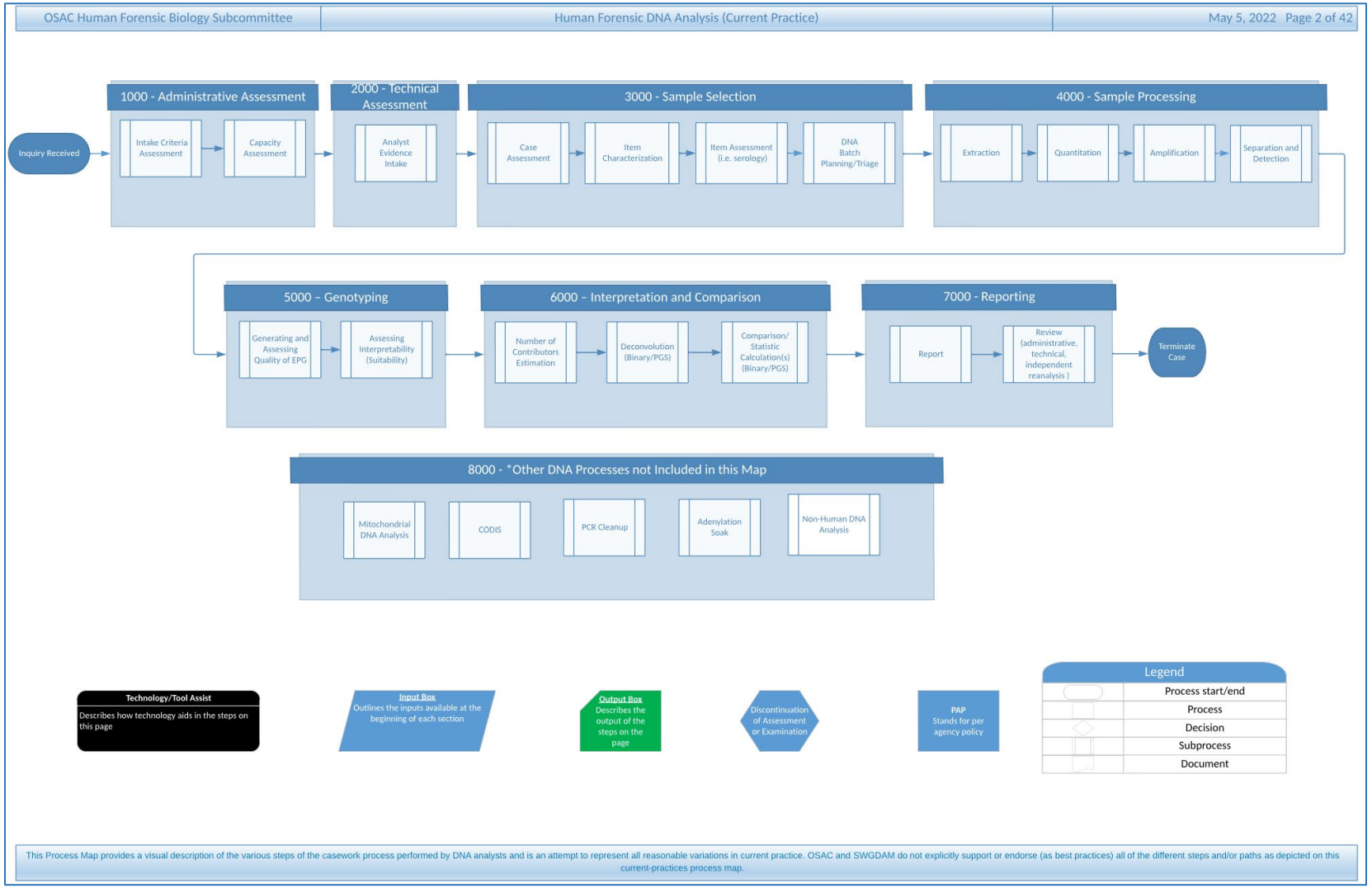
OSAC FORENSIC BIOLOGY PROCESS MAP



https://www.nist.gov/system/files/documents/2022/05/05/OSAC%20Forensic%20Biology%20Process%20Map_5.5.22.pdf

PROMEGA ARCHIVED WEBINAR SERIES

Promega

DNA Standards and Best Practices Developed by OSAC and ASB

Part 1: The Process

Part 2: Mixture Interpretation Validation, and Protocol Development and Verification (Standards 20 & 40)

Part 3: Training Standards Overview (Standards 22 & 23)

Part 4: ANSI/ASB Standard 018, Standard for Validation of Probabilistic Genotyping Systems

https://www.promega.com/resources/webinars/#q=forensic%20DNA%20standards&sort=%40webinarstartdate%20ascending

ADDITIONAL RESOURCES

Academy Standards Board

Information and Education

https://www.aafs.org/academy-standards-board/information-education

HOW TO GET INVOLVED

1) Join OSAC Human Forensic Biology Subcommittee to draft new standards (https://www.nist.gov/organization-scientific-area-committees-forensic-science/apply-join-osac)

2) Attend meetings and join ASB DNA Consensus Body to develop standards and assist with the revisions at the 5 year anniversary (https://www.aafs.org/academy-standards-board/calendar)

3) Review documents during Public Comment Period at ASB and OSAC and suggest revisions (https://www.aafs.org/academy-standards-board; https://www.nist.gov/organization-scientific-area-committees-forensic-science/standards-open-comment)

4) Implement Standards in your laboratory (https://www.nist.gov/organization-scientific-area-committees-forensic-science/osac-registry-implementation)

THANK YOU!!!

Brian Adams
Rob Allen
Tabitha Bandy
Bicka Barlow
Howard Baum
Jason Befus
Susan Berdine
Todd Bille
Charles Brenner
Lisa Brewer
Tebah Browne
Ryan Buchanan
John Buckleton
Eric Buel
Jason Bundy
Lynn Burley
John Butler
Tom Callaghan
Kris Cano
Amber Carr
Jessica Charak
Jessica Cino
Michael Coble
Jillian Conte
Jerilyn Conway
Kathleen Corrado
Robin Cotton
Heather Coyle
James Curran
Angelo Della Manna
Phil Danielson
Marsha Deitz
Julie Demarest
Mary Jones Dukes
Lisa Dziegiekewski
Debbie Epstein
Seth Faith
Erin Forry
Julie French
Jennifer Friedman
Susan Friedman
Kristen Fripp
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Peter Gill
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Debra Glidewell
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Kristine Kadash
Tim Kalafut
Rebekah Kay
Marla Kaplan
Susannah Kehl
Jarrah Kennedy
Phil Kinsey
Jody Koehler
Melissa Kotkin
Melissa Lavigne
Eugene Lien
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Steve Lee
Sarah Lewis
Chris Lindberg
Mark Loudon-Brown
Desmond Lun
Michael Marciano
Bruce McCord
Stacy McDonald
Amy McGuckian
Heather McKiernan
Andrew McWhorter
Amber Moss
Bonnie Mountain
Shawn Montpetit
Kim Murga
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Taylor Scott
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Rachel Singer
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Janel Smith
Carl Sobieralski
Melisa Staples
Melissa Suddeth
Joel Sutton
Jane Taupin
Caitlyn Taveira
Pete Vallone
Susan Walsh
Amy Watroba
Bruce Weir
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Charlotte Word
Darren Wright
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Brian Young
Tim Zolandz
Sandy Zabell
Caroline Zervos
Erika Ziemak
Candy Zuleger

Green Mountain DNA Conference

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Funding for the factsheets, checklists and partial funding for this presentation are made possible through the following financial assistance award 70NANB21H097 awarded to AAFS from U.S. Department of Commerce, National Institute of Standards and Technology.

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NIST-AAFS Cooperative Agreement

Factsheets

Training

Checklists

Training, tools and resources made possible through the following financial assistance award 70NANB21H097 awarded to AAFS from U.S. Department of Commerce, National Institute of Standards and Technology