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 ANSI/ASB Standard 040, *Standard for Forensic DNA Interpretation and Comparison Protocols,* First Edition, 2019[1] ("Standard"). The sections of this Assessment Guide include:

- Instructions - Instructions for the Laboratory and Instructions for the Assessment Team to prepare for the assessment and for use of this guide and Assessment Worksheet;
- Requirements - The Requirements stated in Standard 040 in a question format;
- Assessment Cover Page - A cover page to be completed by the laboratory staff and individuals performing the assessment; and
- Standard 040 Excel Assessment Worksheet (hereafter referred to as "Worksheet") - The Worksheet contains areas for completion by the laboratory prior to the assessment (highlighted in yellow) and areas for completion by the individual(s) conducting the assessment (highlighted in green). The Worksheet includes pop-up boxes and drop-down aids inserted as appropriate to assist user interaction. The Worksheet will serve as the summary documentation of the assessment conducted.

This Assessment Guide is designed to be used only for the assessment of compliance with Standard 040; however, portions of the assessment for Standard 040 overlap with, and can be evaluated in conjunction to, the assessment of other standards including 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,[2] ANSI/ASB Standard 018, *Standard for Validation of Probabilistic Genotyping Systems*, First Edition, 2020,[3] and the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories,[4] as applicable.

Due to the Requirements of the Standard, the assessment will require careful evaluation of the protocol under review, relevant validation studies, and casework files that demonstrate the appropriate application and documentation of the use of the protocol for interpretation and comparison of DNA test results. The preparation for this assessment, the documentation provided to the assessment team, the assessment process, and the recorded documentation associated with the assessment may differ from the processes typically employed during audits and assessments of other standards and accreditation requirements. The assessment of the criteria may be supplemented with interviews when needed to demonstrate understanding and compliance. See *Instructions for the Laboratory* and *Instructions for the Assessment Team* below for additional information regarding the use of this Assessment Guide.

This assessment may be completed on-site, virtually or via a hybrid approach depending on factors, such as the size and experience of the assessment team, number of analysts in the laboratory, cost-effectiveness and the agreed upon time frame to ensure a thorough assessment.

If the laboratory has multiple interpretation and comparison protocols for different methods, assays or software, a separate Assessment Worksheet shall be completed for each method, assay or software being assessed. For example, a laboratory using binary/manual interpretation of some STR profiles and probabilistic genotyping software for other STR profiles shall be assessed separately for each set of protocols, thereby resulting in the completion of two Assessment Worksheets. Similarly, autosomal nuclear STR protocols shall be assessed separately and independently from protocols for Y-STR testing, mtDNA or other sequencing assays, SNPs, rapid DNA testing, etc.

The objective of Standard 040 and this Assessment Guide is that a laboratory fulfills and is assessed for all Requirements of the Standard; partial implementation and/or assessment will not constitute documented compliance with this Standard. However, it is possible that a limited number of Requirements may not be applicable (N/A) in a particular laboratory based on the type of work performed and the specific laboratory protocols in place.

This Assessment Guide was drafted by the Human Forensic Biology Subcommittee of the Organization of Scientific Area Committees for Forensic Science (OSAC).

INSTRUCTIONS FOR THE LABORATORY

The list below details the steps the laboratory staff shall follow during the assessment process.

1. For each Interpretation and Comparison Protocol to be assessed:

    a. Complete the portions of the Cover Page designated for completion by the laboratory; and

    b. Start a separate Worksheet for each interpretation method to be assessed (e.g., autosomal STRs vs. Y STRs; binary/manual autosomal STR interpretation and comparison vs. probabilistic genotyping; autosomal STRs vs. mtDNA).

        i. At the top of the Worksheet, fill in “Laboratory Name;”

        ii. Provide the title for the “Interpretation and Comparison Protocol being reviewed” and the associated version/date; and

        iii. Provide the type of testing being assessed (e.g., Autosomal STR, Y-STR, MPS/NGS, Binary, Probabilistic Genotyping, etc).

2. To demonstrate compliance with Requirement 4.1, identify at least five (5) criteria from the relevant protocol that the laboratory would like to have evaluated during the assessment. This may be done by selecting specific sections in the protocol provided by the laboratory, or by specifying a particular topic for which the laboratory will provide the relevant section in the protocol based on the Requirements 4.2-4.4 (e.g., criteria for declaring single source vs. a mixture; criteria for declaring a major and/or minor contributor; criteria for assessing number of contributors).

    a. On the Worksheet, list the selected criteria separately under Section I "Laboratory requested criteria for review to comply with 4.1". Additional lines may be added if the laboratory is requesting evaluation of more than five (5) criteria during the assessment.

    b. For each of the identified criteria, separately list the reference to the specific protocol section and/or direct hyperlink, and the supporting validation study, in the "Protocol Section/Link" and "Validation Study" columns, respectively.

    c. Ensure that detailed descriptions of the studies conducted, the data relied upon, the methods used for evaluation, and summaries of each study are available for the assessment team. Under Section I, "Validation Study" add a title or brief description of the relevant validation study that should be reviewed by the assessment team for each of the listed criteria.

3. On Section II of the Worksheet, complete the "Protocol Section/Link" column for all Requirements of 4.2, 4.3, and 4.4. After completing this column, all areas highlighted in yellow on the Worksheet should be completed. This section may be completed by #6 but no later than #8 below.

4. Identify a qualified assessment team with relevant, collective experience to include validation design and evaluation, protocol development, and case review, for the protocol criteria being assessed.

5. Determine if the assessment will be on-site, virtual or via a hybrid approach. Agree upon a schedule for providing documentation, conducting the assessment and completion of the assessment.

6. Provide the assessment team with the completed Worksheet and the relevant Interpretation and Comparison Protocol and validation studies associated with each procedure and methodology to be assessed.

7. To fulfill Requirement 4.1, the assessment team will identify five (5) additional criteria for review. These assessor-identified criteria will be listed in the green-highlighted area of Section I. Upon receipt of the Worksheet from the assessment team, review the additional criteria and update the "Protocol Section/Link" and "Validation Study" columns for each assessor-identified criteria as was previously completed in step #2 above.

8. Return the completed Worksheet to the assessment team.

9. Determine with the assessment team what information will be provided in advance vs. on-site. Provide the requested documentation for review in advance of the assessment within the timeline agreed upon with the assessment team.

10. Identify and provide casework files that address each of the Requirements listed in 4.2, 4.3, and 4.4. A single case may be reviewed to address multiple criteria and Requirements. It is recommended that the cases selected for review be from different analysts or analyst teams. It may be helpful to flag relevant sections of the casefile for the various criteria being assessed to aid in the review.

11. During the assessment, provide additional requested documentation and information.

12. Address any possible discrepancies or findings with the assessment team.

INSTRUCTIONS FOR THE ASSESSMENT TEAM

The list below details the steps the assessment team shall follow during the assessment process. It is recommended that the team choose a lead as the point of contact for the laboratory.

1. Review the Cover page and Worksheet provided by the laboratory to ensure:

    a. Completion of the relevant information as outlined above in # 1 and #2 under "Instructions for the Laboratory," including the listing of at least five (5) criteria the laboratory is requesting for review for Requirement 4.1 and its associated relevant documentation (yellow highlighted areas in Section I), and

    b. The assessment team personnel are current or previously qualified examiners to evaluate the validation studies, protocol and casework documentation for each of the sections of the protocol to be evaluated.

2. Determine if the assessment will be on-site, virtual or via a hybrid approach. Agree upon a timeline for providing documentation, conducting the assessment and completion of the assessment.

3. Identify five (5) additional criteria related to interpretation and/or comparison to be evaluated during the assessment for Requirement 4.1. List each criteria separately under the "Assessor identified criteria for review of compliance with 4.1" column. When possible, these criteria should be focused on the limitations of the methods and complex or rarely used interpretation methods. This may be done by identifying specific sections in the protocol provided by the laboratory, or by specifying a particular topic for which the laboratory will provide the relevant section in the protocol based on the Requirements 4.2-4.4 (e.g., criteria for declaring single source vs. a mixture; criteria for declaring a major and/or minor contributor; criteria for assessing number of contributors).

4. On the Worksheet under Section II for Requirements 4.2, 4.3 and 4.4, include the number of casework examples for each protocol section to be available for review during the assessment period under the column titled “Number of examples for review.” The assessment team shall select a reasonable number to evaluate each criteria based on the specific Requirement and the complexity of the protocol, the frequency of its use in the laboratory or other relevant criteria. The laboratory may request a revision to the number of examples requested if locating that number is not feasible.

5. Return the completed Worksheet to the laboratory. The laboratory will add the remaining relevant information for Section I and Section II in the yellow highlighted areas and return the Worksheet to the assessment team.

6. Discuss with the laboratory to determine the information that will be provided in advance vs. on-site.

7. Relevant documents may be reviewed in advance of or during the live assessment, as applicable. Request any additional or missing documentation as needed.

8. Complete all green highlighted areas of the Worksheet as documentation for each of the Requirements reviewed. Drop-downs are provided, as applicable to each requirement. Under the column titled “Objective Proof” provide a brief summary of the materials reviewed, information obtained, etc. to permit the “Yes” or “No” response. For example, for Requirement 4.2.2A, the summary may read: “Reviewed Section 6.5.2 of the protocol, 20 DNA profiles from 9 cases worked by 5 different analysts in the lab, and interviewed 2 additional analysts. No deviations from the stated protocol were noted.”

9. In Section III, the findings associated with the assessment will be detailed and summarized by the assessment team. All Requirements marked “No” must be described in sufficient detail such that the laboratory can develop an appropriate corrective action for compliance.

10. The Worksheet is intended to be an objective summary checklist. It shall not include specific analyst names, case names or case numbers. The assessors are encouraged to maintain separate notes that list cases reviewed, analysts interviewed, etc. for objective proof of conformance or lack of conformance to the Requirements based on that review. These notes will be retained by the assessment team until the completion of the assessment process; however, they should not be retained with the final Assessment Guide.

11. Keep the laboratory apprised of the assessment progress.

12. Additional portions of the protocol and/or casework files reviewed that are not directly applicable to the assessment of Standard 040 should not be included on the Assessment Worksheet for Standard 040.

13. Upon completion of the assessment:

    a. Determine the date the final documents will be provided to the laboratory;

b. Complete the Worksheet with clear and objective documentation of the review performed;

c. Have each assessment team member review the completed Worksheet and sign the cover page to document approval;

d. Submit the finalized Worksheet to the laboratory.

PROCEDURAL NOTES

1. If the assessment is conducted by an assessment team functioning under an accrediting agency or other body with specified procedures for conducting audits/assessments, where possible, the procedures and policies of the overarching body shall be followed. If an assessment is being conducted by individuals internal or external to the laboratory at the request of the laboratory, then the necessary procedures and policies for the process to occur shall be determined by the laboratory and the individuals performing the assessment; this includes setting the dates of the assessment, whether it will be conducted on-site or virtually and when the completed Assessment Guide will be provided to the laboratory.

2. For subsequent assessments of the validation studies and laboratory protocols for Requirement 4.1 using this Assessment Guide, it is advised that different criteria and sections of the protocol be identified by the laboratory and the assessment team to ensure a more thorough review of the protocol. However, if there were findings noted in a prior assessment, it may be prudent to include those relevant sections in the subsequent assessment. The selection of criteria from the protocol may be informed by additional validation studies and/or sections added to the protocol since the last review, changes in the field related to interpretation and comparison, or other relevant criteria.

3. Each of the specified criteria detailed in Requirements 4.2-4.4 must be reviewed during each assessment (e.g., single source vs. mixture in 4.2.1; number of contributors in 4.2.2; limitations in 4.2.4). However, the assessment of the associated underlying validation for each of the protocol statements need not be reviewed unless specifically listed as one of the criteria for review in Section I of the Worksheet.

APPEAL OF ASSESSMENT RESULTS

In the absence of an available formal appeal process, a laboratory wishing to challenge a finding documented during an assessment may do any of the following:

1. Provide the assessment team, in writing, relevant explanations and documentation, and request consideration of a modification to the assessment based on the supplemental information;

2. Attach relevant explanations and documentation to the completed Assessment Guide as a permanent addition that will be provided with the assessment teams' comments whenever the Assessment Guide is requested (e.g., during future assessments, discovery, etc.);

3. Provide the assessment team documentation of the completion of additional studies and/or modifications to the protocol, appropriate approvals, training, and competency testing, as applicable, for evaluation.

Assessment Cover Page

for ANSI/ASB Standard 040,

Standard for Forensic DNA Interpretation and Comparison Protocols, First Edition, 2019

Laboratory Name and Section of the Laboratory:

Address:

Title of Protocol being assessed with date/version:

Type of testing: (circle one protocol)

autosomal STR – binary Y-STR

autosomal STR – probabilistic genotyping software SNPs

mtDNA Sequencing Rapid

Other _____

Date of assessment:

When was the last assessment to this protocol?

Date of previous assessment: Internal / External

Assessor name and signature (employer)

1.

2.

3.

4.

STANDARD 040 REQUIREMENTS

It is the intent of the Standard 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. Having an adequately detailed protocol tightly connected to internal validation studies that addresses the expected variables of DNA data ensures more consistent and reliable interpretation, comparison, and reporting by all members of the laboratory.[1]

Each Requirement listed in Standard 040 is provided below in a question format as well as in the Worksheet for use in the assessment. Requirement statements having two or more requisite components are specified individually as sub-requirement "A, B, C, etc." as necessary.

See Section 3 of the Standard for definitions of terms used in this document. See Annex B of the Standard for additional guidance to the Requirements.

4.1 Are the laboratory interpretation protocols and comparison protocols, including criteria for drawing conclusions from comparisons between evidentiary data and reference (or other evidentiary) data:

A. Based on and developed from internal validation studies?
B. Supported by internal validation studies?

NOTE Published scientific literature or other appropriate scientific resources, where available, may supplement internal validation studies.

4.2 Does the laboratory maintain and follow documented DNA interpretation protocols that address the following:

4.2.1 Criteria for assessing the DNA data as originating from a single source?

A. Criteria for assessing the DNA data as originating from multiple sources?

4.2.2 Does the protocol state specific criteria upon which assumptions may be made and the types of assumptions that may be used in data interpretation including, but not limited to:

A. The number of contributors?
B. The presence of assumed contributors?
C. Other laboratory defined assumptions?

4.2.3 Does the protocol state specific criteria for evaluating other considerations used in the interpretation of the data, such as the:

[1] From the Foreword of the Standard 040

A. Presence of major and minor contributors?
B. Possibility of allele sharing?
C. Relative mixture ratio for contributors?
D. Possibility of inhibition or degradation for one or more contributors?
E. Possibility of stochastic effects?
F. Presence of stutter?
G. Other laboratory defined considerations?

4.2.4 Does the protocol provide limitations of the interpretation methods used such as:

A. Characterizing and defining the maximum number of contributors?
B. Issues associated with low-level data?
C. Issues associated with low-level contributors?
D. Issues associated with potential contamination events?
E. Other limitations?

4.2.5 Does the protocol have criteria defining what data are interpretable versus data that cannot be interpreted?

4.2.6 Does the protocol have criteria for defining data (or a subset of data) that are suitable for comparison versus data that are unsuitable for comparison.

4.3 Does the laboratory have a documented policy requiring the interpretation of evidentiary data prior to the comparison to any reference data?

A Does the policy include documentation of interpretation prior to comparison?

B. Does the policy include documentation of all assumptions used prior to comparison?

4.3.1 Is there documentation of the suitability of the single source or DNA mixture data for comparison?

4.3.1.1 If the data or a subset of the data [e.g., major contributor(s)] were deemed suitable for comparison, were the loci eligible for use in the comparison and in a subsequent statistical calculation(s) documented in the case record?

4.3.1.2 If the data or a subset of the data [e.g., minor contributor(s)] were deemed unsuitable for comparison, was the qualitative reason(s) documented in the case record?

4.3.2 Is the subsequent interpretation of new evidentiary data completed prior to comparison to any previously generated reference data?

A. Was the subsequent analysis documented prior to comparison?

4.3.3 When an assumption of an expected contributor was used for interpretation, was the use of that assumption documented in the case record along with the DNA data of the assumed contributor?

4.4 Does the laboratory maintain and follow documented protocols for drawing conclusions from the comparison of suitable evidentiary data to reference (or other evidentiary) data?

A. Single source?
B. Mixed Source?
C. Limited quality/quantity data?

4.4.1 When the following terms are used by the laboratory, do the laboratory protocols describe the criteria used for concluding that the source of the reference data when compared to evidentiary data is:?

A. Included?
B. Excluded?
C. Inconclusive?
D. If a comparison is deemed inconclusive, are the reason(s) documented in the case record?
E. Are criteria given for other terms used?

4.4.2 Does the laboratory have protocols that address reevaluation of evidentiary data after the comparison to reference (or other evidentiary) data has been performed?

A. Are all re-evaluations of, and changes to, the original evidentiary data interpretation thoroughly documented within the case record?

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[1] http://www.asbstandardsboard.org/wp-content/uploads/2019/10/Std_040_e1.pdf
[2] https://asb.aafs.org/wp-content/uploads/2018/09/020_Std_e1.pdf
[3] http://www.asbstandardsboard.org/wp-content/uploads/2020/07/018_Std_e1.pdf
[4]https://www.fbi.gov/file-repository/quality-assurance-standards-for-forensic-dna-testing-laboratories.pdf/view

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