DNA
Procedures for Case File Assembly and Reviews

1 Purpose

These procedures address the preparation and review of DNA Casework Unit (DCU) and Scientific and Biometrics Analysis Unit (SBAU) DNA case files and *Laboratory Reports* (7-1 or 7-1 LIMS).

2 Scope

This document applies to DNA personnel in the DCU and the SBAU and establishes procedures for the preparation and review of DNA discipline case file records and *Laboratory Reports* and supplements the relevant practices in the FBI *Laboratory Operations Manual* (LOM).

3 Procedures

DNA personnel with responsibilities related to the assembly of case files will follow the responsibilities identified in the FBI *Quality Assurance Manual* (QAM) and LOM.

3.1 Case Records

3.1.1 All case-related records will be retained as physical supporting records or electronic supporting records in accordance with the appropriate LOM Practices.

3.1.1.1 The DCU and SBAU use Sample Tracking and Control Software (STACS) in lieu of Forensic Advantage (FA) to record and/or generate many of the case-related administrative and examination records.

3.1.1.2 Electropherograms retained as supporting records (i.e., printouts or PDFs) should be of sufficient resolution to demonstrate that all DNA types are supported by the analytical data during technical review.

3.1.1.3 When a single lab number has multiple Case Records for examination in the DNA units, the supporting records retained for each Case Record may be truncated to the pages of examination and administrative records that support the examinations reported under the specific Case Record.

3.1.1.4 When supporting records are retained electronically, the Examiner will ensure they have reviewed the records. If the Examiner's initials (or secure electronic equivalent) are not on each page of the examination records, the Examiner will record their review typically by using available electronic tools (e.g., Adobe Acrobat Pro) to mark at least the first page of a PDF, by

approving the record when uploaded to the Case Record Object Repository in FA, or by recording their review in a communication log.

3.1.1.5 Copies of examination or administrative records generated by other Laboratory units or outside entities that are not used by the examiner in the evaluation of the evidence or to support the results or conclusions do not need to be retained in the DNA electronic supporting records (i.e., Case Record Object Repository) or the DNA *Supporting Documentation Envelope* (7-251), commonly referred to as a physical 1A.

3.1.2 If amendments to technical records are made, DNA personnel ensure the change can be tracked to the previous versions or the original observation. Amendments include the date of the alteration, an indication of the altered aspects, and the personnel responsible for the alteration. Nothing in the administrative and/or examination records may be obliterated or erased.

3.1.2.1 Contemporaneous revisions are not considered amendments. Changes are considered contemporaneous if made before reaching a decision point. Decision points may include transferring samples to the next stage of processing, uploading completed examination records to STACS or FA, or submitting the file for technical review.

3.1.2.2 If an identifier or similar addition is made to the case records (e.g., laboratory number, the "SECRET" or "copy" designation) manually or through the use of a stamp or other electronic means (e.g., page counter), this addition is not considered an amendment and does not require the date or initials of the person making the addition.

3.1.2.3 The following methods may be used to track changes made to completed records.

- Changes to hard copy and/or handwritten records may be tracked using a single strike-out, dating and initialing the change or by retaining any pages that are replaced in the 1A.
- Changes to electronic records in STACS are tracked within STACS.
- Electronic record pages may be annotated, added, or amended when the revised or additional pages are clear. If a page is replaced, the original page will be retained but marked to indicate it was replaced.
- A new file may revise a portion of, or the entirety of, the original file, as appropriate through a version history for the file.
- Changes to electronic records not otherwise tracked may be summarized in a communication log.

3.1.3 Sufficient information (i.e., barcode or other unique identifier) regarding the instruments and reagents used in the examination will be recorded as prompted by STACS or the templates used to record case notes (e.g., the mtDNA Workbook).

3.1.4 A list of commonly used abbreviations/symbols in DNA records is available within the DNA QA Manual (i.e., DNAQA 601).

3.1.5 Administrative Records

The following are examples of administrative records in the DNA Units:

- Record of the Technical and Administrative Review
- Case Record Report, for FA cases
- *Laboratory Work Sheet* (7-2), for Legacy cases
- Copy of incoming communication(s)
- Communication Logs and records
- Chain-of-Custody Log(s)
- Copy of *Examination Plan* (7-262), for Legacy cases
- Deviation Requests
- Records of the Combined DNA Index System (CODIS) or other appropriate database(s) eligible profile/sequence(s)

3.1.6 Examination Records

Examination records consist of all work notes generated by a biologist and/or examiner that support the results and/or conclusions in the case. The following are examples of examination records in the DNA Units:

- Serology Notes
- Collection Notes
- Extraction Notes
- Quantification Notes
- Sample Dilution/Combination Notes
- Amplification/Cycle Sequencing/CE Notes
- Electropherograms
- SequencherTM sheets
- Allele Tables/Sequence Summary Sheets
- Statistical Calculations (e.g., STRMix, EMPOP, YHRD, KinCAlc)
- Database match and/or rarity calculator results (e.g., Moderate Match Estimate [MME], Match Rarity Estimate [MRE], COSTaR)
- Compact disc(s) containing Genetic Analyzer 3130xl or 3500xL analysis files and/or SequencherTM files (when applicable)

3.1.7 For cases with CODIS eligible profiles, the following information must be recorded and verified prior to upload to SDIS. The information may be recorded and verified as case file records or via STACS, as applicable. Refer to the appropriate DNA procedure for CODIS entry and eligibility requirements (i.e., DNA 209).

- DNA profile and Amelogenin (if applicable) results being entered
- Specimen category (e.g., Forensic Unknown, Missing Person)
- Relevant eligibility information
- Database match and/or rarity calculator results, if applicable

- Pedigree and metadata for missing person, if applicable (Missing Persons cases only)
- Consent forms (Missing Persons cases only)

3.1.8 Case-Related Records from Non-FBI Laboratories

Relevant examination and administrative records generated by a non-FBI laboratory for a case assigned to the DCU or SBAU will be categorized as administrative records and will be retained in the physical 1A and/or may be uploaded with the administrative records to the Case Record Object Repository in FA.

3.2 Expedited Results

3.2.1 When results are disseminated prior to the issuance of the *Laboratory Report*, the following results or conclusions require verification/technical review by another qualified Examiner and that verification/technical review recorded in the case notes prior to dissemination:

- Mitochondrial DNA (mtDNA) conclusions of "cannot be excluded" or "inconclusive"
- Comparisons to nuclear DNA (nDNA) mixture profiles evaluated with STRMix
- Statistical results
- Conclusions based on kinship calculation results

3.2.2 The following do not require verification/technical review prior to dissemination of expedited results:

- Comparisons to single source nDNA profiles (if statistical results are not provided)
- Comparisons to nDNA profiles resulting in a manual exclusion
- mtDNA exclusions
- Parent/offspring comparisons to full profiles (if no statistical results provided)
- Other testing results (e.g., serology)

3.2.3 DNA examination records will not be released without a recorded technical review.

3.2.4 Any dissemination of expedited results will be recorded in accordance with the appropriate LOM Practices. The record must include the opinions or interpretations communicated by dialog with the contributor.

3.3 Sequence Confirmation

The mtDNA sequences for all samples and associated controls (HL60, NC, and RB) will be confirmed/verified by a second qualified individual. Sequence confirmation may be completed prior to completion of the *Laboratory Report* or during technical review. Refer to the appropriate DNA procedure (i.e., DNA 410).

3.4 Formatting and Content of a Laboratory Report

3.4.1 An Examiner will prepare a *Laboratory Report* in accordance with the appropriate LOM Practices. The *Laboratory Report* will contain or reference the following information, as appropriate:

- Case identifier (i.e., laboratory number(s) and/or Case ID number(s)).
- Description of the evidence received or examined by the DNA Units and identification of the samples tested for DNA, when applicable.
- DNA technology (e.g., STR, YSTR, mtDNA) used for analysis.
- Identification of the loci or amplification system or region(s) for which characterization was attempted.
- Results and/or conclusions for each forensic sample tested.
- Qualitative interpretative statement and/or a quantitative (statistical) statement to support all inclusions or for all conclusions supported by a STRmix analysis.
- Report date.
- Disposition of evidence.
- Name of the Examiner responsible for the content of the *Laboratory Report*.

3.4.1.1 The date on the *Laboratory Report* will be the date the technical content of the report was finalized and will reflect the date on or prior to which all technical work supporting the results and/or conclusions in the *Laboratory Report* was complete. The report date will be updated, as appropriate, during the review process if revised or additional examination records are generated, unless the new records contain no additional technical content (e.g., reprint of STACS notes for an administrative edit).

3.4.2 The Results of Examination section of the *Laboratory Report* will include, as appropriate, sampling descriptions, results and/or conclusions, statistical calculation results, information pertaining to the entry of sample(s) profiles into the CODIS or other appropriate databases, and a Methods/Limitations section. Evidence listed in the *Laboratory Report* as received but not examined may be addressed in the Listing and Description of Evidence, Results of Examination, or the Remarks sections, as appropriate.

3.4.2.1 The initial entry of a profile into a DNA database will be included in the *Laboratory Report*.

3.4.2.2 The extent of database searches will be communicated to the contributor and updated as needed.

3.4.3 The Remarks section of a *Laboratory Report* will contain the disposition of evidence and other remarks as required by the appropriate LOM practice. This section may also contain requests for additional samples (e.g., additional bones from an Unidentified Human Remains (UHR), additional relatives of a Missing Person), information pertaining to samples retained for future testing (e.g., for the National Missing Persons DNA Database (NMPDD), population databasing), and potential additional testing that may be suitable (i.e., Y-STRs).

3.4.3.1 Evidence will be dispositioned as consumed when no evidence material remains for future testing (e.g., the entire swab tip is cut from the swab, an entire bone fragment is pulverized and used for extraction).

3.5 Reviewing a Laboratory Report

3.5.1 Technical and administrative reviews will be conducted in accordance with the appropriate LOM Practices. The case file records will reflect that the technical and/or administrative review(s) were conducted and who performed those review(s).

3.5.2 Technical and administrative reviewers may be self-assigned in STACS and/or FA.

3.5.2.1 The technical reviewer(s) must be currently or previously qualified in the method, technology, typing test kit, platform, and interpretation software being reviewed, be authorized to conduct technical reviews, and be proficiency tested semi-annually as a Forensic Examiner (i.e., conducting interpretation and/or technical review).

3.5.2.2 If a portion of the examination records are technically reviewed by a separate technical reviewer (e.g., expedited results), the review of the affected portion of the examination records will be noted in the case file. The technical reviewer cannot be the author of the report or review their own work, with the exception of confirmation/verification records. Sequence confirmation and technical review may be completed by the same or different individuals provided neither are the primary interpreting examiner or the author of the report.

3.5.2.3 An administrative reviewer does not need to be currently or previously qualified in the methodology being reviewed or be semi-annually proficiency tested.

3.5.3 Unresolved discrepant conclusions between the reporting Examiner and the reviewer(s) will be resolved by the Technical Leader unless elevation to Section Chief or above, as described by the appropriate LOM practice, becomes necessary.

3.5.3.1 The file will reflect the resolution reached to the agreement of all parties and will be clearly communicated to all personnel involved.

3.5.4 Technical Review

Completion of the technical review signifies agreement with the examination process and technical information in the case file and *Laboratory Report*.

3.5.4.1 In addition to the requirements in the appropriate LOM Practice, the technical reviewer will review:

- The administrative and examination records and the *Laboratory Report.*
- The *Laboratory Report* to ensure the presence and accuracy of the report elements listed above.

- The *Laboratory Report* to verify that the results/conclusions are supported by the data for each item tested and in compliance with laboratory guidelines.
- The statistical calculations, if applicable.
- The CODIS eligibility, or eligibility for other appropriate databases, of the DNA profile/sequence(s), including the DNA types and specimen category for eligible samples, if applicable.
    - The specimen category may be reviewed within STACS and not captured in the case file.

3.5.4.1.1 The technical reviewer will ensure that calculations and data transfers subject to human error (i.e., manual calculations or transcriptions) are checked, unless these values are checked by STACS or other electronic tools. If the technical records do not indicate a necessary check was performed, the technical reviewer will perform the check.

3.5.4.2 In addition, for nuclear DNA results, except for those generated using an NDIS approved Rapid DNA System on casework reference samples, the technical reviewer will:

- Review all supporting electropherograms to verify that all DNA types and conclusions are supported by the analytical data, if applicable. If electropherogram printouts or PDFs are not of sufficient resolution to verify all DNA types, the technical reviewer must request additional electropherogram printouts or PDFs or review the data electronically and record that the data was electronically reviewed.
- Ensure all controls, internal size standards and allelic ladders meet the interpretation guidelines for reported results, if applicable.

3.5.4.3 For mitochondrial DNA results, the sequence confirmation will fulfill the technical review requirement of the supporting electropherograms, the DNA types (aka sequences), and controls. The technical reviewer, if necessary, will generate the appropriate sequence confirmation records. If the sequence confirmation is done prior to the technical review, the technical reviewer will review the sequence confirmation records, to include:

- The Sequencher™ project and profile sheets from the Examiner and confirmer to ensure they are included.
- The case summary sheet to ensure it contains all analyzed sequences with the correct sequence ranges and profiles.
- Sequence results to ensure the appropriate sequences were compared to known phylogenetic alignments, if applicable.
- The review of the controls.

3.5.5 Administrative Review

Completion of the administrative review indicates that the *Laboratory Report* has been approved and is authorized for issuance.

3.5.5.1 In addition to the requirements in the appropriate LOM Practice, the administrative reviewer will:

- Review the administrative and examination records and the *Laboratory Report* for clerical accuracy and ensure the presence and accuracy of the report elements listed above.
- Review the Chain-of-Custody and disposition of evidence.
- Ensure that a technical review was completed, when applicable, and properly recorded.

3.5.6 The electronic signatures of the technical and administrative reviewer are captured in STACS and/or FA.

3.6 Issuing a Laboratory Report

3.6.1 Upon completion of the appropriate reviews, the *Laboratory Report* and supporting records will be serialized in Sentinel in accordance with the appropriate LOM Practice.

3.6.1.1 When a physical 1A is created, a physical attachment will be added in Sentinel. At least the total number of physical pages and/or data discs of administrative and examination records retained within the 1A envelope will be accounted for on the outside of the 1A envelope.

3.6.1.2 When supporting records are compiled electronically, a digital 1A will be created and uploaded to Sentinel as a digital attachment.

3.6.2 The *Laboratory Report* will be considered issued when the *Laboratory Report* is uploaded to Sentinel. The issue date is the date of upload approval and is captured on the official record of the *Laboratory Report* in Sentinel. This record contains the FBI file copy of the *Laboratory Report.* The issue date is not required on the copy of the *Laboratory Report* retained within the physical 1A.

4 Records

Examination and administrative records will be generated and retained in accordance with this procedure and the appropriate LOM Practices.

5 References

FBI Laboratory Operations Manual (LOM)

FBI Laboratory Quality Assurance Manual (QAM)

DNA Procedures Manual

FBI Laboratory National DNA Index System (NDIS) DNA Data Accepted at NDIS (Operational Procedures), latest version.

Federal Bureau of Investigation, Quality Assurance Standards for Forensic DNA Testing Laboratories, latest version.

Federal Bureau of Investigation, Quality Assurance Standards Audit for Forensic DNA Testing Laboratories, latest version.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Rev #	Issue Date	History
11	09/13/19	Updated BAU to SBAU after LD reorganization. Removed responsibilities section and renumbered remaining sections. 3.1.1.3 Added allowance for truncated records. 3.1.1.4 Added requirements for FE review of electronic records. 3.2 Update section to reflect changes to level 1 requirements and provide examples for application by the DNA units. 3.1.5 Deleted ECS search slip. Moved Laboratory Report to 4.1.6. 3.1.6 Added issued Laboratory Report and MME calculation. 3.2.1 and 3.2.2 Added Kinship requirements. 3.2.4 Added requirement to record opinions and interpretations. 3.4.2 Evidence listed in the report but not worked can be addressed in any of the report sections. 3.4.2.1 & .2 Added database entry requirements 3.4.3 Added other LOM required remarks. 3.5.4.1 and 3.5.5.1 Added reference to LOM requirements 3.5.4.2 Added exception for profiles generated using an NDIS approved Rapid DNA system. 3.1.6.2 Revised requirement for digital attachments.
12	07/01/21	Editorial revisions throughout. Revisions to reflect use of FA to generate digital 1As. Updated wording to reflect changes in QAS2020. 3.1.6: Deleted copy of report as an exam record as reports are retained as technical records in Sentinel. 3.1.6/3.1.7: Consolidated DB calculator results examples. 3.4.1.1: Added guidance on the report date. 3.5.2.2: Additional guidance on TR and confirmation. 3.5.3.1: Additional wording for resolution of disagreements. 3.5.4.1.1: Clarified that checks can be performed by STACS or other electronic tools.

Approval

Redact - Signatures on File

DNA Technical Leader Date: 06/30/2021

DCU Chief Date: 06/30/2021

SBAU Chief Date: 06/30/2021

QA Approval

Quality Manager Date: 06/30/2021