

Quality Assurance Guideline for DNA Laboratories

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1. AIMS

The ENFSI DNA Working Group has developed this guideline to provide a framework for quality assurance management. This framework supports forensic DNA laboratories to establish and maintain competence and produce results of high quality. Additionally, it aims to identify relevant aspects of quality management which the laboratories should address when seeking or maintaining accreditation under ISO 17025(1). This accreditation is a requirement following the Council Framework Decision(2), and complies with the ENFSI DNA Working Group recommendations for the exchange of DNA data between laboratories, according to the *ENFSI BPM*(3).

2. SCOPE

This guideline outlines how forensic DNA laboratories can fulfil the ISO 17025 requirements when conducting forensic DNA analysis. Aspects of the ISO 17025 standard that are covered in other existing ENFSI DNA WG documents are not extensively addressed in this guideline (e.g. Training).

This guideline is not intended to replace or restrict other alternative quality assurance programmes that exist within countries of Europe.

3. DEFINITIONS AND TERMS

- (a) **Accreditation** is a formal, independent verification that a programme or institution meets established quality standards and is competent to carry out specific conformity assessment tasks. Conformity assessment tasks may include, but are not limited to, testing, inspection and certification.
- (b) **Audit** is an inspection, either internal or external, used to evaluate, confirm, or verify activities related to quality.
- (c) **Blank/negative control** consists of all reagents used in the test process without any sample. This control is used to detect contamination of the analytical reagents and consumables and can also indicate other quality issues as cross contamination.
- (d) **Contamination** is an undesirable introduction of a substance to an item at any point in the forensic process.
Note 1: This includes undesirable transfer of a substance within an item or between items (also referred to as cross-contamination).

Note 2: Contamination may arise from various sources, such as items, DNA samples, persons, reagents and consumables, and laboratory environment (e.g. instruments and benches).
- (e) **Positive control** is a sample of known characteristics. This control is used to monitor the validity of results and/or performance of the test.

Note: For a DNA positive control, it should be heterozygous at majority of the loci.

- (f) **Proficiency testing** is the assessment of a laboratory's ability to perform specific technical activities. It allows for the inter-laboratory comparisons to determine the performance of individual laboratories for specific tests or measurements in addition to monitoring laboratories' continuing performance.
- (g) **Quality assurance** encompasses all systematic and planned actions that provide confidence that a product or service will meet defined quality standards.
- (h) **Quality control** is a measure to verify the performance of a test. Such measure can be using positive and/or negative controls, or performing verifications (refer to Table 1).
- (i) **Quality management review** is a review of the quality management system. In this document, this is also referred to as management review.
- (j) **Quality management system** comprises the organisational structure, responsibilities, procedures, processes and resources needed for quality management.
- (k) **Reference material (certified or standard)** is a material with characteristics certified through technically valid procedures, and accompanied by or traceable to a certificate or other documentation from a certifying body.
- (l) **Standard operating procedure (SOP)** is a specified written method, procedure or protocol used by the organisation.
- (m) **Traceability** enables the review and tracking of how the item/sample/result flows through the chain of different events in the forensic DNA laboratory.

4. QUALITY ASSURANCE

4.1 General requirements

Quality assurance is the responsibility of all members of the organisation and should be endorsed by the senior management.

The organisation shall have policies and procedures in place:

- 1) to safeguard confidentiality of the information and data provided by the mandating authority and/or generated by the laboratory;
- 2) to ensure forensic DNA analysis is carried out impartially;
- 3) to ensure the entire laboratory workflow, from submission of item to reporting, is documented and controlled; and
- 4) to ensure calculations and data transfers (manual and automatic) are checked in an appropriate and systematic manner.

Such policies and procedures shall be readily available to relevant personnel.

4.2 Resource requirements

4.2.1 Staff

The laboratory management shall ensure that all staff receive the necessary training according to their job description. Additionally, the roles and responsibilities of all staff shall be defined. More details regarding competency requirements, competency testing and maintenance can be found in the *ENFSI Guideline(4)*.

4.2.2 Accommodation and environmental conditions

The laboratory shall have written procedures for minimizing the risk of contamination, monitoring of environmental conditions, cleaning and decontaminating facilities and equipment. See also *ENFSI Guideline(5)*.

Laboratory facilities shall be designed to provide:

- controlled and limited access to ensure the integrity of items/samples, data and equipment is not compromised;
- separation between reference items/samples and crime scene items/samples during processing as well as separation of pre-PCR and post-PCR procedures, either spatially or temporally. See *ENFSI Guideline(5)*; and
- appropriate storage conditions to prevent deterioration, contamination and loss of items/samples. See *ENFSI BPM(3)*.

4.2.3 Equipment

The laboratory shall:

- use equipment that are suitable for the forensic analysis. See *ENFSI BPM(3)*;
- have a documented programme to ensure that instruments are properly maintained and calibrated. Such events shall be recorded in traceable logs;
- use, where available and appropriate, standards traceable to national or international standards, for calibration; and
- evaluate periodically suppliers of critical instruments, reagents and consumables according to the laboratory's evaluation procedures.

The laboratory should consider using suppliers of critical reagents and consumables that adhere to requirements in ISO 18385 (Minimizing the risk of human DNA contamination in products used to collect, store and analyze biological material for forensic purposes – Requirements).

The laboratory can also consider consumable batch testing, ETO treatment or gamma radiation treatment according to internal procedures.

4.3 Process requirements

4.3.1 Selection, verification and validation of methods

The laboratory shall use validated methods and procedures. See *ENFSI BPM(3)* and *ENFSI Guideline(6)*.

4.3.2 Handling and sampling of items

See *ENFSI BPM(3)*.

4.3.3 Chain of custody and traceability

The laboratory shall have SOPs to ensure the integrity of physical items/samples and data.

These SOPs shall require that:

- Items and samples have a unique identification.
- The chain of custody for all items/samples processed in the laboratory is documented.
- Where possible, the laboratory retains a portion of the item, sample, or extract, for additional/further testing. If the complete item/sample or extract is used in the analysis, this shall be traceable.

4.3.4 Subcontracting/Outsourcing of analytical testing

The laboratory shall ensure that the sub-contractor meets the quality requirements defined by the laboratory through a supplier evaluation procedure and this shall be recorded. Before subcontracting/outsourcing, the laboratory should consider:

- 1) where possible, a sub-contractor accredited under ISO 17025 for the intended, outsourced activity;
- 2) how sensitive genetic data are transferred/handled;
- 3) whether DNA material will be conserved; and
- 4) national legislation requirements.

Importantly, any outsourced activity shall be clearly mentioned in the laboratory report.

4.3.5 Technical guidelines for STR profiling systems

- All methods, kits, critical reagents, instruments or software, including probabilistic software, should be validated/verified. See *ENFSI Guideline(6)*.
- Significant/critical changes to the specified conditions and equipment affecting the validity of results should be validated/verified. See *ENFSI Guideline(6)*.
- STR systems which include the European Standard Set (ESS) of loci are recommended for STR typing for national DNA databases and European/Interpol DNA Data exchange. See *ENFSI BPM(3)* and *ENFSI Guideline(8)*.

4.4 Ensuring the validity of results

The laboratory shall have a procedure for monitoring the validity of results. Such procedure could include the use of quality controls (Refer to Table 1). If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action shall be taken to prevent incorrect results from being reported.

Table 1: Recommended quality controls for laboratory activities

Laboratory Activity/Test	Recommended Quality Control
Searching for traces using a forensic light source or specific detection reagents	Conduct search on positive (and negative as appropriate) controls. The positive control shall be traces of known body fluids.
Characterization of biological material	Verify new reagent lots before use, which may include using positive/negative controls. The positive control shall be a trace of known body fluid.
Recovery/extraction of DNA	Use positive/negative controls concurrent with testing. The laboratory may decide the type of biological material of a known source(s) used for positive controls.
DNA quantification	Use positive/negative controls concurrent with testing. The positive controls shall be DNA of known quantity e.g. DNA standards.
Autosomal and Y-STR analysis	Use positive/negative controls concurrent with testing. The positive control shall be DNA with known autosomal/Y-STR profile.
Mitochondrial DNA (mtDNA) analysis	Use positive/negative controls concurrent with testing. The positive control shall be DNA with known mtDNA variations.
Massively Parallel Sequencing (MPS)	Use positive/negative controls concurrent with testing. The positive control shall be DNA with known sequence.
Rapid DNA system	Verify new reagent lots before use, which may include using positive/negative controls. The positive control shall be DNA with known autosomal profile.

Note:

- 1) *Positive/negative controls shall be processed according to the same SOP used for the unknown traces/items/samples.*
- 2) *Verification of reagent lots may be performed more frequently, as deemed fit by the laboratory, e.g. depending on the performance of the reagent.*

4.4.1 Monitoring and trend analysis

Monitoring and trend analysis is the collection and analysis of data over time to detect performance deviations from specified criteria. It serves as a proactive measure to allow the laboratory to assess and improve laboratory activities.

To perform trend analysis, the laboratory shall keep records of data obtained in the monitoring activities. The recorded data shall be reviewed to detect trends and variations that might affect the results obtained by the laboratory. Such trends and variations impacting the results should be addressed and the actions taken should be documented.

Trend analysis can be performed on 1) quality control (QC) data, and 2) quality issues.

1) QC data

QC data reflects test performance which includes test efficiency and accuracy. In the immediate term, QC data can indicate the acceptability of casework sample results, while longer-term QC data monitoring may shed insights on systematic issues in laboratory activities.

Before analysing QC data for trend detection, performance indicators and their corresponding pre-defined criteria should be established, which could be based on verification/validation and/or empirical data. Such data represent the expected performance from laboratory activities.

Examples of performance indicators include DNA yield from extraction controls; quantification controls; R^2 and slope value from quantification; peak heights from amplification controls; peak heights from capillary electrophoresis (CE) ladders. Examples of pre-defined criteria include upper and lower limits (template DNA quantity); minimum peak height; baseline and threshold; and expected results/profiles for controls. For the comparison against pre-defined criteria, the laboratory may employ different methods, e.g. frequency plot and statistical analysis.

A non-exhaustive list of recommended performance indicators and criteria for each process is shown in Table 2.

Table 2: Recommended performance indicators and criteria

Process	Performance indicator(s)	Data	Trend analysis
Search for traces	Positive/negative controls on cloth, made from known material	- Results of controls tested	Frequent failure of controls may indicate that the light source has lost its detection capacity and/or is malfunctioning.
Characterization of biological material	- Checks of new reagent lots before use - Kit internal positive controls	- Results of checks - Internal control pass/failure	Frequent failure of checks and/or controls may indicate reduced quality of the reagent/kits

Table 2 (continued)

Process	Performance indicator(s)	Data	Trend analysis
Recovery/extraction of DNA	- Positive and negative extraction controls	- Quantitation data of positive and negative controls	Frequently having values for negative controls or low values for positive controls may indicate inefficiency of instruments/reagents/operator
DNA quantitation	- NTC (neg control) - R ² - Slope	- Unexpected Quantitation data of NTC - Unexpected values of R ² and slope	Frequently having unexpected values for NTC is an indication of recurrent contamination Frequent failure of R ² and slope may indicate inefficiency of equipment/operator
Autosomal and Y-STR analysis	- Positive and negative amplification controls, ladders	- Peak heights of positive and negative controls and ladders and allelic calls of ladders	Frequent presence of peaks for negative controls for contamination detection or low values of positive controls or ladders incorrect allele calling (including intra/inter locus balances) may indicate inefficiency of equipment/reagents/operator
mtDNA analysis	Use of blank control samples Use of positive controls	Negative controls Positive controls	Negative controls for contamination detection Positive control for amplification and CE performance
MPS	Use of blank control samples Use of positive controls	Negative controls Positive controls mean reads	Negative controls for contamination detection and variations of analytical threshold Positive control for amplification and MPS performance

Rapid DNA system	Testing of new lot of reagents before use	Negative controls Positive controls	Negative control from new lot testing for contamination detection Positive control for instrument performance
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2) Quality issues

Trend analysis can also be performed on tracked quality issues such as:

- 1) the frequency and types of contamination,
- 2) errors found during (peer) review and in reports,
- 3) failures in proficiency testing,
- 4) non-conformity findings, and
- 5) performance indicators of equipment.

The laboratory can assess these quality issues to identify possible systematic and/or human error, to allow the laboratory to take appropriate actions for improvement/risk management.

4.4.2 Proficiency testing

The laboratory shall participate regularly in a proficiency testing programme that covers the scope of the laboratory's accreditation. The laboratory shall maintain the records generated for proficiency tests participation. See *ENFSI BPM(3)*.

If the laboratory is involved in multi-disciplinary activities, it is recommended to include these aspects in the proficiency testing or collaborative exercise programme.

4.4.3 Risk assessment and opportunities

Risks and opportunities shall be identified by the laboratory and actions to address these should be in place as a procedure for achieving improved results, preventing negative effects and increasing the effectiveness of the management system of the laboratory. See *ENFSI Guideline(9)*.

The laboratory shall decide which risks and opportunities need to be addressed and actions required should be planned, implemented and evaluated, as part of its quality management system. Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results.

Note 1: Although this document specifies that the organization plans actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. The laboratory can decide whether to develop a more extensive risk management methodology than is required by this document, e.g. through the application of other guidelines or standards.

Note 2: To further improve the quality of the forensic services, it is advisable for the organization to adopt a risk-driven approach:

In a risk-driven organization, risks are proactively identified. How risks can be eliminated/reduced is investigated, and measures for improvement are introduced by using for example the PDCA cycle (Plan, Do, Check and Act).

This is a systematic process for gaining valuable learning and knowledge for the continual improvement of a product, process, or service. The cycle begins with the Plan step (identifying a goal or purpose, formulate a theory or putting a plan into action). In the Do step the components of the plan are implemented. In the Check (Study) step outcomes are monitored to test the validity of the plan for signs of progress and success, or problems and areas for improvement. The Act step closes the cycle, integrating the learning generated by the entire process, which can be used for example to adjust the goal (Plan step). These four steps can be repeated over as a cycle of continual learning and improvement.

4.4.3.1 Risk assessment

The laboratory should have a written procedure regarding risk assessment including in which circumstances risk assessment is needed e.g. introduction of new technology, change in existing technology, multi-disciplinary approach in case work as well as the frequency of repeated risk evaluation.

The laboratory should prioritize which risks to address through various methods. Examples of such methods:

- identifying and avoiding threats
- accepting evaluated risks to pursue opportunities
- eliminating risk sources
- reducing the likelihood of occurrences
- reducing the severity of consequences
- sharing risks
- retaining risks by informed decision

Actions required to assess and address risks should be planned, implemented and reassessed, as part of the laboratory's quality management system. For example, the laboratory could follow the following steps:

1. Identify potential risks.
2. Determine potential root causes.
3. Assign every risk a priority based on but not limited to the frequency of occurrence, the impact and likelihood of detection.
4. Assign a timeframe for managing potential risks according to the laboratory's risk assessment strategy.
5. Assess the effectiveness of measures taken.

There are many risk assessment approaches/tools that the laboratory may adopt. This document only provides examples of some.

Root Cause Analysis (RCA) may be used to improve procedures / methods and describe possible solutions for removing or minimizing identified risks. Five steps can be distinguished in the RCA process:

1. Describe the uncertainty or risk
2. Collect data.
3. Determine the root cause.
4. Recommend a solution or measure.
5. Evaluate and record the effectiveness of the measures taken.

“**Ishikawa (Fishbone) Diagram**” (Fig. 1), **Bow Tie**, or/and the “**Multiple Why’s technique**” (Fig. 2) can be used for RCA.

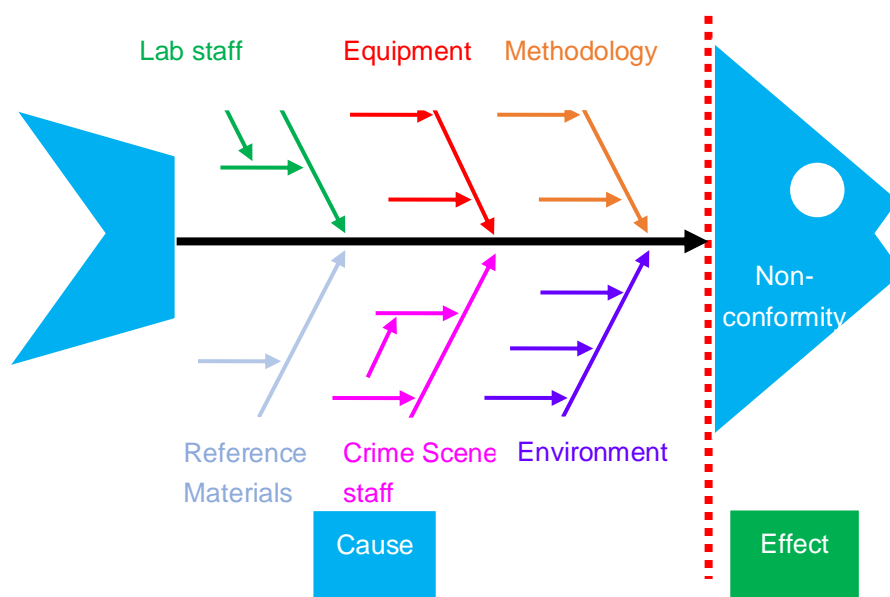


Figure 1. Ishikawa (Fishbone) Diagram.

The fishbone diagram facilitates the evaluation process for the identification of possible root causes of negative effects, i.e. non-conformities. Each diagonal fishbone represents a major variable or component of a process where potential risks (indicated by the smaller fishbones) can negatively impact the process either independently or collectively leading to the same negative effect or non-conformity.



Figure 2. Multiple Why's technique.

The Multiple Whys approach also facilitates the evaluation process for the identification of possible root causes of negative effects, i.e. non-conformities. Each consecutive Why/question provides explanations as to the sequence of risks that manifested and lead to the non-conformity.

A non-exhaustive list of potential identifiable risks as well as procedures that should be implemented are described in Table 3. Examples of potential risks that may be assessed are also described in the *ENFSI BPM(3)*.

Table 3: Examples of potential risks and their management

Source of Risk	Mitigation Action	Integration/ Implementation of Action	Evaluation/ Measurement of Action's Effectiveness
Contamination in the lab (staff, reagents)	Elimination database, QA samples	Training, SOP	Trend analysis
Contamination in crime scene	Elimination database	Training	Trend analysis
Inappropriate handling of and compromised test items before their submission to the lab	Guidelines for collection, storage and packaging of items, to collaborating authorities and assuring chain-of-custody	Training	Trend analysis

Table 3 (continued)

Source of Risk	Mitigation Action	Integration/ Implementation of Action	Evaluation/ Measurement of Action's Effectiveness
Delay in reporting results due to e.g. backlog	Item/case prioritization	Training of mandating authorities Issuing guidelines Communication with mandating authorities Possible sub-contracting	Trend analysis
Inappropriate use of Methods, software and procedures leading to invalid results	Internal validation, competency reassessment	Training of staff, SOPs	Proficiency tests
Loss of electronically stored primary data	Back up, effective IT policies & procedures to minimize and/or retrieve data loss	SOP	Trend analysis
Compromised Facilities and environmental conditions	Safety measures e.g. controlled access, Contamination control of equipment and lab areas	SOP	Trend analysis
Insufficient Quality & quantity of resources	Procurement criteria	SOP	Trend analysis
Equipment & software malfunction-downtime consequences	Preventive maintenance schedule, back-up equipment or manual protocols	SOPs, Preventive Maintenance contract, calibration	Trend analysis

Table 3 (continued)

Source of Risk	Mitigation Action	Integration/ Implementation of Action	Evaluation/ Measurement of Action's Effectiveness
Error and bias in reporting interpretation and opinions	Training and peer review	SOPs	Trend analysis
Staff Inappropriate training or loss of competence	Training and specific authorizations	SOPs, continuous competence monitoring	Participation in proficiency tests, collaborative exercises
Loss of Impartiality	1) Impartiality policy, agreement and disciplinary action. 2) Access given only to information required to implement assigned tasks. 3) Quality control procedures, peer review of data and reports.	SOP, signed agreements	Trend analysis
Confidentiality Breach	1) Confidentiality policy, agreement and disciplinary action. 2) Access given only to information required to implement assigned/agreed tasks. 3) All staff should attend GDPR training. 4) Restricted access and supervision of students, visitors in areas where confidential data are stored and processed. 5) Guard patrol &/or CCTV cameras of premises on a 24/7 basis.	SOP, signed agreements	Trend analysis

Table 3 (continued)

Source of Risk	Mitigation Action	Integration/ Implementation of Action	Evaluation/ Measurement of Action's Effectiveness
Overlooking/ damaging traces of other disciplines on testing items during searching	Interdisciplinary training, competence testing, Internal procedure describing how to proceed in case of finding traces of disciplines not requested	SOPs, continuous competence monitoring	Trend analysis

Note: The above measures described could also be part of a Business Continuity Plan of an organization.

4.4.3.2 **Actions to address opportunities for improvements**

The laboratory shall have a procedure to address opportunities for improvements. Such procedure includes identifying potential improvements, integrating and implementing such improvements into the management system, and evaluating their effectiveness in relation to laboratory activities. This is intended to lead to overall improvement and customer satisfaction and to give assurance that the laboratory management system achieves its intended objectives.

Opportunities for improvement can be identified through e.g. review of the operational procedures, use of the policies, overall objectives, audit results, corrective actions, management review, suggestions/brainstorming from staff, risk assessment, analysis of laboratory data, customer satisfaction surveys and proficiency testing results.

Table 4: Examples of potential opportunities and their management

Source of Opportunity	Action	Integration/ Implementation of Action	Evaluation/ Measurement of Action's Effectiveness
New technology to allow expansion of scope of accreditation to provide new services	Procure and validate equipment. Develop and validate new methods and seek accreditation	SOPs, training, new equipment	Measure the overall improvement in the services provided by laboratory & customer satisfaction in the management review
Strategic staff planning and Professional development	provide new challenges, long term planning with advanced/evolving competencies, participate in training programmes	Training Hiring of new staff from different disciplines to support innovation	Measured by performance appraisal, wellbeing, Measure the overall improvement in the services provided by laboratory in the management review
Networking with other forensics institutes to exchange expertise and attract new customers	Establish collaborations for common objectives e.g. Participate in scientific meetings, collaborative exercises	Assign competent staff, delegate duties and time frames	Measure the overall improvement in the services provided by laboratory. Assess the increase in service output.

Table 4 (continued)

Source of Opportunity	Action	Integration/ Implementation of Action	Evaluation/ Measurement of Action's Effectiveness
Networking with other forensics institutes to exchange expertise	Establish collaborations for common objectives and exploit grant opportunities	Assign competent staff, delegate duties and time frames	Assess the deliverables and milestones
Adopt state-of-the-art high throughput automation and digitalization in the laboratory	Robotics, LIMS	SOP, training, new equipment	Measure the overall improvement in the services provided by laboratory, improving turn-over time through management review

4.5 Interpretation and reporting of results

The laboratory shall have written procedures for interpretation and reporting of results, and for the conclusions and opinions derived from them, as applicable. These procedures should fulfil the requirements of the ISO 17025 standard as well as the recommendations of the *ENFSI BPM(3)*.

Conclusions are statements based on objective findings and scientific data, and are logically derived from them. The laboratory procedures for the interpretation of results should be derived from internal validations of the laboratory.

In contrast, opinions are statements expressed by the DNA expert based on professional experience in combination with available relevant, peer-reviewed literature and/or case relevant experiments. The laboratory should determine when it is appropriate to express opinions and should have specific procedures available. If an opinion is included in a written report, it shall be clearly differentiated, and the information that led to that opinion shall be clearly stated.

Results, opinions and interpretations expressed in reports shall be based on the results obtained from the tested item and shall be clearly identified as such within the report.

4.6 Management system

The laboratory management shall establish, implement and maintain a quality management system appropriate to the scope of its laboratory activities, including the type, range and volume of the testing the laboratory undertakes. The laboratory management shall document its policies, systems, programmes, procedures and instructions, to the extent necessary to enable the laboratory to assure the quality of tests it carries out. This documentation shall be readily available to all appropriate staff involved in its implementation.

The laboratory shall continually improve the efficiency and effectiveness of its management system through e.g. the use of the quality policy, quality objectives, audit results, trend analysis of quality controls, proficiency tests, management of non-conformities, corrective actions, risk-based thinking and management review.

4.7 Internal audits

The laboratory shall conduct regular audits at planned intervals for all aspects of the DNA workflow, including administrative and technical aspects. They shall be scheduled in a documented programme taking into consideration all requirements of ISO 17025 and the National Accreditation Body.

Additionally, such planning should consider potential risks and their management. If the laboratory is involved in multi-disciplinary activities, such aspects should be included in the internal audit programme.

Internal auditors should be objective, appropriately trained according to the laboratory's policies in conducting internal audits in accordance with ISO 17025 standard and be independent of the activities being audited as far as possible to avoid bias. Their competence should be monitored according to the laboratory's policy.

The laboratory shall retain the relevant documentation regarding the audits, including any remedial or corrective actions taken, in accordance with the laboratory's policies and procedures.

4.8 Management of non-conformities

Whenever discrepancies or deviations from procedures, including Laboratory Information Management System (LIMS) failures, which may constitute a risk for the validity of the laboratory results are detected, the laboratory shall implement corrective actions according to its internal procedures within a defined time frame.

The laboratory shall maintain documentation for the corrective action which should include details such as nature of discrepancy/deviation/complaint, the extent and impact, control of non-conforming testing, details of improvements and risk analysis.

4.9 Quality management review

The management of the laboratory with executive responsibility shall periodically (for example once every 12 months) conduct a review of the laboratory's quality management system and testing activities to ensure their continuing suitability and effectiveness and to introduce any necessary changes or improvements. The quality management review shall include all aspects mentioned in the ISO 17025 standard.

Findings from the management reviews and the remedial/corrective/mitigation actions taken, shall be recorded. The management shall ensure that those actions are addressed within an appropriate and agreed time frame.

5. HEALTH AND SAFETY

The laboratory shall have a documented environmental health and safety programme as documented in the *ENFSI BPM*(3).

6. REFERENCES

- (1) EN ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories.
- (2) European Council framework Decision 2009/905/JHA of 30 November 2009 on Accreditation of forensic service providers carrying out laboratory activities. Available at: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32009F0905>
- (3) DNA-BPM-003, ENFSI BPM for Human Forensic Biology and DNA Profiling, version 001, December 2022. Available at www.ENFSI.eu.
- (4) DNA-GDL-001, ENFSI Guideline for the training of staff in Forensic DNA-Laboratories, version 002, 05/03/2022 . Available at www.ENFSI.eu.
- (5) DNA-GDL-003, ENFSI DNA Contamination Minimization Guideline for DNA Laboratories, version 003, 05/10/2023 . Available at www.ENFSI.eu.
- (6) DNA-GDL-002, ENFSI Guideline for internal validation/verification of various aspects of the DNA profiling process, version 001, 10/05/2023 . Available at www.ENFSI.eu.
- (7) Council Resolution of 30 November 2009 on the exchange of DNA analysis results 2009/C 296/01 ESS extension. Available at: [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32009G1205\(01\)](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32009G1205(01))
- (8) DNA-GDL-004, ENFSI Guideline on DNA-Database Management Review and Recommendations, version 001, 05/10/2023. Available at www.ENFSI.eu.
- (9) ENFSI Guideline for Risk Management (to be published)

Other useful references:

- (10) ENFSI Guideline for Evaluative Reporting in Forensic Science, version 3.0, 08/03/2015. Available at www.ENFSI.eu.
- (11) Guideline for the internal validation of probabilistic software to undertake DNA mixture interpretation. (In preparation)
- (12) European Council Decision 2008/616/JHA of 23 June 2008 on the implementation of Decision 2008/615/JHA on the stepping up of cross-border cooperation, particularly in combating terrorism and cross-border crime. Available at: <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1481187358403&uri=CELEX:32008D0616>
- (13) European Council Resolution of 9th June 1997 on the exchange of DNA analysis results (97/C 193/02). Available at: [http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1500304564609&uri=CELEX:31997Y0624\(02\)](http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1500304564609&uri=CELEX:31997Y0624(02))
- (14) ILAC-G19:06/2022 Modules in a Forensic Science Process. Available at www.ilac.org.

- (15) ISO 18385:2016, Minimizing the risk of human DNA contamination in products used to collect, store and analyze biological material for forensic purposes – Requirements.
- (16) ISO 21043-1:2025, Forensic sciences – Part 1: Vocabulary
- (17) ISO 21043-2:2018, Forensic sciences – Part 2: Recognition, recording, collecting, transport and storage of items
- (18) ISO 31000:2018, Risk management – Guidelines
- (19) ISO 31010:2019, Risk management – Risk assessment techniques
- (20) ISO 9000:2015, Quality management systems – Requirements
- (21) SWGDAM - Quality Assurance Standards for Forensic DNA Testing Laboratories, 1/07/2025. Available at: www.swgdam.org/publications.

7. AMENDMENTS AGAINST PREVIOUS VERSION

This document replaces the ENFSI Quality Assurance Programme For DNA Laboratories Issue No. 016 (April 2010).