1. INTRODUCTION

1.1.1 This appendix provides further explanation of some of the requirements of the Codes of Practice and Conduct for Forensic Science Providers and Practitioners in the Criminal Justice System (the Codes), Forensic Science Regulator (2014), specifically pertaining to the provision of DNA analysis and is therefore primarily intended for laboratory managers and staff involved in the examination of DNA evidence.

1.1.2 This appendix should be read alongside the Codes, BS EN ISO/IEC 17025:2005 and ILAC-G19 2002¹ and will generally follow the heading titles used in the Codes with cross references to ISO/IEC 17025:2005 given in parentheses where appropriate.

2. SCOPE

2.1.1 This appendix provides further explanation of some of the requirements of the application of the Codes specifically pertaining to the detection, recovery, analysis and the use of the DNA evidence.

2.1.2 The requirements are for all short tandem repeat (STR) based analyses and other chromosomal or mitochondrial DNA analyses conducted for the criminal justice system, whether performed in a conventional DNA profiling laboratory or by an alternative analysis method elsewhere.

3. TERMS AND DEFINITIONS

3.1 The terms and definitions set out in the Codes apply to this Appendix. Terms and definitions employed in this Appendix are listed in the Glossary.

4. MODIFICATION

4.1.1 This is the first issue of this document.

5. IMPLEMENTATION

5.1.1 This appendix is available for incorporation into a providers’ quality management system from the date of publication. Compliance to the

¹ ILAC G19 has been extensively reviewed and an updated published version is awaited.
requirements set out in this appendix against the specified ISO/IEC 17025 clauses is effective from 1 April 2015 for ISO/IEC 17025 accreditation of DNA evidence for forensic use.

5.1.2 The Forensic Science Regulator requires that the Codes and this appendix are included in the providers’ schedule of accreditation by October 2017 as detailed in the Codes.

6. PACKAGING AND GENERAL CHEMICALS AND MATERIALS (ISO/IEC 17025:2005, 4.6)

6.1.1 It is critical for consumables and reagents used for recovery and analysis to have an absence of detectable human DNA; quality assurance testing can be in the form of batch testing to demonstrate successful clean production standards, a validated technique of post-production treatment, or both.²

6.1.2 The limit of detection chosen for any testing must be equal to, or more sensitive than, the procedures that the consumables and critical reagents are to be used in.

6.1.3 All testing must be traceable and the results available for disclosure. The use of potentially misleading phrases such as ‘DNA-free’ and ‘DNA-clean’ should be avoided, phrases such as ‘forensic science grade’ or ‘polymerase chain reaction (PCR) grade’ would be acceptable alternatives provided that the exact nature of the test is disclosed.

6.1.4 Any detected or reported problems with packaging or materials already in the evidential chain will require an appropriate risk or case assessment.

² This can be demonstrated by consumable manufacturers and kit assemblers meeting the requirements set out in the publicly available specification (PAS) 377:2012 Specification for consumables used in the collection, preservation and processing of material for forensic analysis – Requirements for product, manufacturing and forensic kit assembly.
7. CONTAMINATION AVOIDANCE, MONITORING AND DETECTION (ISO/IEC 17025:2005, 5.3.3, 5.8)

7.1.1 The forensic science provider shall have policies and procedures to ensure that access to laboratory areas is restricted to individuals covered by an adequate elimination database. See section 10.

7.1.2 Elimination databases\(^3\) should include all those who are associated with the collection/recovery of evidence, its analysis, and the processing environment, including staff, visitors and sub-contractors who have access to areas where these activities occur.

7.1.3 Policies and procedures for elimination databases of laboratory staff, visitors and equipment suppliers should include, but are not limited to:

a. reporting policies;

b. data formats;

c. searching procedures and algorithms;

d. retention periods;

e. sharing agreements (i.e. between laboratories/providers);

f. agreements/consents; and

g. release forms.

7.1.4 Casework DNA analysis laboratories shall maintain a log of negative (blank/no template) control results to record drop-in and gross contamination events. The purpose will be to act as a monitoring tool and also to provide data that may be used in probabilistic models for reporting purposes.

7.1.5 Any detected or reported contamination problems with packaging or materials already in the evidential chain will require an appropriate risk or case assessment.

\(^3\) See FSR-P-302 DNA contamination detection - The management and use of staff elimination DNA databases.
8. **SELECTION OF METHODS** (THE CODES, 17; ISO/IEC 17025:2005, 5.4.2)

8.1.1 It is expected that all providers to the criminal justice system shall use a validated human specific quantification technique\(^4\) for casework samples,\(^5\) which is verified to demonstrate its limit of detection, limit of quantitation, accuracy, reproducibility and measurement of uncertainty appropriate to the sensitivity of the DNA profiling service offered.

a. The quantification method may also be capable of demonstrating whether PCR inhibition is likely to occur due to the nature of the tested sample. Where a quantification method is used that does not demonstrate whether PCR inhibition is likely, when a partial or no profile has been obtained then the possibility of inhibition should be explored.\(^6\)

b. If no profile or an unsatisfactory or unexpected result is obtained, the possibility of inhibition, contamination (by reference to elimination databases), degradation, or over amplification should be explored, and reworking considered and recorded.

c. In exceptional instances where in the professional opinion of the scientist a separate quantification step normally required in a protocol is not advisable or not required, this should be clearly communicated to the customer and recorded.\(^7\)

8.1.2 The interpretation method\(^8\) using qualitative or probabilistic techniques (or a combination of the two) should include consideration of:

a. allele drop-in;

b. allele drop-out;

---

\(^4\) Validated methodologies such as direct polymerase chain reaction (PCR) are acceptable; however such methodologies should also cover the issue of potential inhibition, etc. covered in 8.1.1a–c.

\(^5\) A casework sample is biological material believed to be related to a crime. Samples from individuals (i.e. reference samples) are not considered to be casework samples.

\(^6\) Policies may require this routinely or only when the quantification value indicates an unexpected profiling result.

\(^7\) Such instances include where the amount of available evidential material is considered in the professional opinion of the scientist to be so low that using some of the material risks the ability to obtain an interpretable profile.

\(^8\) See FSR-G-202 *The interpretation of DNA evidence (including low-template DNA)*, 2012.
c. gross-contamination;

d. stochastic characteristics, and if used, any associated thresholds or triggers such as heterozygote balance relative to peak height, area or DNA quantity;

e. stutter and artefactual peak characteristics;

f. mixtures of two or more individuals; and

g. methodology for reporting a single test result or replicate analyses as a single figure, for example, likelihood ratio.

9. VALIDATION OF METHODS (THE CODES, 20.2; ISO/IEC 17025:2005, 5.4.5)

9.1.1 The validation procedure contained in the Codes will be followed whether this is an adopted method that has been developed and validated elsewhere or developed at a laboratory of the provider. The Codes allow for tailoring of the validation procedure through verification of the extent and scope of supporting external validation studies.

9.1.2 The validation procedure shall be expected to include, but is not limited to:

a. a determination of the end-user’s requirements;

b. risk assessment of the method;

c. a review of the end-user’s requirements and specification;

d. the acceptance criteria;

e. development plan;

f. the validation plan;

g. the outcomes of the validation exercise;

h. assessment of acceptance criteria compliance;

i. validation report;

j. statement of validation completion; and

k. implementation plan.
Validation of measurement based methods (the Codes, 20.8)

For DNA methods the parameters/characteristics in the validation plan shall include, as appropriate:\(^9\)

- equipment calibration/performance, reagents, reference materials, consumables;
- characterisation of the genetic markers (mode of inheritance, chromosomal location, detection mechanism, polymorphism);
- species specificity (human/non-human, targeted species);
- sensitivity (for example, limits of detection, quantitation and/or the range of DNA quantity that will produce reliable results with reference to stochastic effects);
- contamination;
- matrix and substrate effects;
- interferences and cross-sensitivities;
- stability (for example, to environmental and chemical factors);
- repeatability and reproducibility;
- ruggedness/robustness;
- performance variation between representative case type materials;
- population studies (databases, independence);
- effect of mixtures on obtaining reliable results;
- precision;
- accuracy (measurement standards);
- measurement uncertainty;
- match criteria;

r. PCR conditions (thermocycling parameters, concentration of primers, magnesium chloride, DNA polymerase, etc.) and preferential amplification/co-amplification; and

s. post-PCR treatments, electrophoresis and detection parameters.

10. DATABASES (THE CODES, 20.18.4; ISO/IEC 17025:2005, 5.4.7)

10.1.1 Laboratories shall maintain local databases of profiles detected from batch testing reagents and negative (blank/no template) controls as a way of detecting contamination events as part of an integrated elimination database.

10.1.2 Elimination databases may be locally or remotely maintained. Laboratories may maintain local DNA databases of volunteers for staff, visitors, suppliers and subcontractors. See FSR-P-302, DNA contamination detection: The management and use of staff elimination DNA databases.

10.1.3 Laboratories shall utilise, as required, DNA allele frequency and haplotype (for example, mitochondria, Y chromosome) databases constructed without identifiable individuals. They should be relevant to the issues on which an interpretation of the significance of the evidence is based. Any limitations on their use shall be documented and revealed alongside any interpretation or opinion provided.

10.1.4 Other databases (subject to acting within the law) may be held as directed by the customer as the data owner (such as for intelligence led screens) or the Forensic Science Regulator (for quality assurance checks, such as batch to batch for casework contamination checks).

11. REVIEW

11.1.1 This document is subject to review in accordance with the Codes [A] and other appendices.

11.1.2 If you have any comments please send them to the address as set out on the Internet site at www.gov.uk/government/organisations/forensic-science-regulator or email: FSREnquiries@homeoffice.gsi.gov.uk
12. REFERENCES


13. **ABBREVIATIONS**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>DNA</td>
<td>Deoxyribonucleic Acid</td>
</tr>
<tr>
<td>ISO</td>
<td>International Organization for Standardization</td>
</tr>
<tr>
<td>PCR</td>
<td>Polymerase Chain Reaction</td>
</tr>
<tr>
<td>STR</td>
<td>Short Tandem Repeat</td>
</tr>
<tr>
<td>SWGDAM</td>
<td>Scientific Working Group for DNA Analysis Methods</td>
</tr>
</tbody>
</table>

14. **GLOSSARY**

**Casework sample**: Biological material of unknown origin believed to have originated from a person of interest (perpetrator or victim) that may connect them to a specific crime event.

**DNA analysis**: The processes of DNA recovery (includes sampling and extraction), quantitation, amplification, separation, sequencing, designation, data analysis and profile interpretation.

**DNA evidence**: Evidence provided to an investigating agency, prosecuting authority or court that sets out the results of DNA analysis or the relevance of such results in the context of a criminal prosecution. It covers any material seized as evidence with the intention that it be subjected to DNA analysis.

**Elimination database**: Collection of DNA profiles held in a searchable format from staff whose access/role/activities are deemed to be a potential DNA contamination risk. The profiles are used to identify instances of inadvertent contamination.

15. **FURTHER READING**

