



LAB32

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Accreditation for Suppliers to the UK National DNA Database

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CHANGES SINCE LAST EDITION

This is a significant re-write to incorporate changes in the positioning of the Custodian of the National DNA Database (NDNAD) within the National Policing Improvement Agency (NPIA) and provide clarity to Forensic Suppliers with respect to which activities in the process are subject to compliance with Lab 32.

1 INTRODUCTION

- 1.1 Laboratories that have been assessed by UKAS as meeting the requirements of ISO/IEC 17025 *General Requirements for the Competence of Testing and Calibration Laboratories* may be granted UKAS accreditation. Several publications providing guidance on the application of these requirements are listed on the UKAS website (www.ukas.com).
- 1.2 This publication has been prepared by UKAS in collaboration with the NPIA's NDNAD Delivery Unit (NDU) which is responsible for the delivery of the NDNAD. It sets out how the requirements ISO/IEC 17025 shall be applied to organisations undertaking DNA analysis for the purpose of submitting data to the NDNAD. It does not cover all the requirements of ISO/IEC 17025, which remains the authoritative document.
- 1.3 It should be noted that the scope of the agreement relates only to laboratories that have been or wish to be accredited to analyse samples and have been authorised to generate and load DNA profiles to the NDNAD. The agreement does not cover the search and recovery of body fluids.

2 REQUIREMENTS FOR SUPPLIERS TO THE UK NATIONAL DNA DATABASE

- 2.1 The Criminal Justice and Public Order Act 1994 amends the Police and Criminal Evidence Act (PACE) 1984 and sets out the general conditions under which DNA samples could be taken, used, retained and speculatively searched against samples from unsolved crimes. Following on from this, the Home Office has published circular 16/95, which sets out the arrangements for the analysis of DNA samples, and the management and use of the NDNAD.
- 2.2 The amended PACE legislation allows for non-intimate samples to be taken for the purposes of DNA profiling from anyone suspected of involvement in a recordable offence, and for the profiles obtained to be checked against existing records of unsolved crime stains in a speculative search.
- 2.3 Custodianship of the NDNAD is established through the overall Governance arrangements for oversight of the Database. The NPIA, through the NDU, is accountable to the NDNAD Strategy Board for delivery of operational NDNAD services, the setting and maintenance of Forensic Supplier standards and maintenance of NDNAD quality and integrity.

- 2.4 All Forensic Suppliers that are accredited to load DNA profiles to the NDNAD are required to use documented protocols that are acceptable to the NDU.
Forensic Suppliers shall also:-
- demonstrate to the NDU that they are competent and able to produce profiles that are compatible with those on the NDNAD
 - adopt internal handling processes and procedures that conform to the rules of continuity and preservation of evidence
 - carry out an internal quality assurance program in accordance with the specification set by the NDU
 - be UKAS accredited for their profiling services
- and
- be registered under the Data Protection Act.
- 2.5 The agreement that exists between the NDU and UKAS provides for UKAS to incorporate the additional requirements of the NDU set out in the relevant NDU Quality Management System (QMS) documents, into the assessment and accreditation process for laboratories acting as Forensic Suppliers, or intending to apply for approval to act as Forensic Suppliers of profiles to the NDNAD. The application process for new Forensic Suppliers shall be initiated in writing by each Forensic Supplier to both the NDU and UKAS. Copies of the NDU QMS documents are available to prospective Forensic Suppliers by request to the NDU. Both existing and applicant Forensic Supplier laboratories are required to provide written authorisation to UKAS to disclose relevant information relating to assessment and accreditation to the NDU who may then forward this information to the NDNAD Strategy Board and/or the Office of the Forensic Science Regulator if required.
- 2.6 The Agreement made between the NDU and UKAS is given in Appendix A.

3 METHODS AND PROCEDURES

3.1 General Requirements

- (a) All laboratories supplying DNA profiles to the NDNAD shall meet the requirements of ISO/IEC 17025 and the additional requirements given in the relevant NDU QMS documents. Additional guidance given in other UKAS Publications should be followed except where alternative requirements and guidance are given in this publication.
- (b) UKAS and the NDU shall be informed as soon as changes to a laboratory's activities are planned. This includes changes such as, but not limited to, accommodation, equipment, protocols and/or key staff. UKAS and the NDU shall then evaluate the proposed change and determine the level of assessment required to ensure the continued accreditation status of the organisation.

3.2 Specific Methodology

- (a) Laboratories must have fully documented and validated procedures for carrying out all activities involved in analysis of forensic DNA samples where the profile may be loaded to the NDNAD. These shall be documented in accordance with ISO/IEC 17025 and the requirements of the NDU QMS documents. The documented procedures shall include sample receipt and handling, preparation of samples for DNA processing, laboratory techniques, and analysis and reporting of results.

- (b) A laboratory using accepted published methods shall have determined the performance characteristics of the method and shown its capability to meet the performance criteria described in the method, before accreditation is granted. Additionally, as per UKAS document TPS 47, laboratories preparing for accreditation are required to participate in Proficiency Testing or Inter-laboratory Comparison schemes before accreditation can be granted.
- (c) Specific methods developed in the laboratory shall be fully validated as specified in ISO/IEC 17025, and according to the specified NDU QMS documents before use. Further guidelines on validation of techniques for use in Forensic laboratories are detailed in ILAC G-19 Guidelines for Forensic Science Laboratories.
- (d) After approval, any subsequent changes to methods and procedures (examples of which are included in NDU QMS documents) shall be notified to both UKAS and the NDU before they can be used. The impact of any changes made to methods shall be fully assessed and the method revalidated as appropriate.

3.3 On-going Quality Control

- (a) As part of their quality systems, laboratories shall operate systematic quality control schemes to monitor day-to-day and batch-to-batch analytical performance of all the analysis undertaken.
- (b) Procedures shall incorporate the need to carry out repeat analysis in accordance with NDU requirements.
- (c) Procedures must also incorporate the requirement for validating/confirming prospective matches.

3.4 Retention of samples

Laboratories must operate a suitable system for retention of a part, or all samples where testing does not use the entire item, and for the destruction of samples all as required by current legislation and ACPO guidance.

Similarly, laboratories shall operate a suitable system for the deletion of profiles as required by current legislation.

4 ASSESSMENT PROCEDURES

- 4.1 Assessment shall follow the normal UKAS procedure as detailed in relevant UKAS Publications and shall aim to establish the laboratory's compliance with all of the requirements of ISO/IEC 17025, the NDU QMS documents, and any other relevant criteria of competence specified by UKAS.
- 4.2 In addition the assessment will include:
 - (a) the laboratory's reporting arrangements for supply of profiles to the NDNAD;
 - (b) arrangements for business continuity;
 - (c) storage of samples and their associated data, including suitability of the facilities, access and security;

- (d) vertical audit of samples selected at random to cover all aspects of analysis and reporting;
 - (e) confirmation that the laboratory is registered under the Data Protection Act;
 - (f) issues identified through performance monitoring by the NDU in the proficiency testing programme, the repeat analysis programme and the reporting of unexpected results;
 - (g) any aspect of the laboratory, its procedures, methods or staff that the assessment team considers necessary to confirm compliance with the requirements.
- 4.3 The granting and renewal of accreditation will be afforded only to a laboratory which continually complies with the above requirements.
- 4.4 The UKAS assessment team may include a member of staff from the NDU acting as a technical assessor.

5 MONITORING OF LABORATORY PERFORMANCE IN PROFICIENCY TESTING SCHEMES

- 5.1 The NDU has set out specific requirements for Forensic Suppliers of DNA profiles to the NDNAD to participate in a proficiency testing scheme as a condition of continued approval to load to the NDNAD. Laboratories are required to make available to UKAS assessors the data and results associated with the specified monitoring scheme (eg, declared, undeclared proficiency testing samples, duplication samples). Laboratory management should take steps to ensure that, wherever possible, declared proficiency tests are allocated in such a way that all staff involved in DNA analysis will, over a period of time, be included in the analysis of proficiency test samples. Continuing satisfactory performance, as defined by the scheme organisers, will be a condition for maintenance of accreditation for suppliers to the NDNAD. Where satisfactory performance is not achieved, the laboratory shall investigate the cause of the apparent poor performance. If necessary, accreditation and permission to load to the NDNAD will be suspended until such time as satisfactory performance, as determined by NDU and UKAS, has been resumed.
- 5.2 The NDU will inform the NDNAD Strategy Board where laboratories fail to satisfy the defined performance requirements. This may result in a removal of approval to load to the NDNAD.

6 SCOPE OF ACCREDITATION

- 6.1 The Schedule of Accreditation for a laboratory will describe the scope of accreditation in terms of materials tested, or types of test and method of test. Forensic Suppliers accredited to load profiles to the NDNAD will be confirmed as such by the use of the phrase: 'for the purpose of supply of profiles to the National DNA Database'. The phrase will be applied to subject samples and/or crime stain samples as appropriate. Additionally, the NDU will hold a Statement of Unit

Configuration (SoUC) for each individual unit within an organisation. Any changes that are required to the SoUC must be communicated to both the NDU and UKAS.

7 REFERENCES

ISO/IEC 17025:2005 *General Requirements for the Competence of Testing and Calibration Laboratories*.

Memorandum of Understanding between ACPO and Custodian of the National DNA Database, September 2005.

Custodian QMS documents (available to applicant suppliers, on request, from NDU).

8 GLOSSARY OF TERMS

ACPO	Association of Chief Police Officers
APA	Association of Police Authorities
Custodian	Responsible organisation for control, maintenance and delivery of NDNAD and related services
ILAC	International Laboratory Accreditation Cooperation
National DNA database Strategy Board	a tripartite board composed of ACPO, APA and the Home Office responsible for overseeing and directing the NDU and NDNAD activities
NPIA	National Policing Improvement Agency
NDNAD	National DNA Database
NDU	NDNAD Delivery Unit
PACE sample	DNA sample taken from an individual under Police and Criminal Evidence Act 1984
QMS	Quality management system
SoUC	Statement of Unit Configuration
UKAS	United Kingdom Accreditation Service
URL	Unexpected results log

APPENDIX A - Agreement between the Custodian of the National DNA Database® and the United Kingdom Accreditation Service

AGREEMENT

This agreement is effective on the date of signatures below, and replaces that made on 29 June 2001 between

- (1) The Custodian of the National DNA Database (NPIA)
- (2) The United Kingdom Accreditation Service (UKAS)

1 *Background*

- 1.1 The Criminal Justice and Public Order Act 1994 amends the Police and Criminal Evidence Act 1984 and set out the general conditions under which DNA samples could be taken, used, retained and speculatively searched against samples from unsolved crimes. Following on from this the Home Office published circular 16/95, which set out the arrangements for the analysis of DNA samples, and the management and use of the National DNA Database.
- 1.2 The amended PACE legislation allows for non-intimate samples, to be taken for the purposes of DNA profiling from anyone suspected of involvement in a recordable offence, and for the profiles obtained to be checked against existing records of unsolved crime stains in a speculative search.
- 1.3 Custodianship of the National DNA Database was established in a *Memorandum of Understanding* between The Association of Chief Police Officers (ACPO) and the Forensic Science Service (FSS) in 1995. This was updated in 2000, and again in 2003. At the end of 2005, Custodianship transferred from the FSS to the Home Office Forensic Science and Pathology unit, and a new MoU between the National DNA Database Strategy Board and the Custodian was put in place. The role of delivering the National DNA Database service is now overseen by NPIA. The NDU is the department within the NPIA responsible for the day to day delivery of the NDNAD and associated services.
- 1.4 Forensic Suppliers of DNA profiles to the NDNAD are required to conform to the standards, performance monitoring requirements, and service levels specified by the NDU. The NDU operates a scheme for the approval of Forensic Suppliers and their performance monitoring, which has been designed to reflect these requirements and to give the Custodian confidence in the quality of the data held on the NDNAD.
- 1.5 The United Kingdom Accreditation Service (UKAS) offers accreditation to ISO/IEC 17025 to laboratories for sampling and analysis activities. In collaboration with UKAS, the NDU has set out how the requirements of ISO/IEC 17025 shall be interpreted when applied to organisations undertaking all aspects of DNA analysis for the purposes of submitting data to the NDNAD. This agreement provides for UKAS to incorporate the additional requirements of the NDU set out in the NDU QMS documents into the assessment and accreditation process for laboratories acting as suppliers, or intending to apply for approval to act as Forensic Suppliers to the NDNAD.
- 1.6 NDU personnel may be used by UKAS as Technical Assessors as part of the team performing assessment visits to Forensic Suppliers to the NDNAD.

- 2 *Variation of agreement*
- 2.1 The terms of the Agreement may be varied at any time at the request of the NDU to reflect any relevant changes in legislation or authoritative guidance. The terms of the Agreement may also be varied at the request of either the NDU or UKAS subject to both the NDU and UKAS agreeing to the variation.
- 2.2 Laboratories will be notified of any changes by the NDU and/or UKAS as appropriate.
- 3 *Obligations on UKAS and the Custodian*
- 3.1 UKAS will comply with the general criteria for laboratory accreditation bodies laid down in ISO/IEC 17011:2004 evidenced by its continued status as a signatory to the EA (European cooperation for Accreditation) Multilateral Agreement.
- 3.2 All assessors appointed by UKAS to assess an organisation for DNA database purposes shall be appointed in accordance with the requirements of ISO/IEC 17011:2004.
- 3.3 UKAS shall perform assessments to the requirements of ISO/IEC 17011:2004 and will incorporate the technical requirements of the NDU as identified in UKAS Publication Lab 32. All laboratories shall therefore be subject to a full assessment against the requirements of ISO/IEC 17025 and Lab 32 (which incorporates the additional requirements of the NDU) and other relevant UKAS publications, before accreditation is awarded or reinstated following suspension of such accreditation.
- 3.4 In order to retain accreditation to ISO/IEC 17025 all laboratories shall be visited by UKAS annually. These visits shall normally be surveillance visits with a full reassessment every fourth visit, as defined in the agreement between UKAS and suppliers.
- 3.5 UKAS shall keep the NDU fully informed of all initial applications for accreditation related to the NDNAD, and of all awards, suspensions, revocations and voluntary withdrawals from accreditation related to the database. UKAS shall provide the NDU with details of the scope of accreditation of all laboratories who supply profiles to the NDNAD and will keep the NDU informed of their accreditation status. Prior to any initial assessment, the NDU shall provide UKAS with details of a laboratory's performance in relevant proficiency testing schemes and of any issues raised. Following the initial assessment visit UKAS will provide the NDU with details of any relevant non-conformances raised in order for the NDU to confirm compliance with the requirements of the approval scheme. At all subsequent surveillance and reassessment visits the NDU will provide UKAS with any relevant details relating to the laboratory's performance in relevant proficiency testing and performance monitoring schemes and following the visit UKAS will provide the NDU with details of any relevant non-conformances raised during the visit, in order for the NDU to confirm compliance with the requirements of the approval scheme.
- 3.6 UKAS shall provide the NDU with a schedule of proposed assessment and surveillance visits to all Forensic Suppliers. The NDU will then inform UKAS of any specific quality issues to be covered on their behalf during the assessment/surveillance visits.
- 3.7 The NDU shall inform UKAS of any recommendations it makes to ACPO about acceptance of new Forensic Suppliers or any agreed change in status of Forensic Suppliers.

3.8 The NDU and UKAS will inform each other of any changes in legislation, quality standards or its procedures which may affect this Agreement including the Schedules and Annexes to the Agreement. The NDU or UKAS will inform laboratories as appropriate.

3.9 UKAS and the NDU will meet periodically to discuss the status of all Forensic Suppliers and any other relevant issues.

4 *Implementation*

4.1 This Agreement will take effect from 1st September 2011 and replaces the agreement made on 29 June 2001.

5 *Payments*

5.1 All parties shall be responsible for their own costs and expenses incurred as a result of this Agreement.

6 *Termination*

6.1 This Agreement may be terminated without notice should either UKAS or the NPIA knowingly fail to meet any of its obligations under Clause 3.

6.2 This Agreement will apply throughout the period that the Custodianship of the NDNAD sits within the NPIA. It may be terminated by either UKAS or the NPIA giving six months notice or by mutual agreement.

7 *Liabilities*

7.1 The NPIA shall not be liable to UKAS for any loss or damage including injury to reputation suffered by UKAS as a result of any of its activities or reports.

7.2 UKAS shall not be liable to the NPIA for any loss or damage including injury to reputation suffered by the NPIA as a result of any of its activities or reports.

8 *Disputes*

8.1 Disputes concerning this Agreement shall normally be resolved by the parties to the Agreement. Where such a resolution is not possible, a dispute may be referred, with the agreement of the parties to the Agreement, to a single arbitrator. Arbitration will not be binding on the parties.

9 *Obligations on laboratories*

9.1 Laboratories must meet the requirements of the Standards set out in the NDU QMS documents relevant to Forensic Suppliers.

9.2 Laboratories shall, when making application for UKAS accreditation for the purposes of approval as a provider to the NDNAD, give permission in writing for UKAS to release information relevant to their accredited status to the NDU, who may then forward this information to the National DNA Database Strategy Board and/or the Office of the Forensic Regulator if required.

Dr S Bramble
Head of Police Science and Forensics

Date

Dr J Beaumont
Accreditation Director
United Kingdom Accreditation Service

Date

ANNEX I: DOCUMENTS REFERRED TO IN THIS AGREEMENT

- 1 *General Requirements for the Competence of Testing and Calibration Laboratories, ISO/IEC 17025:2005*
- 2 *NDU QMS documents (current version) available from the NDU*
- 3 *Memorandum of Understanding between ACPO and Custodian of the National DNA Database, August 2000 <governance Doc>*
- 4 *Accreditation for the Suppliers to the National DNA Database, Lab 32, August 2011.*