ILAC GUIDELINES

FOR

FORENSIC SCIENCE LABORATORIES

CONTENTS

INTRODUCTION

The general requirements for the competence of testing and calibration laboratories are described in ISO/IEC 17025. These requirements are designed to apply to all types of calibration and objective testing and therefore need to be interpreted with respect to the type of calibration and testing concerned and the techniques involved.

This document has been produced in consultation with Working Group 4 of the ILAC Committee on Technical Accreditation Issues and is intended to provide guidance for laboratories involved in forensic analysis and examination by providing interpretation and amplification of ISO/IEC 17025. This document does not re-state all the provisions of ISO/IEC 17025 and laboratories are reminded of the need to comply with all of the relevant criteria detailed in ISO/IEC 17025.

This document may also be used by accreditation bodies to provide appropriate criteria for the assessment and accreditation of laboratories providing forensic services.

Laboratories are also reminded of the need to comply with any relevant statutory or legislative requirements.

1. SCOPE

Forensic science refers to the examination of scenes of crime, recovery of evidence, laboratory examinations, interpretation of findings and presentation of the conclusions reached for intelligence purposes or for use in court. The activities range from instrumental analysis with unequivocal results, such as blood alcohol determination and glass refractive index measurement, to the investigation of suspicious fires and vehicle accidents, to comparison work such as handwriting and toolmark examination, which is largely subjective in nature but which, with training, can produce consistent outcomes between different forensic scientists.

1.1 Forensic science work involves the examination of a wide range of items and substances. The following list describes the activities that may be encountered in a forensic laboratory. This does not, however, preclude other activities being undertaken in a forensic laboratory.

a) Controlled Substances

- Controlled pharmaceutical and illicit drugs
- Related chemicals and paraphernalia
- Botanical material

b) Toxicology

- Pharmaceutical products
- Alcohol
- Poisons

c) Hairs, Blood, Body Fluids and Tissues

- Serology
- DNA profiling

d) Trace Evidence

- Fire debris
- Hydrocarbon fuels
- Pyrotechnic devices
- Explosives and explosion debris
- Glass
- Light filaments
- Paint
- Vehicle components
- Metals and alloys
- Firearm discharge residues
- Fibres and hairs
- Clothing/garments
- Adhesives
- Dyes and pigments
- Oils and greases
- Cosmetics
- Lachrymatory chemicals
- Lubricants and spermicidal agents
- Soils
- Fertilisers
- Corrosives
- Acids
- Alkalis
- Food
- Feedingstuffs and ancillary items
- Components of technical or household appliances
- Electrical devices and components
- Manufacturers' marks (including serial number restoration)
- Botanical material (excluding controlled substances)

e) Firearms and Ballistics

- Firearms
- Bullets and cartridges

f) Handwriting and Document Examination

- Handwriting
- Paper
- Rubber stamps
- Security marks
- Typewriters and typewritten material
- Printers and other printed objects
- Embossing and embossed materials
- Inks and printing materials
- Copiers and copied material
- Indentations

g) Fingerprints

- Fingerprints
- Footprints
- Palmprints

h) Marks and Impressions

- Toolmarks
- Shoe prints
- Glove marks
- Toolmarks and impressions
- Tyre prints
- Fabric prints
- Non-friction ridge body prints

i) Audio, Video and Computer Analysis

- Audiotape recordings
- Language samples
- Image enhancement
- Facial mapping
- Speech samples
- Computers (hard and software)
- Videogrammetry
- Recovery of information

j) Accident Investigation

- Tachograph charts
- Component failures
- Speed calculations
- Car immobiliser systems
- Trace evidence
- Unsafe loads
- Electrical failures

k) Crime Scene Investigation

- Scene investigation
- Computer simulations
- Fire investigation
- Evidence recovery
- Photography
- Blood splash pattern interpretation

l) Forensic Pathology, Entomology, Odontology

1.2 The techniques adopted in the analysis and examination of forensic material cover a broad range from visual examination to sophisticated instrumental procedures. Techniques which are employed include but are not limited to:

- Chemical colour tests
- Autoradiography
- Chemiluminescence
- DNA analysis
- Chromatography
- Mass spectrometry
- Atomic absorption and emission spectrometry
- Nuclear magnetic resonance spectroscopy
- Ultraviolet, infrared- and visible spectrophotometry
- Physical measurements eg weight, volume, length, density, refractive index
- Optical and electron microscopy
- X-ray analysis
- Serology
- Immunoassay
- Electrophoresis
- Visual inspections
- Metallurgy
- Odontology
- Osteology
- Microbiology
- Parasitology
- Haematology
- Chemical pathology
- Computer simulations

It is anticipated that the majority of the work carried out in forensic science laboratories will be capable of satisfying the definition of an objective test, although in some instances a different emphasis may be placed on the particular aspect of 'control' required. The level of training and experience for staff involved in the work will be dependent on the nature of the examination or test.

2. REFERENCES

ISO DIS 17025:1999, *General Requirements for the competence of testing and calibration laboratories*.

ISO Guide 30:1992, *Terms and definitions used in connection with reference materials*.

ILAC Policy on Traceability of Measurements

3. TERMS AND DEFINITIONS

3.1 Objective Test

A test which having been documented and validated is under control so that it can be demonstrated that all appropriately trained staff will obtain the same results within defined limits. These defined limits relate to expressions of degrees of probability as well as numerical values.

Objective tests will be controlled by:

- documentation of the test
- validation of the test
- training and authorisation of staff
- maintenance of equipment

and where appropriate by;

- calibration of equipment
- use of appropriate reference materials
- provision of guidance for interpretation
- checking of results
- testing of staff proficiency
- recording of equipment/test performance

Visual inspection, qualitative examinations and computer simulations are included in the definition of objective test.

3.2 Validation

Validation is the developmental process used to acquire the necessary information to assess the ability of a procedure to obtain a result reliably, to determine the conditions under which such results can be obtained and to determine the limitations of the procedure. The validation process identifies critical aspects of a procedure that must be carefully controlled and monitored.

3.3 Reference Material

Material or substance, one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method or for assigning values to materials (ISO Guide 30, Section 3.1).

3.4 Certified Reference Material

A reference material, one or more of whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body (ISO Guide 30, Section 2.2).

3.5 Reference Collection

A collection of stable materials, substances, objects or artefacts of known properties or origin that may be used in the determination of the properties or origins of unknown items.

3.6 Internally Generated Reference Material

A stable material or substance one or more of whose properties have been characterised at least by replicate analysis, using alternative methods where possible.

3.7 Verification

An independent check carried out by a second competent individual, uninfluenced by the findings of the first. This may be carried out on the same item or sample (eg mark comparison, fibre matching, blood splash pattern analysis) but may also be carried out on different samples (eg spot tests).

3.8 Replicate Testing

The multiple analysis of separate portions of a test material using the same test method under the same conditions ie same operator, same apparatus, same laboratory.

3.9 Standard Addition

The addition of a known amount of a pure component known to be present as a constituent of the sample in order to verify and quantify the component.

3.10 Internal Standard

The addition of a known amount of a known substance which is not present as a constituent of the sample in order to quantify other components.

3.11 Court Statement

A written report of the results and interpretations of forensic tests/examinations submitted to court. Such reports are usually in a format prescribed in legislation.

4. MANAGEMENT REQUIREMENTS

4.1 Organisation and Management

No additional interpretation of this clause for forensic science laboratories is required.

4.2 Quality System

No additional interpretation of this clause for forensic science laboratories is required.

4.3 Document Control

No additional interpretation of this clause for forensic science laboratories is required.

4.4 Review of Requests, Tenders and Contracts

No additional interpretation of this clause for forensic science laboratories is required.

4.5 Subcontracting of Tests and Calibrations

No additional interpretation of this clause for forensic science laboratories is required.

4.6 Purchasing of Services and Supplies

No additional interpretation of this clause for forensic science laboratories is required.

4.7 Service to the Client

No additional interpretation of this clause for forensic science laboratories is required.

4.8 Complaints

No additional interpretation of this clause for forensic science laboratories is required.

4.9 Control of Non-conforming Testing and/or Calibration Work

No additional interpretation of this clause for forensic science laboratories is required.

4.10 Corrective Action

No additional interpretation of this clause for forensic science laboratories is required.

4.11 Preventive Action

No additional interpretation of this clause for forensic science laboratories is required.

4.12 Control of Records

4.12.1 The forensic science laboratory shall have documented procedures to ensure that it maintains a coordinated record relating to each case under investigation. The information that is to be included in case records must be documented and may include records of telephone conversations, evidence receipts, descriptions of evidence packaging and seals, subpoenas, records of observations and test/examination results, reference to procedures used, diagrams, print-outs, autoradiographs, photographs, etc. In general, the records required to support conclusions must be such that in the absence of the analyst/examiner, another competent analyst/examiner could evaluate what had been performed and interpret the data.

4.12.2 Where instrumental analyses are conducted, operating parameters must be recorded.

4.12.3 Where appropriate, observations or test results must be preserved by photography or electronic scanning (eg electrophoretic runs, physical matches). Photocopies, tracings or hand-drawn facsimiles may also be suitable (eg thin-layer chromatography results, questioned documents).

4.12.4 When a test result or observation is rejected, the reason(s) must be recorded.

4.12.5 Calculations and data transfers which do not form part of a validated electronic process shall be checked, preferably by a second person. The case record must include an indication that such checks have been carried out and by whom.

4.12.6 Each page of every document in the case record must be traceable to the analyst/examiner and where appropriate, to a uniquely identified case or exhibit. It must be clear from the case record who has performed all stages of the analysis/examination and when each stage of the analysis/examination was performed (eg relevant date(s)).

4.12.7 Laboratory generated examination records must be paginated using a page numbering system which indicates the total number of pages.

4.12.8 The laboratory must have documented policies and procedures for review of case records. Where independent checks on critical findings are carried out by other authorised personnel, the records shall indicate that each critical finding has been checked and agreed and by whom the checks were performed. This may be indicated in a number of ways including entries against each finding, entry on a summary of findings or a statement to this effect in the records.

4.13 Internal Audits

No additional interpretation of this clause for forensic science laboratories is required.

4.14 Management Reviews

No additional interpretation of this clause for forensic science laboratories is required.

5. TECHNICAL REQUIREMENTS

5.1 General

No additional interpretation of this clause for forensic science laboratories is required.

5.2 Personnel

5.2.1 The laboratory shall have a defined policy that ensures that all staff working in the laboratory are competent to perform the work required. The term 'competent' implies possessing the requisite knowledge, skills and abilities to perform the job. The laboratory's policy shall also include procedures for retraining and maintenance of skills and expertise.

5.2.2 A laboratory shall have clear statements of the competencies required for all jobs and records shall be maintained to demonstrate that all staff are competent for the jobs they are asked to carry out. Each laboratory or section shall maintain an up-to-date record of the training that each member of staff has received. These records shall include academic and professional qualifications, external or internal courses attended and relevant training (and retraining where necessary) received whilst working in the laboratory. Where test or technique specific training is given, acceptance criteria shall be assigned eg observation of the relevant tests or analyses by an experienced officer, satisfactory performance in the analysis of quality control/quality assurance samples, correlation of results with those obtained by other trained staff. Records shall be sufficiently detailed to provide evidence that staff performing particular tasks have been properly trained and that their subsequent ability to perform these tests has been formally assessed.

5.2.3 The laboratory shall have and follow a documented procedure whereby the testimony of each examiner is monitored on a regular basis. The evaluation should include appearance, performance and effectiveness of presentation. The monitoring procedure must also prescribe the remedial action that is to be taken should the evaluation be less than satisfactory.

5.3 Accommodation and Environmental Conditions

5.3.1 Access to the operational area of the laboratory must be controllable and limited. Visitors must not have unrestricted access to the operational areas of the laboratory. A record must be retained of all visitors to the operational areas of the laboratory.

5.3.2 Evidence storage areas must be secure to prevent theft or interference and there must be limited, controlled access. The storage conditions must be such as to prevent loss, deterioration and contamination and to maintain the integrity and identity of the evidence. This applies both before and after examinations have been performed.

5.3.3 Special care is needed in forensic testing laboratories involved in the analysis or determination of trace levels of materials. Physical separation of high-level and low-level work is required. Where special areas are set aside for this type of work, access to these areas

shall be restricted and the work undertaken carefully controlled. Appropriate records shall be kept to demonstrate this control. It may also be necessary to carry out 'environmental monitoring' of equipment, work areas, clothing and consumables.

5.4 Test and Calibration Methods and Method Validation

5.4.1 All technical procedures used by a forensic science laboratory must be fully validated before being used on casework.

Methods may be validated by comparison with other established methods using certified reference materials (where available) or materials of known characteristics. In validating test methods, the following issues (among others) may need to be determined, as appropriate:

- matrix effects
- sample homogeneity
- specificity
- linearity range
- precision
- interferences
- concentration ranges
- stability of measured compounds
- population distribution
- measurement uncertainty

Validation studies can be conducted by the scientific community (as in the case of standard or published methods) or by the forensic science laboratory itself (as in the case of methods developed in-house or where significant modifications are made to previously validated methods).

Records of all in-house validations must be maintained for future reference.

5.4.2 Where a laboratory introduces a new (validated) method, it must first demonstrate the reliability of the procedure in-house against any documented performance characteristics of that procedure.

Records of performance verification must be maintained for future reference.

5.4.3 All methods shall be fully documented including procedures for quality control, and, where appropriate, the use of reference materials.

5.4.4 Laboratories must institute a procedure to identify infrequently performed tests or analyses. For these tests or analyses, there are two methods of demonstrating competence, either of which would be equally valid. These are:

a) regular analysis of control samples and use of control charts even when 'real' samples are not being analysed; or

b) reverification before the test or analysis in question is performed on a real sample involving at least the use of an appropriate reference material, followed by replicate testing or analysis of the real sample.

5.4.5 The quality of standard materials and reagents must be adequate for the procedure used. Lot/batch numbers of standard materials and critical reagents must be recorded. All critical reagents must be tested for their reliability. Standard materials and reagents must be labelled with:

- name;
- concentration, where appropriate,
- preparation date;

- identity of preparer.

Where necessary, the following information must also be included on labels:

- expiry date;
- storage conditions;
- hazard warning.

5.5 Equipment

5.5.1 As part of a quality system, all laboratories are required to operate a program for the maintenance and calibration of equipment used in the laboratory. The equipment used in a forensic science laboratory is diverse and will range across a number of different scientific and technical disciplines. In most areas equipment may be categorised into:

a) General service equipment not directly used for making measurements eg hot plates, stirrers, non-volumetric glassware, cameras, refrigerators, thermal cyclers

b) Microscopes including attachments

c) Volumetric equipment

d) Measuring instruments - thermometers, balances, densitometers, chromatographs, spectrometers and spectrophotometers, refractometers, autoanalysers, DNA sequencers.

e) Computers and data processors

5.5.2 General Service Equipment

General service equipment will typically be maintained by visual examination, safety checks and cleaning as necessary. Calibrations or performance checks will only be necessary where the equipment setting can significantly affect the test or analytical result (eg temperature of a muffle furnace or constant temperature bath).

5.5.3 Microscopes Including Attachments

Periodic cleaning and servicing are appropriate. Steps should be taken to ensure that microscopes are properly set up for use and are used only by competent staff. Where microscopes are used for measurement the guidance given in paragraph 5.5.5 applies.

5.5.4 Volumetric Equipment

Volumetric equipment will typically be maintained by visual examination and cleaning but calibration and performance checks will need to be carried out before initial use and at intervals depending on the type and frequency of use.

5.5.5 Measuring Instruments

Correct use combined with periodic servicing, cleaning and calibration will not necessarily ensure that a measuring instrument or detection system is performing adequately. Therefore, where appropriate, periodic performance checks shall be carried out and predetermined limits of acceptability shall be assigned. The frequency of such performance checks will be determined by past history and should be based on need, type and previous performances of the equipment.

It is often possible to build performance checks or system suitability checks into test methods (eg chromatographic systems, measurement of glass refractive index). These checks shall be documented and shall be satisfactorily completed before the equipment is used or before results are accepted.

5.6 Measurement Traceability

5.6.1 The overall program for the calibration of equipment in the forensic science laboratory shall be designed to ensure that where the concept is applicable, all significant measurements are traceable, through certificates of calibration held by the laboratory, to values of national or international standards. Where possible, laboratories shall ensure traceability of their test results in accordance with the ILAC Policy on Traceability of Measurements.

5.6.2 Equipment used in forensic science laboratories may be sub-divided into general classes depending on the type of calibration required:

a) In general, the mechanism exists for ensuring traceability of calibration results for equipment used for the direct measurement of fundamental properties (eg mass, length, temperature and time) or the simpler derived properties (eg area, volume, pressure). Where the properties have a significant effect on the results of a test or analysis, the requirements of paragraph 5.6.1 must be met.

b) Equipment used to measure an empirical property of a sample, such as flash point, may be defined in published standards and traceable reference materials, where available, shall be used for calibration purposes. New equipment shall be checked by a laboratory before use to ensure conformity with specified design and dimensional requirements.

c) Instruments, such as chromatographs and spectrometers, that require calibration as part of their normal operation, shall be calibrated using chemicals of known and adequate purity or reference materials of known composition.

5.6.3 Individual programs shall be established depending on the specific requirements of the testing or analytical work being carried out. It will normally be necessary to check instrument calibration after any shut down, whether deliberate or otherwise, and following service or other substantial maintenance. In general, calibration intervals shall not be less stringent than manufacturers' recommendations.

Where a laboratory performs calibrations in-house by means of comparisons between values obtained from reference standards and those obtained from working measuring instruments (eg thermometers), the calibration procedures shall be documented.

5.6.4 Reference Materials

The ISO definitions of reference materials and certified reference materials are given in Section 3. Where available, use of such materials is essential for the demonstration of the validity of measurements in analytical work if no other method of validation is appropriate and they may also be used to determine the accuracy of results, to calibrate equipment, to monitor laboratory performance and to validate methods.

Wherever possible matched matrix reference materials, which have been certified in a reliable manner, must be used. Where no such reference standard or certified reference material is available, a laboratory reference material with suitable properties and stability shall be used. The required properties of this material must be characterised by repeat testing, preferably by more than one laboratory and using a variety of methods. Detailed records shall be kept.

The laboratory shall have documented procedures which ensure that reference materials and standards are protected from both contamination and loss of determinand.

5.6.5 For many types of analysis, 'calibration' may be carried out using synthetic standards containing the analytes under test, prepared within the laboratory from chemicals of known purity and composition, or matrix matched standards. Alternatively, 'standard' solutions may be purchased. Many chemicals can be purchased with manufacturer's statements or certificates. Wherever possible, laboratories should obtain supplies of chemical standards from suppliers which have implemented quality systems eg as required by ISO 9000.

5.6.6 Reference collections of data or items/materials encountered in casework which are maintained for identification, comparison or interpretation purposes (eg mass spectra, motor vehicle paints or headlamp lenses, drug samples, typewriter printstyles, wood fragments, bullets, cartridges, DNA profiles, frequency databases) must be fully documented, uniquely identified and properly controlled.

5.7 Sampling

Selection, recovery, prioritisation and sampling of materials from submitted test items and from scenes of crime are important parts of the forensic process. In the area of forensic science emphasis is placed on the competence of the scientist and the training of staff in these activities is therefore of prime importance. Laboratories shall ensure that there are documented procedures and training programs to cover this aspect of their work and that detailed competency/training records are kept for all staff involved.

5.8 Handling of Test and Calibration Items

5.8.1 For legal purposes, forensic science laboratories must be able to demonstrate that the items/samples examined and reported on were the ones submitted to the laboratory. Laboratories shall therefore ensure that a 'chain of custody' record is maintained which details each person who takes possession of an item or alternatively the location of that item (eg if in storage).

5.9 Assuring the Quality of Test and Calibration Results

5.9.1 Analytical performance must be monitored by operating quality control schemes which are appropriate to the type and frequency of testing undertaken by a laboratory. The range of quality control activities available to laboratories includes the use of :

- reference collections;
- certified reference materials and internally generated reference materials;
- statistical tables;
- positive and negative controls;
- control charts;
- replicate testing;
- alternative methods;
- repeat testing;
- spiked samples, standard additions and internal standards;
- independent checks (verification) by other authorised personnel

Depending on the particular test being performed, the laboratory may make use of one or several of these examples to demonstrate that the test or examination is 'under control'.

5.9.2 The quality control procedures necessary in any particular area of work must be determined by the laboratory responsible for the work, based on best professional practice. The procedures shall be documented and records shall be retained to show that all appropriate QC measures have been taken, that all QC results are acceptable or, if not, that remedial action has been taken. (Refer also paragraphs 4.9 and 4.10)

5.9.3 An effective means for a forensic laboratory to monitor its performance, both against its own requirements and against the performance of peer laboratories, is to take part in proficiency testing programs. When participating in proficiency testing programs, the laboratory's own documented test procedures must be used. Performance in the programs must be reviewed regularly and where necessary, corrective action must be taken.

Proficiency testing records must include:

- full details of the analyses/examinations undertaken and the results and conclusions obtained;
- an indication that performance has been reviewed;
- details of the corrective action undertaken, where necessary.

5.10 Reporting the Results

5.10.1 It is accepted that forensic science laboratories may not be able to include all of the items in test reports that are detailed in sub-clause 5.10 of ISO/IEC 17025. Forensic science laboratories may therefore elect to adopt one or more of the following means of meeting these requirements.

i) Test reports which include all of the information required by ISO/IEC 17025 shall be compiled.

ii) 'Court Statements' shall be modified to include all of the information required by ISO/IEC 17025.

iii) 'Court Statements' shall be modified to include an annex containing all of the information required by ISO/IEC 17025.

iv) The case record relating to a specific investigation shall contain all of the relevant information required by ISO/IEC 17025.

ANNEX A: BIBLIOGRAPHY

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