



Forensic Requirements for Accreditation FRA-1

REVISION LOG

Version	Issued	Changes
2006/1		Original document
2007/1	June 6, 2007	Replace “should” in most contexts with “shall”; preamble deleted; for clarity, deleted references and bibliography that are available in the ILAC G19:2002 source document.
2008/1	January 25, 2008	Remove FQS-I address and phone numbers from cover page.

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INTRODUCTION

The general requirements for the competence of testing and calibration laboratories are described in ISO/IEC 17025:2005. 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.

The FQS-I Forensic Requirements for Accreditation-1 (FRA-1) are derived from International Laboratory Accreditation Cooperation (ILAC) Guide 19, *Guidelines for Forensic Science Laboratories*. The material in sections 4 and 5, as well as portions of sections 1-3, are reproduced from ILAC G19:2002. The term “should” found in ILAC G19 has been changed to “shall” to reflect the adoption of the document as supplemental standards. Other minor changes have been made for language clarification or for alignment of clause numbers with ISO/IEC 17025:2005.

This document is intended to provide additional interpretation of the ISO 17025 Standard for laboratories conducting testing in the field of forensic analysis and examination. The document does not re-state all the provisions of ISO/IEC 17025:2005, and laboratories are reminded of the need to comply with all of the relevant criteria detailed in the International Standard. The clause numbers in this document follow those of ISO/IEC 17025, but since not all clauses require interpretation, the numbering may not be continuous.

1. SCOPE

Forensic science refers to the examination of scenes, recovery of evidence, laboratory examinations, interpretation of findings and presentation of the conclusions reached for intelligence purposes or for use in civil or criminal court.

The testing will therefore cover a wide range of materials and procedures. The supplementary requirements described in this document are intended to provide interpretative guidance to laboratories on compliance with ISO/IEC 17025:2005. They are to be read in conjunction with the scope of accreditation, which will be specific for each laboratory/department, but which shall cover the materials tested and procedures used. They also are to be read in conjunction with all relevant standards developed by the department (and its host agency). Scope and internal amplification documents (or reference to these documents) for specific laboratories are annexed to these requirements on a laboratory-by-laboratory basis.

2. REFERENCES

ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*

3. TERMS AND DEFINITIONS

For the purposes of FRA-1, the relevant terms and definitions given in ISO/IEC Guide 2, *General terms and their definitions concerning standardisation and related activities*, apply.

Objective Test

It is anticipated that the majority of the work carried out in forensic testing 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.

An objective test is one 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 measurement uncertainty.

Objective tests will be controlled by:

- documentation of the test
- validation of the test
- training and authorization 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.

Reference Collection

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

Court Statement

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

4. MANAGEMENT REQUIREMENTS

4.13 Control of records

4.13.2.1

a) 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 shall 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 shall be such that in the absence of the analyst/examiner, another competent analyst/examiner could evaluate what had been performed and interpret the data.

b) Where instrumental analyses are conducted, operating parameters shall be recorded.

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

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

e) 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 shall include an indication that such checks have been carried out and by whom.

f) Each page of every document in the case record shall be traceable to the analyst/examiner and where appropriate, to a uniquely identified case or exhibit. It shall 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 (e.g., relevant date(s)).

g) Laboratory generated examination records shall be paginated using a page numbering system which indicates the total number of pages.

h) The laboratory shall have documented policies and procedures for the review of case records, including test reports.

Where independent checks on critical findings are carried out by other authorized 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.

5. TECHNICAL REQUIREMENTS

5.2 Personnel

5.2.1 The laboratory shall have a defined process 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.

Where test or technique specific training is given, acceptance criteria shall be assigned, e.g., 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. Where necessary, training programs shall also include training in the presentation of evidence in court.

5.2.5 An 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 while working in the laboratory.

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.

5.3 Physical plant and environment

5.3.3 Special care is needed in forensic testing laboratories involved in the analysis or determination of trace levels of materials, including DNA. 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.

5.3.4

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

b) Evidence storage areas shall be secure to prevent theft or interference and there shall be limited, controlled access. The storage conditions shall 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.

5.4 Test and calibration methods and method validation

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

5.4.2

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

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

Records of performance verification shall be maintained for future reference.

c) Laboratories shall 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:

i. regular analysis of control samples and use of control charts even when 'real' samples are not being analyzed; or

ii. 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.

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

- name;
- concentration, where appropriate;
- preparation date and or expiry date;
- identity of preparer;

- storage conditions, if relevant;
- hazard warning, where necessary.

5.4.5.1 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	interferences
sample homogeneity	concentration ranges
specificity	stability of measured compounds
linearity range	population distribution
precision	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).

5.5 Equipment

5.5.2 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.

a) General service equipment not directly used for making measurements, e.g., hot plates, stirrers, non-volumetric glassware, cameras, refrigerators

Such 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 (e.g., temperature of a muffle furnace or constant temperature bath).

b) Microscopes including attachments

Microscopes shall be cleaned and serviced periodically. Steps shall 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 d) applies.

c) Volumetric equipment

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

d) Measuring instruments - thermometers, balances, densitometers, chromatographs, spectrometers and spectrophotometers, refractometers

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 shall be determined by need, type and previous performance of the equipment.

It is often possible to build performance checks or system suitability checks into test methods (e.g., 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.

e) Computers and data processors

5.6 Measurement traceability

5.6.1 Individual calibration 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 should not be less stringent than manufacturers' recommendations.

5.6.2.2 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 shall obtain supplies of chemical standards from suppliers which have implemented quality systems, e.g., as required by ISO 9000.

5.6.3.2 Reference collections of data or items/materials encountered in casework which are maintained for identification, comparison or interpretation purposes shall be fully documented, uniquely identified and properly controlled.

5.7 Sampling

5.7.1 Selection, recovery, prioritization 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 shall be able to demonstrate that the items/samples examined and reported on were those submitted to the laboratory. A 'chain of custody' record shall be maintained from the receipt of items/samples which details each person who takes possession of an item or alternatively the location of that item (e.g., if in storage).

5.8.4 There shall be documented procedures which describe the measures taken to secure exhibits in the process of being examined which must be left unattended.

5.9 Assuring the quality of test and calibration results

5.9.1

a) Analytical performance shall 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 authorized 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'.

The quality control procedures necessary in any particular area of work shall 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.

b) An effective means for a forensic science 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 shall be used. Performance in the programs shall be reviewed regularly and where necessary, corrective action shall be taken.

Proficiency testing records shall 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.

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

5.10 Reporting the results

5.10.2 It is accepted that forensic science laboratories may not be able to include all of the items in 'Court Statements' that are detailed in sub-clause 5.10 of ISO/IEC 17025, as the format of these documents is prescribed in legislation. Forensic science laboratories may therefore elect to adopt one or more of the following means of meeting these requirements:

- the preparation of a test report which includes all of the information required by ISO/IEC 17025;
- the preparation of an annex to the Court Statement which includes any additional information required by ISO/IEC 17025;
- ensuring that the case record relating to a specific investigation contains all the relevant information required by ISO/IEC 17025.