SPECIFIC CRITERIA 1.1 (SC 1.1)

SPECIFIC CRITERIA FOR ACCREDITATION OF FORENSIC SCIENCE TESTING

Issue 2, 29 January 2007
(Supplementary to MS ISO/IEC 17025)
PREAMBLE

The general requirements for the competence of testing and calibration laboratories are described in MS 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 does not re-state all the provisions of MS ISO/IEC 17025 and laboratories are reminded of the need to comply with all of the relevant criteria detailed in MS ISO/IEC 17025. 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.

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.

PURPOSE

This document is intended to provide supplementary requirements for laboratories involved in forensic analysis and examination by providing application of MS ISO/IEC 17025.

AUTHORSHIP

This document has been produced in consultation with STANDARDS MALAYSIA Technical Working Group 17 of STANDARDS MALAYSIA Technical Working Group Committees, based on ILAC G19:2002 – Guidelines for Forensic Science Laboratories.
<table>
<thead>
<tr>
<th>SECTION</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>PREAMBLE</td>
<td>1</td>
</tr>
<tr>
<td>PURPOSE</td>
<td>1</td>
</tr>
<tr>
<td>AUTHORSHIP</td>
<td>1</td>
</tr>
<tr>
<td>1 SCOPE</td>
<td>3</td>
</tr>
<tr>
<td>2 REFERENCES</td>
<td>5</td>
</tr>
<tr>
<td>3 TERMS AND DEFINITIONS</td>
<td>6</td>
</tr>
<tr>
<td>4 MANAGEMENT REQUIREMENTS</td>
<td>7</td>
</tr>
<tr>
<td>4.13 Control of records</td>
<td>7</td>
</tr>
<tr>
<td>5 TECHNICAL REQUIREMENTS</td>
<td>8</td>
</tr>
<tr>
<td>5.1 General</td>
<td>8</td>
</tr>
<tr>
<td>5.2 Personnel</td>
<td>8</td>
</tr>
<tr>
<td>5.3 Accommodation and environmental conditions</td>
<td>8</td>
</tr>
<tr>
<td>5.5 Equipment</td>
<td>10</td>
</tr>
<tr>
<td>5.6 Measurement traceability</td>
<td>11</td>
</tr>
<tr>
<td>5.7 Sampling</td>
<td>12</td>
</tr>
<tr>
<td>5.8 Handling of test and calibration items</td>
<td>12</td>
</tr>
<tr>
<td>5.9 Assuring the quality of test and calibration results</td>
<td>13</td>
</tr>
<tr>
<td>5.10 Reporting the results</td>
<td>14</td>
</tr>
</tbody>
</table>

NOTE: Clause numbers correspond to those in the standard MS ISO/IEC 17025
1. **SCOPE**

This document shall be read in conjunction with MS ISO/IEC 17025 and other specific criteria published by Department of Standards Malaysia (STANDARDS MALAYSIA).

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.

**Controlled Substances**

1. Controlled pharmaceutical and illicit drugs
2. Botanical material
3. Related chemicals and paraphernalia

**Toxicology**

1. Pharmaceutical products
2. Alcohol
3. Poisons

**Hairs, Blood, Body Fluids and Tissues**

1. Serology
2. DNA profiling

**Trace Evidence**

1. Fire debris
2. Hydrocarbon fuels
3. Pyrotechnic devices
4. Explosives and explosion debris
5. Glass
6. Light filaments
7. Paint
8. Vehicle components
9. Metals and alloys
10. Firearm discharge residues
11. Fibres and hairs
12. Clothing/garments
13. Adhesives
14. Dyes and pigments
15. Oils and greases
16. Cosmetics
17. Lachrymatory chemicals
18. Soils
19. Fertilisers
20. Corrosives
21. Acids  
22. Alkalis  
23. Food  
24. Lubricants and spermicidal agents  
25. Feedingstuffs and ancillary items  
26. Electrical devices and components  
27. Components of technical or household appliances  
28. Manufacturers marks (incl. serial number restoration)  
29. Botanical material (excluding controlled substances) 

**Firearms and ballistics**  
1. Firearms  
2. Bullets and cartridges

**Handwriting and Document Examination**  
1. Handwriting  
2. Inks and printing materials  
3. Paper  
4. Copiers and copied material  
5. Rubber stamps  
6. Indentations  
7. Security marks  
8. Typewriters and typewritten material  
9. Printers and other printed objects  
10. Embossing and embossed materials

**Fingerprints**  
1. Fingerprints  
2. Palmprints  
3. Footprints

**Marks and Impressions**  
1. Toolmarks  
2. Tyre prints  
3. Shoe prints  
4. Fabric prints  
5. Glove marks  
6. Non-friction ridge body prints  
7. Toolmarks and impressions

**Audio, Video and Computer Analysis**  
1. Audiotape recordings  
2. Speech samples  
3. Language samples  
4. Computers (hardware and software)  
5. Image enhancement  
6. Videogrammetry  
7. Facial mapping  
8. Recovery of information

**Accident Investigation**  
1. Tachograph charts  
2. Trace evidence  
3. Component failures  
4. Unsafe loads  
5. Speed calculations  
6. Electrical failures  
7. Car immobiliser systems

**Scene Investigation**  
1. Crime scene investigation  
2. Evidence recovery
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:

<table>
<thead>
<tr>
<th>Chemical colour tests</th>
<th>Autoradiography</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemiluminescence</td>
<td>DNA analysis</td>
</tr>
<tr>
<td>Chromatography</td>
<td>Mass spectrometry</td>
</tr>
<tr>
<td>Atomic absorption and emission spectrometry</td>
<td>Nuclear magnetic resonance spectroscopy</td>
</tr>
<tr>
<td>Ultraviolet, infrared and visible spectrophotometry</td>
<td>Physical measurements eg weight, volume, length, density, refractive index</td>
</tr>
<tr>
<td>Optical and electron microscopy</td>
<td>X-ray analysis</td>
</tr>
<tr>
<td>Serology</td>
<td>Immunoassay</td>
</tr>
<tr>
<td>Electrophoresis</td>
<td>Visual inspections</td>
</tr>
<tr>
<td>Metallurgy</td>
<td>Computer simulations</td>
</tr>
</tbody>
</table>

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

i. MS ISO/IEC 17025:1999, General requirements for the competence of testing and calibration laboratories.

ii. ISO/IEC Guide 2, General terms and their definitions concerning standardisation and related activities.


iv. ILAC-P10: 2002, ILAC Policy on Traceability of Measurement Results

v. ILAC-G2: 1994, Traceability of measurements
3. TERMS AND DEFINITIONS

For the purposes of the Guide, the relevant terms and definitions given in ISO/IEC Guide 2 apply.

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:
1. documentation of the test
2. validation of the test
3. training and authorisation of staff
4. maintenance of equipment

and where appropriate by;
1. calibration of equipment
2. use of appropriate reference materials
3. provision of guidance for interpretation
4. checking of results
5. testing of staff proficiency
6. 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

4.12 Control of records

4.12.2.1 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 (e.g. 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 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.

5. TECHNICAL REQUIREMENTS

5.1 General

As in the standard MS ISO/IEC 17025.

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. 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.

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. 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 Accommodation and environmental conditions

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 a 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 casework samples are not being analysed; or

ii. reverification before the test or analysis in question is performed on a casework 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 labeled 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, thermal cyclers). 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 calibration and 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, autoanalysers and DNA sequencers.

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 shall not be less
stringent than manufacturers’ recommendations.

5.6.2.2.2 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 competent suppliers.

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

5.7 Sampling

5.7.1 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 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 native 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’.

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

1. Supt. Dr Yew Chong Hooi (Chairman)  PDRM Forensic Laboratory
2. Pn. Fariza Wan Abdullah (Secretary)  Department of Standards Malaysia
3. En. Poon Wai Lum (Advisor)  Department of Standards Malaysia
4. Dr. Abdul Halim Hj. Mansar  Institut Perubatan Forensik Negara (IPFN)
5. Dr. Hj Abd Karim Tajudin  Hospital Serdang
6. Prof. Madya Dr Shahrom Wahid  Hospital Universiti Kebangsaan Malaysia (HUKM)
7. En. Chan Kee Bian  Jabatan Kimia Malaysia, Petaling Jaya