



STANDARDS
MALAYSIA

SKIM AKREDITASI MAKMAL MALAYSIA (SAMM)
LABORATORY ACCREDITATION SCHEME OF MALAYSIA

**STR 1.11 – SPECIFIC TECHNICAL REQUIREMENTS
FOR ACCREDITATION OF ANALYSIS OF DANGEROUS
DRUGS AND OTHER CONTROLLED SUBSTANCES FOR
FORENSIC SCIENCE TESTING LABORATORIES**

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(Supplementary to MS ISO/IEC 17025)



MS ISO/IEC 17025

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SPECIFIC TECHNICAL REQUIREMENTS FOR ACCREDITATION OF ANALYSIS OF DANGEROUS DRUGS AND OTHER CONTROLLED SUBSTANCES FOR FORENSIC SCIENCE TESTING LABORATORIES

1 Introduction and scope

The purpose of this document is to describe specific technical requirements for accreditation of analysis of dangerous drugs and other controlled substances for forensic science testing laboratories on the following scopes:

- i) Illicit drugs
- ii) Controlled pharmaceuticals
- iii) Botanical materials
- iv) Related chemicals and paraphernalia

This document shall be read in conjunction with MS ISO/IEC 17025:2005 standard, Specific Criteria 1.1 and related SAMM Policy requirements. The clause numbers in this document correspond to those in the standard.

2 Normative references

- i) MS ISO/IEC 17025: 2005 - General Requirements for the Competence of Testing and Calibration Laboratories
- ii) Specific Criteria 1.1 (SC 1.1) - Specific Criteria for Accreditation of Forensic Science Testing

3 Terms and definitions

- 3.1 Dangerous drug means any drug or substance which is for the time being comprised in the First Schedule of the Dangerous Drugs Act 1952.
- 3.2 Controlled substance means a drug or chemical whose manufacture, possession and use are regulated by the government. This may include illegal drugs or prescription medications.
- 3.3 Exhibit means a sample or an item of evidence submitted for the purpose of forensic examination and analysis.

- 3.4 Analyst means an individual who performs casework related duties on exhibits within the laboratory and issues reports concerning the findings and observations resulting from the work.
- 3.5 Technical support personnel means a person or persons who perform casework related duties on exhibits within the laboratory under the supervision of an analyst.
- 3.6 Chain of custody means procedures and documents that account for the possession and integrity of an exhibit by tracking its handling and storage from its point of collection to its final disposition.
- 3.7 Confirmatory test means a second test by alternative chemical method for unambiguous identification of a dangerous drug or other controlled substance.
- 3.8 Qualitative analysis means analysis that determines the presence or absence of specific dangerous drug(s) or other controlled substance(s) in an exhibit.
- 3.9 Quantitative analysis means analysis that determines the quantity of dangerous drug(s) or other controlled substance(s) present in an exhibit.
- 3.10 Technical review means review of notes, data and other documents, which form the basis for scientific conclusions.
- 3.11 Administrative review means a procedure used to check for consistency with laboratory policy and for editorial corrections.

4 Management requirements (clause 4.1 to clause 4.15)

As in MS ISO/IEC 17025:2005 standard and SC 1.1.

5 Technical requirements

5.1 General

As in MS ISO/IEC 17025:2005 standard.

5.2 Personnel

5.2.1 The laboratory shall have sufficient personnel with the necessary educational qualification, training, technical knowledge and experience where relevant for the assigned functions.

5.2.2 The analyst shall have:

- i) a minimum academic qualification of a Bachelor of Science degree majoring in Chemistry or related field,
- ii) a minimum of one year working experience in the analysis of dangerous drugs and other controlled substances,
- iii) passed a competency test in the relevant area of analysis of dangerous drugs and other controlled substances, and
- iv) successfully completed a proficiency test at least once a year. Where possible, at least one of these proficiency tests should be from a recognised external proficiency test provider.

5.2.3 The analyst may be assisted by technical support personnel who shall have:

- i) a minimum qualification of Malaysia Certificate of Education (*Sijil Pelajaran Malaysia*) or equivalent,
- ii) undergone a training programme in the analysis of dangerous drugs and other controlled substances,
- iii) passed a competency test in the relevant area of analysis of dangerous drugs and other controlled substances, and
- iv) successfully completed a proficiency test at least once a year.

5.2.4 The laboratory shall monitor the competency and the proficiency test performance of its analysts and technical support personnel for compliance with specified requirements. Records of actions taken to check compliance shall be maintained by the laboratory.

5.2.5 The laboratory shall have a documented training program for training personnel in the knowledge, skills and abilities needed to perform the necessary casework related duties. The training program for analyst shall also cover presentation of evidence in the court of law.

5.2.6 The laboratory shall have documented procedures to monitor and review court testimony of each analyst.

5.3 Accommodation and environmental conditions

- 5.3.1 Access to operational area of the laboratory by any visitor should be restricted and accompanied by assigned laboratory personnel.
- 5.3.2 The laboratory shall establish procedures and maintain appropriate practices to ensure a safe and healthy working environment.

5.4 Test and calibration methods and method validation

- 5.4.1 Where possible, the laboratory shall use recommended test method by United Nations International Drug Control Programme for analysing each type of the dangerous drugs or controlled substances.
- 5.4.2 When only a portion or fraction of an exhibit is required and taken for analysis, the laboratory shall ensure that the sample is homogenous and that the portion or fraction taken is representative of the bulk from which it has been drawn.
- 5.4.3 When necessary and depending on the form of the exhibits, appropriate sampling plan and technique shall be applied to the exhibits being analysed.
- 5.4.4 In cases where the sample materials by their very nature are inhomogenous, the laboratory shall perform sampling from multiple locations of the bulk material in order to obtain as nearly a representative sample as possible.
- 5.4.5 Where the materials in all the units or packages were found to be similar by visual examination and contained the same suspected drug or substance and if not all the units or packages can be analysed, a statistically-valid number of samples, conforming to the principles of analytical chemistry, shall be taken and used for analysis.
- 5.4.6 When the materials in all the units or packages were found to be similar by visual examination and contained the same suspected drug or substance, the contents of the packages may be combined and the combined bulk material homogenised and analysed unless otherwise requested by the submitting authority.

When in doubt, the analyst shall discuss individual situation with investigating officer to ensure adequate compliance with the needs of the law enforcement system.

5.4.7 Any positive result from presumptive test shall be confirmed by the use of an alternative technique.

5.4.8 The identity of any dangerous drug or other controlled substance shall be established at least with two independent analytical techniques, of which one shall be a confirmatory test, to the satisfaction of the analyst.

5.4.9 The laboratory shall have documented procedures for taking and maintaining case notes and shall maintain all documentation generated in relation to each case analysed.

5.5 Equipment

5.5.1 Each time before use, any analytical instrument to be used for identification and quantification of dangerous drug(s) or other controlled substance(s) shall be subjected to checks using blank and appropriate standard(s).

5.6 Measurement Traceability

5.6.1 The laboratory shall use certified reference material and that this reference material shall be appropriately identified in terms of its name, batch number, date of manufacture, expiry date, etc. Any other standard to be used shall be verified against certified reference material before use.

5.6.2 When not in use, reference standards shall be stored under appropriate condition and in a secured environment.

5.7 Sampling

5.7.1 When sampling is carried out by the laboratory, proper documented procedures with appropriate sampling plan and technique shall be followed.

5.8 Handling of test and calibration items

5.8.1 All samples submitted for analysis shall be accompanied by a formal request form or letter from the submitting authority and upon registration, an official receipt shall be issued by the laboratory.

5.8.2 The laboratory shall ensure that all exhibits under its custody is properly secured and protected from loss, damage or mix-up. A record of the chain of custody for all exhibits from the time of its acceptance until its proper disposition shall be maintained by the laboratory.

5.9 Assuring the quality of test and calibration results

5.9.1 All test results shall be subjected to a technical review.

5.10 Reporting the results

5.10.1 The laboratory report shall where applicable, include but not limited to the following information:

- (a) case reference number
- (b) date of issue
- (c) description of the exhibit received and analysed
- (d) additional marking or labeling introduced by the analyst (if any)
- (e) disposition of exhibit
- (f) method and technique used
- (g) results of analysis
- (h) interpretation of results, conclusion or opinion of the analyst on the case
- (i) name, designation and signature of the analyst

5.10.2 In the event that the form of a sample had been changed during analysis, a note stating this fact should be included in the test report.

5.10.3 All reports shall accurately record and reflect the analyst's findings in the analysis. The results shall be reported in accordance with the request from the submitting authorities.

5.10.4 Test report signatory shall be the analyst who is involved in the testing activities.

5.10.5 The report shall be subjected to administrative and technical reviews. The signatory shall sign on each page of the report.

5.10.6 Where a drug or substance has been defined or listed in the Act, a note stating the identity of the drug or substance or the schedule under which it is listed in the Act shall be included in the test report.

5.10.7 The laboratory shall record information related to the release of the case report and exhibit(s).

References:

1. Dangerous Drugs Act 1952
2. Poison Act 1952
3. United Nations International Drug Control Programme (www.unodc.org)

Acknowledgements:

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