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

SC 1.2 - SPECIFIC CRITERIA FOR ACCREDITATION IN THE FIELD OF CHEMICAL TESTING

Issue 2, 13 May 2022

(Supplementary to MS ISO/IEC 17025)

MS ISO/IEC 17025

JABATAN STANDARD MALAYSIA
Department of Standards Malaysia

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Introduction

This document addresses the specific criteria for chemical testing and items that are essential or important for the proper conduct of a test. It provides detail or adds extra information to the general stated requirements of the SAMM accreditation criteria.

This document shall be read in conjunction with MS ISO/IEC 17025, *Skim Akreditasi Makmal Malaysia* (SAMM) policies and other relevant requirements published by Department of Standards Malaysia (Standards Malaysia).

The clause numbers in this document correspond to those of MS ISO/IEC 17025 but since not all clauses require additional requirements, the numbering may not be continuous.

1 Scope

This document sets out the specific requirements a chemical testing laboratory has to meet, in addition to the general requirements of MS ISO/IEC 17025:2017 and SAMM relevant requirement documents.

2 Normative references

MS ISO/IEC 17025:2017 - General Requirements for the Competence of Testing and Calibration Laboratories

3 Terms and definitions

3.1 Certified reference material (CRM): Reference material (RM) characterized by a metrologically valid procedure for one or more specified properties, accompanied by an RM certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability (ISO 17034:2016).

3.2 Equipment: Facilities that are accessible to the laboratory including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus required for the correct performance of laboratory activities (MS ISO/IEC 17025:2017).

3.3 Fitness for purpose: Degree to which data produced by a measurement process enables a user to make technically and administratively correct decision for a stated purpose (IUPAC).

3.4 Standard method: Method that has been developed, validated, collaborated, peer reviewed, published in international, regional and national standards or by regulatory body.

3.5 Non-standard method: Method that does not meet 3.4, such as:

i) Method developed by a laboratory;
ii) Method developed by a customer or manufacturer;

iii) Modified standard test methods (example: change in technical requirements);
iv) Method developed by or for industry group;
v) Method from scientific publications.

3.6 Industrial hygiene: The science of anticipating, recognising, evaluating and controlling health hazards at the workplace that may cause worker's injury or illness. The scope of test involves the analysis of samples or materials for the purpose of evaluating occupational exposure to chemicals hazardous to health resulting from occupational activities. The samples may be in the form of relevant sampling media used to collect contaminants and blood or urine taken from the worker.

3.7 Measurement uncertainty: Non-negative parameter characterising the dispersion of the quantity values being attributed to a measurand, based on the information used (VIM 2012).

3.8 Method validation: Confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled (EURACHEM Guide).

3.9 Metrological traceability: Property of a measurement results whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty (VIM 2012).

3.10 Performance characteristic: Functional quality that can be attributed to an analytical method. Examples of typical performance characteristics include selectivity, accuracy, trueness, recovery, precision, repeatability, reproducibility, detection limit, limit of quantitation, detection capability, ruggedness and stability (EC Directive).

3.11 Performance criteria: Requirements for a performance characteristic according to which it can be judged that the analytical method is fit for the purpose and generates reliable results (EC Directive).

3.12 Reference material (RM): material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process. (ISO 17034:2016).

4 General requirements

Same as in MS ISO/IEC 17025.

5 Structural requirements

Same as in MS ISO/IEC 17025.

6 Resource requirements

6.1 General

Same as in MS ISO/IEC 17025.

6.2 Personnel

6.2.1 Signatory

Test reports of any chemical composition or specifications of any substances or product consumed or used by, or intended for the consumption or use of, public or any section thereof, shall be signed by:

a) registered chemist; or

b) registered food analyst with annual practising certificate in the field of food analysis; or

c) registered pharmacist and the chemical analysis that he gives or provides, or certifies or declares in writing the result of, is for the purpose of determining the composition or specifications of a food, medical or pharmaceutical substance or product, including cosmetics and toiletry, or any part or component thereof; or

d) employee working under the supervision of a registered chemist or registered pharmacist and gives or provides, or certifies or declares in writing the result of, the chemical analysis for the purpose and in the course of his employment and, in case of an employee working under the supervision of a registered pharmacist, the chemical analysis is for the purpose of determining the composition or specifications of a food, medical, or pharmaceutical substance or product, including cosmetics and toiletry, or any part or component thereof; or

e) gazetted officer under relevant Act, directives or regulations.

Notwithstanding the above the signatory shall meet the requirements of SAMM Policy 6: *Requirements for SAMM Approved Signatory***.**

6.2.2 Recommended format for signing the test report is as follow:

a) The signatory for 6.2.1 (a), (b) and (c) should include name, function and *Institut Kimia Malaysia* (IKM) membership number or *Majlis Juruanalisis Makanan Malaysia* (MJMM) annual practising certificate number or *Lembaga Farmasi Malaysia* registration number.

b) The signatory for 6.2.1 (d) should include name and function of the employee and must also be counter-signed by the same supervising registered

chemist/registered pharmacist giving his/her name, function and the IKM membership number/registered pharmacist number.

c) The signatory for 6.2.1 (e) should include name, function and gazetted designation.

Note: Signatory approval is for specific classes of test(s) and product(s) (refer to Appendix 1).

6.2.3 The competency of personnel performing specific tests shall be demonstrated by the ability to achieve relevant performance characteristics of the tests or perform successfully in suitable proficiency testing programmes as listed in SAMM Policy 4: *Policy for Participation in Proficiency Testing Activities* (refer to Clause 4.2 of the SP 4 document).

6.3 Facilities and environmental conditions

Same as in MS ISO/IEC 17025.

6.4 Equipment

Same as in MS ISO/IEC 17025.

6.5 Metrological traceability

6.5.1 The calibration interval may be reduced or extended based on factors such as history on stability, accuracy required and ability of staff to perform regular checks.

6.6 Externally provided products and services

Same as in MS ISO/IEC 17025.

7 Process requirements

7.1 Review of requests, tenders and contracts

Same as in MS ISO/IEC 17025.

7.2 Selection, verification and validation of methods

Same as in MS ISO/IEC 17025.

7.2.1 Selection and verification of methods

The laboratory shall verify that it can achieve the performance characteristics of standard method before introducing the tests.

7.2.2 Validation of methods

The extent to which validation/verification is to be performed by the laboratory depends on the test method. These requirements together with method reference or identification are as stated in Table 1 below:

Table 1: Validation or verification requirements

Test method description	Validation or verification requirements	Method reference no. / ID
a) Standard method	Verification of published performance characteristics	<Method>, <year/edition>, <section no.> Examples: i) APHA 5520 B, 23rd Edition, 2017; ii) ASTM D7042-21; iii) MS 2458:2012, First Revision; iv) HACH Method 8149, 10th Edition, 2017; v) JIS A 1460:2021
	In the absence of published performance characteristics, validation required	
b) Method published in the scientific literature	Validation. If no published performance characteristics are available	
	Verification if performance characteristics from a MS ISO/IEC 17025 accredited laboratory that originally developed the method is available	
c) Published method developed by or for industry group	Validation. If no published performance characteristics are available	
	Verification if performance characteristics from a MS ISO/IEC 17025 accredited laboratory that originally developed the method is available	

Test method description	Validation or verification requirements	Method reference no. / ID
d) Commercial test kits	Validation. If no published performance characteristics are available	<Method>, <year/edition>, <section no.> Examples: i) APHA 5520 B, 23rd Edition, 2017; ii) ASTM D7042-21; iii) MS 2458:2012, First Revision; iv) HACH Method 8149, 10th Edition, 2017; v) JIS A 1460:2021
	Verification if performance characteristics from a MS ISO/IEC 17025 accredited laboratory that originally developed the method is available	
e) Standard methods used outside its intended scope or otherwise modified	Validation is required and the extent will vary e.g. having similar properties to those of representative matrices and analytes	<In-house Method>, <ref. no.>, <based on xxxx version/issue no., year> Examples: i) In-house Method TM C123-1 based on AOCS Cc3-25, 7th Edition, 2017; ii) In-house Method STP/WL232/08 based on ISO 8124-3: 2020, Part 3
f) Method developed by a customer or manufacturer	In the absence of performance characteristic, validation required	
	Verification of published performance characteristics	
g) Method developed in the laboratory	Validation	

7.3 Sampling

Same as in MS ISO/IEC 17025.

7.4 Handling of test items

Same as in MS ISO/IEC 17025.

7.5 Technical records

Same as in MS ISO/IEC 17025.

7.6 Evaluation of measurement uncertainty

For measurement uncertainty, requirements of SAMM Policy 5: *Policy on Measurement Uncertainty Requirements for SAMM Testing Laboratories* shall be met.

7.7 Ensuring the validity of results

7.7.1 Quality control samples shall be typical sample of the test method.

7.7.2 For industrial hygiene:
The laboratory shall participate in proficiency testing programme where available. Otherwise competency programme shall be implemented at least once a year to demonstrate the laboratory competence in industrial hygiene testing.

7.8 Reporting of results

7.8.1 The laboratory should incorporate security features in test report (e.g.: by printing on security paper, use of watermark / embossment, QR code, etc.).

7.8.2 The form of reporting of results shall not give a wrong impression of the uncertainty of measurement (refer to Clause 7.6 of the MS ISO/IEC 17025).

7.8.3 Test report shall conform to the requirements of MS ISO/IEC 17025 and Accreditation Policy 1 (AP1): *Policy on the Use of Accreditation Symbol and Reference to Accreditation.*

7.8.4 All reports (whether hard copy or electronic) must not be released to the customer until authorised by individuals with the authority to do so.

7.8.5 All pages of test report (hardcopy) shall be either signed or initialed by approved signatory for authentication (refer to Clause 6.2.1 of this SC document for the format of signing), unless the laboratory has valid reasons for not doing so. For test report issued via electronic transmission, the laboratory shall have procedures to control access to its laboratory information management system by personnel authorising the test report.

7.9 Complaints

Same as in MS ISO/IEC 17025.

7.10 Nonconforming work

Same as in MS ISO/IEC 17025.

7.11 Control of data and information management

Same as in MS ISO/IEC 17025.

8.0 Management system requirements

Same as in MS ISO/IEC 17025.

APPENDIX 1

Classes of Test and Product

The classes of test and product shall be included in the scope of accreditation.

1) Adhesives (Organic Resins) and Glues

a) Adhesives
b) Binders
c) Cement
d) Glues
e) Putty
f) Sealant
g) Others

2) Agricultural Products and Materials

a) Compost
b) Feed meal
c) Fertilizers and liming materials
d) Fungicide formulations
e) Herbicide formulations
f) Oil seeds and by products (including palm kernel)
g) Pesticide formulations
h) Plant material
i) Soils
j) Wood and timber treatment materials
k) Others

3) Biological Specimens

a) Specified human specimens
b) Specified veterinary specimens
c) Other biological specimens

4) Cement, Concrete and Related Products

a) Aggregates
b) Blended cement
c) Ceramics
d) Clays and soils
e) Concrete
f) Fibre cement
g) Fly ash/clinker
h) Glass
i) Limestone, lime gypsum
j) Masonry cement

k) Mortar
l) Portland cement
m) Pozzolans
n) Sand
o) Others

5) Cosmetics and Essential oils

a) Cosmetics and toiletries
b) Essential oils
c) Herbal-based cosmetics
d) Intermediates and miscellaneous chemicals for cosmetics
e) Perfumes
f) Others

6) Drugs and Pharmaceuticals

a) Antibiotics
b) Enzymes
c) Health supplements
d) Hormones
e) Intermediates and finished products
f) Natural products (herbal preparations)
g) Pharmaceutical formulation
h) Raw materials
i) Synthetic drugs
j) Vaccines and sera
k) Veterinary medicines
l) Others

7) Dye and Dye Intermediates

a) Dye intermediates
b) Natural dyes and colouring materials
c) Synthetic dyes
d) Others

8) Environmental Monitoring

a) Air (including stack emission and ambient monitoring)
b) Industrial effluent (including palm oil mill and rubber effluent)
c) Leachates
d) Sewage water
e) Soil/sediment/slugde
f) Solid wastes (including municipal and industrial)
g) Water and wastewater
h) Others

9) Explosives and Pyrotechnics

a) Ammunitions
b) Industrial explosives and associated material
c) Pyrotechnics
d) Explosives chemicals and allied materials
e) Others

10) Foods

a) Alcoholic beverages
b) Airy products
c) Edible oils, fats and their products
d) Eggs and egg products
e) Essential nutrients, including vitamins
f) Fish and fish products
g) Flour and confectionery
h) Food additives and supplements
i) Honey and honey products
j) Infant foods
k) Meat, poultry and derived products
l) Non-alcoholic beverages
m) Nuts, fruits and vegetables and derived products
n) Residues in foodstuffs
o) Sauces, herbs, spices and condiments
p) Sugars and sugar products
q) Other specified foods

11) Industrial Hygiene

a) Biological specimen (e.g. blood, urine etc.)
b) Bulk material samples (e.g. asbestos, roof, ceiling etc.)
c) Fibres (e.g. asbestos, refractory ceramic etc.)
d) Fumes (e.g. welding fumes, diesel fumes etc.)
e) Gases (e.g. carbon monoxide, sulfur dioxide, nitrogen dioxide etc.)
f) Oil mists (e.g. mineral oil mists etc.)
g) Particulates and dust (e.g. respirable quartz etc.)
h) Vapours (e.g. benzene vapours, toluene vapours etc.)
i) Others

12) Leather

a) Natural leather
b) Synthetic leather
c) Others

13) Medical Devices

a) Breathing apparatus and equipment
b) Catheters
c) Condoms
d) Diagnostic instruments
e) Health care and health hazard technologies
f) Limbs (prostheses)
g) Medical gloves
h) Pacemakers
i) Resuscitators
j) Surgical instruments
k) Syringes
l) Treatment equipment
m) Others

14) Metals and Alloys

a) Aluminium and aluminium alloys
b) Copper and copper alloys
c) Ferrous materials
d) Precious metals
e) Recycle waste
f) Tin, lead and their alloys
g) Zinc and zinc alloys
h) Others

15) Oleochemicals

a) Biodiesel
b) Fatty acid
c) Fatty alcohol
d) Fatty esters
e) Glycerin / glycerol
f) Soap noodles
g) Surfactant
h) Others

16) Ores and Minerals

a) Ferrous ores
b) Minerals
c) Precious metal ores
d) Radioactive ores
e) Trace elements for geochemical prospecting and metal recovery
f) Other ores and minerals

17) Paints, Varnishes, Inks, Coatings and Allied Products

a) Inks
b) Lacquers
c) Paints and protective coatings
d) Varnishes
e) Others

18) Paper, Paper Board and Wood Pulp

a) Composite packing materials
b) Newsprint and board packing materials
c) Paper, paper board and speciality papers
d) Pulp
e) Others

19) Petroleum and Petroleum Products

a) Bituminous materials
b) Crude petroleum
c) Fuels
d) Lubricants and hydraulic oil
e) Antifreeze additives to fuels and lubricants
f) Oil shale
g) Solvents
h) Others

20) Polymers

a) Natural polymers
b) Plastics
c) Polymer and plastic compounding materials
d) Synthetic polymers
e) Others

21) Rubber and Rubber Products

a) Compounding materials
b) Formulated products
c) Latex
d) Natural
e) Synthetic
f) Technically Specified Rubber (TSR)
g) Tyres
h) Others

22) Soap, Detergents and Toiletries

a) Soaps
b) Synthetic detergents
c) Wetting and emulsifying agents
d) Others

23) Solvent

a) Inorganic solvents
b) Organic solvents
c) Others

24) Textiles and Textile Products

a) Analysis of mixtures and blends of fibres
b) Chemical tests
c) Colour fastness tests
d) Flammability
e) Identification of fibres
f) Others

25) Water

a) Distilled demineralized
b) Dialysis water
c) Ground water
d) Industrial/cooling purposes
e) Mineral water
f) Pharmaceutical water
g) Potable/drinking and domestic
h) Processed water
i) Recycled water
j) Reverse osmosis water
k) Saline water
l) Steam raising/boiler water
m) Surface water
n) Swimming pool and spa
o) Ultrapure water
p) Others

26) Others

a) Animal and pet foods
b) Tobacco and by-products
c) Industrial chemicals
d) Nanomaterials
e) Others

Bibliography

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2. Chemist Act 1975 [Act 158].

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4. EURACHEM - Guide to Quality in Analytical Chemistry: An Aid to Accreditation (3rd Edition).

5. Food Analysts Act 2011 [Act 727].

6. IKM Circular Number 2/2008 - Signing of Certificate of Analysis (CoA).

7. IUPAC - International Union of Pure and Applied Chemistry.

8. ISO 17034:2016 - General Requirements for the Competence of Reference Material Procedures.

9. ISO 9000:2015 - Quality Management Systems - Fundamentals and Vocabulary.

10. MS ISO/IEC 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories.

11. SAMM Policy 4 (SP4) - Policy for Participation in Proficiency Testing Activities.

12. SAMM Policy 5 (SP5) - Policy on Measurement Uncertainty Requirements for SAMM Testing Laboratories.

13. SAMM Policy 6 (SP6) - Requirements for SAMM Approved Signatory.

14. Specific Criteria for Accreditation - Chemical Testing (IANZ).

15. VIM - International Vocabulary of Metrology - Basic and General Concepts and Associated Terms (2012 Edition).

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