MINISTRY OF INVESMENT, TRADE AND INDUSTRY
JABATAN STANDARD MALAYSIA

SC 1.3 - SPECIFIC CRITERIA FOR ACCREDITATION IN THE FIELD OF MICROBIOLOGICAL TESTING

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(Supplementary to MS ISO/IEC 17025)

MS ISO/IEC 17025

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

TABLE OF CONTENTS

Introduction

This document addresses the specific criteria that are essential for the proper conduct of test in the field of microbiological testing as stated in the scope below. It provides detail or additional information to the general stated requirements of the *Skim Akreditasi Makmal Malaysia* (SAMM) accreditation criteria.

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

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 covers the field of microbiological testing as stated in the Appendix 1(a) and Appendix 1(b).

2 Normative references

i) MS ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories;

ii) SAMM Policy Documents; and

iii) Specific Criteria 1.7 (SC 1.7) – Specific Criteria for the Accreditation in the Field of Molecular Testing

3 Terms and definitions

3.1 **Microbiology testing** includes virology, mycology, parasitology, bacteriology and immunology testing where these can be classified into several subdisciplines such as;

i) Microbial physiology
ii) Microbial genetics
iii) Cellular microbiology
iv) Medical microbiology
v) Veterinary microbiology
vi) Environmental microbiology
vii) Evolutionary microbiology
viii) Industrial microbiology
ix) Aeromicrobiology

x) Food microbiology

xi) Pharmaceutical microbiology

xii) Agricultural microbiology

xiii) Soil microbiology

xiv) Water microbiology

xv) Generation microbiology

xvi) Nano microbiology

3.2 **Related fields** mean degree in food science and/or technology, biomedical science, veterinary, fisheries, biotechnology etc. which has microbiology subject in their study syllabus.

3.3 **Reference cultures** mean collective term for reference strain, reference stocks and working cultures.

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

6.2.2 Microbiological testing shall be supervised by an experienced person, qualified in microbiology and shall be competent in the technical areas covered by the scope of accreditation. The supervisory staff shall be able to oversee the technical operations and cope with any problems that may arise.

6.2.3 Laboratory personnel shall have relevant work experience and competent before being allowed to perform tests covered by the scope of accreditation without supervision.

6.2.4 The laboratory management shall ensure that all personnel have received adequate training for the competent performance of tests and operation of equipment.

6.2.5 The competency of personnel performing specific tests shall be demonstrated by the ability to achieve performance characteristics of the tests.

6.2.6 Laboratory personnel competency and trend analysis shall be monitored and evaluated at least once a year.

6.2.7 Laboratory shall ensure the record for competency of staff is easily retrievable.

6.2.8 Requirements for approved signatory shall be as follows:

a) Qualification and experience:

i) Degree or higher in microbiology or related fields with;

- One year or more laboratory working experience in related fields requires 3 months working experience in current laboratory; or

- Less than one year laboratory working experience in related fields requires 6 months working experience in current laboratory.

ii) Gazetted officer under relevant act, directives or regulations; and

iii) Other requirements as stipulated in the relevant specific technical requirements.

Notwithstanding the above, the signatory shall meet the requirements of Accreditation Policy 4 (AP4): Policy on The Requirements for Key Personnel of Conformity Assessment Bodies.

b) Technical and operational requirements

Knowledge and understanding of the technical and laboratory operational requirements as follow:

i) Requirements of MS ISO/IEC 17025 and related SAMM requirements and relevant regulatory requirements;

ii) The principles of testing;

iii) The standards, methods and specifications for accreditation sought or held; and

iv) The evaluation of measurement uncertainties for the accreditation sought or held.

6.3 Accommodation and environmental conditions

6.3.1 The laboratory layout shall be designed to minimise potential contamination.

6.3.2 The internal layout should generally provide for sample receipt, washing-up and sterilisation, media preparation, general testing and incubation areas.

6.3.3 The design of workbenches, cupboards, shelves and the finish of all surfaces (i.e. benches, floors, ceilings, walls and windows) should facilitate cleaning and sterilisation. Walls, floors, ceilings and work surfaces should be easy to clean and disinfect.

6.3.4 There shall documented cleaning programme for laboratory fixtures, equipment and surface.

6.3.5 The laboratory environment, where relevant, shall be microbiologically monitored for trends and anomalies and records shall be kept. Laboratories should devise appropriate programmes of monitoring with respect to the type of testing being carried out.

6.3.6 As a minimum, monitoring should be of airborne contamination e.g. exposure plates and swabbing of critical surfaces such as testing benches.

6.3.7 Where necessary, appropriate pest and vermin control measures are expected to be in place.

6.3.8 Laboratory performing molecular techniques involving in-vitro nucleic acids amplification, the premises shall follow requirement as in SC 1.7.

6.3.9 Procedures that involve the handling of pathogens and reference stock cultures should be operated within a biological hazard safety cabinet and appropriate Personal Protective Equipment (PPE) commensurate with the risk level of the microorganism handled.

6.4 Equipment

6.4.1 It shall be noted that calibration requirements would vary depending on method specifications.

6.4.2 Maintenance of essential equipment shall be carried out at specific interval as needed.

6.5 Metrological traceability

Same as in MS ISO/IEC 17025 and SAMM Policy 2 (SP2) - Policy on the Metrological Traceability of Measurement Results.

6.5.1 Reference standards and reference materials

Reference cultures

a) Reference cultures are required for establishing acceptable performance of media (including test kits), for validating methods and for assessing/evaluating on-going performance. To demonstrate traceability, laboratories should use reference strains of microorganisms obtained directly from a recognised national or international collection.

b) Reference cultures should be sub-cultured once to provide reference stocks. Purity and biochemical checks should be made in parallel as appropriate. Working cultures for routine use should be primary subcultures from the reference stock. If reference stocks have been thawed, they should not be re-frozen and re-used.

c) Working cultures shall not be sub-cultured to replace reference stocks. Commercial derivatives of reference cultures may only be used as working cultures.

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

7.2.1 General

Internationally or nationally accepted standard test procedures or non-standard procedures that have been appropriately validated and which are performed regularly should be used.

7.2.2 Selection of methods

7.2.2.1 Standard methods

Method that has been developed, validated, collaborated, peer reviewed, published in international, regional and national standards or by reputable technical organisations/regulatory body such as AOAC, APHA, FDA/BAM, EPA and ISO.

Where standard methods are prescribed and followed, the laboratory is expected to maintain current versions of the standard methods (reference texts) and up-date laboratory bench methods in accordance with these. Although full

validation is not required, a laboratory shall verify that it can properly operate the method and demonstrate the limits of detection, selectivity, specificity, repeatability, reproducibility and robustness.

7.2.2.2 Non-standard methods

Non-standard methods are in house method developed or modified or used outside their intended scope from the listed methods as follows:

a) Methods developed in the laboratory;

b) Methods developed by a customer / an industry group;

c) Modified Standard test methods; and

d) Methods from scientific publications.

Validation requirements for non-standard methods as in **Table 1**:

Table 1: Validation requirements for non-standard methods

Test method description	Validation requirements	Method reference no./ID in scope of accreditation
a) Method developed in the laboratory	Full validation	e.g.: In-house method JKM-M-1020 based on AOAC 2008
b) Method developed by a customer / an industry group	Full validation	e.g.: In-house method JKM-M-1021 based on Nestle 123
c) Modified standard test method	Full validation	e.g.: In-house method JKM-M-1022 based on BAM 2008
d) Methods from scientific publications	Full validation	e.g.: In-house method JKM-M-1022 based on International Journal of Food Microbiology

7.2.2.3 Kits

Commercial test kits shall be verified before use. Validation is required if the laboratory is unable to source the validation data from manufacturers with a recognised quality assurance system or reputable validation based on collaborative testing, e.g. AOAC Official Methods and associated JAOAC Publications or independently reviewed methods such as AOAC Performance Tested Methods.

7.2.3 Procedure for method validation

Validation procedures shall involve, as appropriate, the aspects referred to in clause 7.2.2 of MS ISO/IEC 17025.

7.2.3.1 Determine the performance characteristic

7.2.3.1.1 The analytical performance characteristics shall be considered for either validation or verification of method.

7.2.3.1.2 Performance characteristics for qualitative and quantitative methods are determined depending on the types of methods used as in **Table 2** and **Table 3:**

Table 2: Performance characteristics for qualitative method

	Standard method	Non-Standard method
Trueness /Accuracy		√
Precision		√
Sensitivity		√
Specificity		√
Selectivity		√
Limit of Detection (LOD)	√	√
Robustness	√	√

Table 3: Performance characteristics for quantitative method

	Standard method	Non-Standard method
Trueness /Accuracy	√	√
Precision	√	√
Sensitivity	√	√
Specificity		√
Selectivity		√
Limit of Quantitation (LOQ)		√
Robustness	√	√

7.3 Sampling

Same as in MS ISO/IEC 17025.

7.4 Handling of test items

For classification of samples, refer to Appendix 1(a).

7.5 Technical records

Same as in MS ISO/IEC 17025.

7.6 Evaluation of measurement uncertainty

7.6.1 Measurement of uncertainty shall be estimated for microbiology quantitative test methods.

7.6.2 Measurement of uncertainty shall be re-evaluated when changes in critical factors are made to the validated method. Examples: changes of media, analyst, equipment, relocation of premises and etc.

7.6.3 Same as in MS ISO/IEC 17025 and SAMM Policy 5 (SP5) - Policy on Measurement Uncertainty Requirements for SAMM Testing Laboratories.

7.7 Ensuring the validity of results

Same as in MS ISO/IEC 17025 and Accreditation Policy 6 (AP6) - Policy for Participation in Proficiency Testing Activities.

7.7.1 Ensuring the quality of test and calibration results

7.7.1.1 Laboratories should have developed, documented and implemented appropriate quality control program. Where relevant quality control data should be analysed, and where it is found to be outside pre-defined action criteria, the defined action shall be taken to correct the problem and to prevent incorrect results from being reported.

7.7.1.2 The quality control program should be designed in such a way as to demonstrate the on-going control of both the accuracy and precision of each test is being maintained. Where the tests are performed infrequently the laboratory should carry out regular performance checks to demonstrate the continuing competence to perform them.

7.7.1.3 Some of the most common quality control programs are summarised as follows:

a) Personnel;

b) Valid test method;

c) Laboratory accommodation and environment;

d) Equipment and its calibration;

e) Maintenance of reference organism;

f) Consumables used including reagent and media; and

g) Laboratory supplies and equipment having direct contact with samples under test.

7.8 Reporting of results

Same as in MS ISO/IEC 17025.

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 Management system requirements

Same as in MS ISO/IEC 17025.

Appendix 1(a)

TYPE OF PRODUCTS

1.0 Microbiological tests on foods

- Cereal products
- Nuts and nut products
- Dairy products
- Meat and meat products
- Fish, crustaceans and mollusks
- Poultry and poultry products
- Eggs and egg products
- Edible fats and oils
- Margarine
- Vegetables and vegetable products fruit, jams and other fruit products
- Fruit juices and concentrates sugar products, honey and confectionery
- Beverages
- Mixes foods
- Nutritional supplements
- Additives to foods
- Gelatin and other gums
- Herbs and spices
- Others

2.0 Microbiological tests on pharmaceutical and cosmetics

- Cream
- Lotion
- Ointment
- Powder
- Solution
- Syrup
- Tablet
- Sanitizer
- Others

3.0 Microbiological environmental sample

- Air
- Effluents
- Surfaces
- Waste
- Water
- Others

4.0 Medical devices

- Personnel protective devices (e.g.: glove, face mask etc.)
- Procedural instrumentation (e.g.: tubing, syringe, etc.)
- Others

5.0 Miscellaneous materials and product

- Biocides
- Biological cleaning agent
- Animal feeds
- Others

Appendix 1(b)

TYPE OF TESTS

1.0 Qualitative and quantitative tests for different groups of microorganisms

- Acid-forming bacteria
- Acid-tolerant bacteria
- Aerobic mesophilic bacteria
- Anaerobic bacteria
- Anaerobes producing H2S
- Bacterial spores
- Bacteriophage
- Coliforms
- Coliforms (faecal)
- Enteric viruses
- Enterococci
- Flat sour type bacteria
- Gelatine liquefying organism
- Howard mould count
- Iron bacteria
- Lactic acid organisms
- Lipolytic organims
- Mycoplasma
- Osmophilic moulds
- Osmophilic yeasts
- Proteolytic organisms
- Psyschrotrophic organisms
- Plate count
- Rope spores
- Spore-forming aerobic bacteria
- Spore-forming anaerobic bacteria
- Streptococci
- Streptococci (faecal)
- Sulphate reducing clostridia
- Sulphate reducing bacteria
- Sulphate spoilage
- Thermactinomycetes
- Thermoduric organisms
- Thermophilic bacteria
- Yeasts viability
- Yeasts and moulds
- Parasite
- Others

2.0 Qualitative and quantitative tests for specific genera/species etc.

- *Aeromonas spp.*
- *Aeromonas hydrophila*
- *Bacillus spp.*
- *Bacillus cereus*
- *Bifidobacterium sp*
- *Campylobacter*
- *Campylobacter coli*
- *Campylobacter jejuni*
- *Candida albicans*
- *Cladosporium resinae*
- *Clostridium spp*
- *Clostridium botulinum*
- *Clostridium perfringens*
- *Desulphovibrio*
- *Enterobacteracieae*
- *Escherichia coli*
- *Escherichia coli 0157*
- *Helicobacter pylori*
- *Pathogenic Escherichia coli*
- *Lactobacillus spp.*
- *Lactobcillus acidophilus*
- *Legionella spp.*
- *Legionella pneumophila*
- *Listeria spp.*
- *Listeria monocytogenes*
- *Microcystis aeruginosai*
- *Proteus spp.*
- *Pseudomonas spp.*
- *Pseudomonas aeruginosa*
- *Salmonella spp.*
- *Shigella spp.*
- *Streptococcus spp.*
- *Staphylococcus aureus*
- *Thiobacilllus spp.*
- *Vibrio cholerae*
- *Vibrio parahaemolyticus*
- *Vibrio vulnificus*
- *Xanthomonas maltophilia*
- *Yersinia spp.*
- *Yersinia enterocolitica*
- Others

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