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

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(Supplementary to MS ISO/IEC 17025)

JABATAN STANDARD MALAYSIA
Department of Standards Malaysia (STANDARDS MALAYSIA)
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1 Introduction and Scope

The purpose of this document is to describe specific criteria for accreditation of microbiological testing as defined in clause 3. Appendix 1(a) and Appendix 1(b) provide guidelines which is applicable for microbiological testing.

This document shall be read in conjunction with the MS ISO/IEC 17025 standard, SAMM Policy requirements and STR1.6 - Specific Technical Requirement for Accreditation of Nucleic Acid Testing Laboratories where applicable.

2 Normative References


ii) SAMM Policy Documents

iii) STR1.6 - Specific Technical Requirement for Accreditation of Nucleic Acid Testing Laboratories

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;

- Microbial physiology
- Microbial genetics
- Cellular microbiology
- Medical microbiology
- Veterinary microbiology
- Environmental microbiology
- Evolutionary microbiology
- Industrial microbiology
- Aeromicrobiology
- Food microbiology
- Pharmaceutical microbiology
- Agricultural microbiology
• Soil microbiology
• Water microbiology
• Generation microbiology
• Nano microbiology

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

4 Management Requirements

As in the MS ISO/IEC 17025:2005.

5 Technical Requirements

As in the MS ISO/IEC 17025:2005.

5.1 General

As in the MS ISO/IEC 17025:2005.

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 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.

5.2.3 Laboratory personnel shall have relevant work experience and competent before being allowed to perform tests covered by the scope of accreditation without supervision.
5.2.4 The laboratory management shall ensure that all personnel have received adequate training for the competent performance of tests and operation of equipment.

5.2.5 Laboratory personnel competency shall be monitored at least once a year.

5.2.6 Requirement for approved signatory shall be as follows:

a) Qualification and experience:

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

a) One year or more laboratory working experience in related fields requires 3 months working experience in current laboratory; or  
b) Less than one year laboratory working experience in related fields requires 6 months working experience in current laboratory

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

b) Technical and operational requirements

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

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;

iv) The estimation of measurement uncertainties for the accreditation sought or held.
5.3 Accommodation and environmental conditions

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

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

5.3.3 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.

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

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

5.3.6 Laboratory performing molecular techniques involving in-vitro nucleic acids amplification, the premises shall follow requirement as in STR 1.6.

5.3.7 Procedures that involve the handling of pathogens and reference stock cultures should be operated within a biological hazard safety cabinet of a class commensurate with the risk level of the microorganism handled.
5.4 Test and calibration methods and method validation

5.4.1 General

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

5.4.2 Selection of methods

5.4.2.1 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.

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 and reproducibility.

5.4.2.2 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.

5.4.2.3 Methods developed by a customer or an industry group

As in clause 5.4.2.2 above.
5.4.2.4-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
(d) Methods from scientific publications

Validation requirements for non-standard methods as in table below:

<table>
<thead>
<tr>
<th>Test method description</th>
<th>Validation requirements</th>
<th>Method Reference No/ID in Scope of Accreditation</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Method developed in the laboratory</td>
<td>Full validation</td>
<td>e.g. : In-house method JKM-M-1020 based on AOAC 2008</td>
</tr>
<tr>
<td>b) Method developed by a customer/ an industry group</td>
<td>Full validation</td>
<td>e.g. : In-house method JKM-M-1021 based on Nestle 123</td>
</tr>
<tr>
<td>c) Modified standard Test Method</td>
<td>Full validation</td>
<td>e.g. : In-house method JKM-M-1022 based on BAM 2008</td>
</tr>
<tr>
<td>d) Methods from scientific publications</td>
<td>Full validation</td>
<td>e.g. : In-house method JKM-M-1022 based on International Journal of food microbiology</td>
</tr>
</tbody>
</table>

Validation procedures shall involve, as appropriate, the aspects referred to in clause 5.4.5 of MS ISO/IEC 17025:2005.
5.4.6 Estimation of uncertainty of measurement

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

As in MS ISO/IEC 17025 and SAMM Policy 5.

5.5 Equipment

As in MS ISO/IEC 17025.

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

5.6 Measurement traceability

5.6.3 Reference standards and reference materials

5.6.3.1-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 strains 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 stocks shall not be sub-cultured to replace reference stocks. Commercial derivatives of reference strains may only be used as working cultures.
5.7 Sampling

As in MS ISO/IEC 17025.

5.8 Handling of test and calibration items

As in MS ISO/IEC 17025.

5.9 Assuring the quality of test and calibration results

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.

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.

Some of the most common Quality programs are summarized 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, media.
g. Laboratory supplies and equipment having direct contact with samples under test.

5.10 Reporting the results

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 molluscs
- 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
- Animal feeds
- Mixes foods
- Nutritional supplements
- Additives to foods
- Gelatine and other gums
- Herbs and spices
- Pet foods
- Other food products

#### 2.0 Microbiological tests on pharmaceutical and cosmetics
- Cream
- Lotion
- Ointment
- Powder
- Solution
- Syrup
- Tablet
- Others

#### 3.0 Microbiological environmental sample
- Air
- Effluents
- Surfaces
- Waste
- Water
- Others

#### 4.0 Medical devices
- Personnel protective devices (eg: glove, musk etc)
- Procedural instrumentation (eg: tubing, syringe, etc)
- Others

#### 5.0 Miscellaneous materials & product
- Biocides
- Biological cleaning agent
# Appendix 1(b)

## TYPE OF TESTS

<table>
<thead>
<tr>
<th>1.0 Qualitative and quantitative tests for different Groups of microorganisms</th>
<th>2.0 Qualitative and quantitative tests for specific genera/species etc.</th>
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<tr>
<td>Acid-forming bacteria</td>
<td>Aeromonas spp.</td>
</tr>
<tr>
<td>Acid-tolerant bacteria</td>
<td>Aeromonas hydrophila</td>
</tr>
<tr>
<td>Aerobic mesophilic bacteria</td>
<td>Bacillus spp.</td>
</tr>
<tr>
<td>Anaerobic bacteria</td>
<td>Bacillus cereus</td>
</tr>
<tr>
<td>Anaerobes producing H2S</td>
<td>Bifidobacterium sp</td>
</tr>
<tr>
<td>Bacterial spores</td>
<td>Campylobacter</td>
</tr>
<tr>
<td>Bacteriophage</td>
<td>Campylobacter coli</td>
</tr>
<tr>
<td>Coliforms</td>
<td>Campylobacter jejuni</td>
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<tr>
<td>Coliforms (faecal)</td>
<td>Candida albicans</td>
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<tr>
<td>Enteric viruses</td>
<td>Cladosporium resinae</td>
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<tr>
<td>Enterococci</td>
<td>Clostridium spp</td>
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<tr>
<td>Flat sour type bacteria</td>
<td>Clostridium botulinum</td>
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<tr>
<td>Gelatine liquefying organism</td>
<td>Clostridium perfringens</td>
</tr>
<tr>
<td>Howard mould count</td>
<td>Desulphovibrio</td>
</tr>
<tr>
<td>Iron bacteria</td>
<td>Enterobacteriaceae</td>
</tr>
<tr>
<td>Lactic acid organisms</td>
<td>Escherichia coli</td>
</tr>
<tr>
<td>Lipolytic organisms</td>
<td>Escherichia coli 0157</td>
</tr>
<tr>
<td>Mycoplasma</td>
<td>Helicobacter pylori</td>
</tr>
<tr>
<td>Osmophilic moulds</td>
<td>Pathogenic <em>Escherichia coli</em></td>
</tr>
<tr>
<td>Osmophilic yeasts</td>
<td>Lactobacillus spp.</td>
</tr>
<tr>
<td>Proteolytic organisms</td>
<td>Lactobacillus acidophilus</td>
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<td>Psychrotrophic organisms</td>
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<td>Rope spores</td>
<td>Listeria spp.</td>
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<td>Spore-forming aerobic bacteria</td>
<td>Listeria monocytogenes</td>
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<tr>
<td>Spore-forming anaerobic bacteria</td>
<td>Microcystis aeruginosai</td>
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<td>Proteus spp.</td>
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<tr>
<td>Streptococci (faecal)</td>
<td>Pseudomonas spp.</td>
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<td>Sulphate reducing clostridia</td>
<td>Pseudomonas aeruginosai</td>
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<tr>
<td>Sulphate reducing bacteria</td>
<td>Salmonella spp.</td>
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<td>Shigella spp.</td>
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<td>Streptococcus spp.</td>
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<td>Thermotrophic organisms</td>
<td>Staphylococcus aureus</td>
</tr>
<tr>
<td>Thermophilic bacteria</td>
<td>Thiobacillus spp.</td>
</tr>
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<td>Vibrio cholerae</td>
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<tr>
<td>Yeasts and moulds</td>
<td>Vibrio parahaemolyticus</td>
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<tr>
<td>Others</td>
<td>Vibrio vulnificus</td>
</tr>
<tr>
<td>Others</td>
<td>Xanthomonas maltophilia</td>
</tr>
<tr>
<td></td>
<td>Yersinia spp.</td>
</tr>
<tr>
<td></td>
<td>Yersinia enterocolitica</td>
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