MINISTRY OF INVESTMENT, TRADE AND INDUSTRY
DEPARTMENT OF STANDARDS MALAYSIA

SC 1.7 - SPECIFIC CRITERIA FOR THE ACCREDITATION IN THE FIELD OF MOLECULAR TESTING

Issue 1, 25 July 2024

(Supplementary to MS ISO/IEC 17025)

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

TABLE OF CONTENTS

Introduction

This document shall be used by Department of Standards Malaysia (JSM) to provide appropriate criteria for the assessment and accreditation of laboratories providing molecular testing based on MS ISO/IEC 17025.

The numbering of clauses in this document correspond to the clauses of MS ISO/IEC 17025, however, as not all clauses necessitate interpretation, there may be breaks in the numbering sequence. Laboratories are also reminded of the need to comply with any relevant statutory or legislative requirements.

This document cancels and replaces the following documents:

i. STR 1.5 - Specific Technical Requirements for Accreditation of Laboratory Testing for Genetically Modified Organisms (GMO); and
ii. STR 1.6 - Specific Technical Requirements for Accreditation of Nucleic Acid Testing Laboratories

1 Scope

This document shall be read in conjunction with MS ISO/IEC 17025, Accreditation Policy (AP) documents, SAMM Policy documents (SP series) and relevant requirements published by JSM.

The document sets out the specific criteria for accreditation of laboratories involved in molecular testing.

Molecular testing refers to the detection and/or quantification of specific *Deoxyribonucleic Acid (DNA)* or *Ribonucleic Acid (RNA)* sequence in a specimen.

Please refer to Appendix 1 for classes of test and product.

2 Normative reference

2.1 This document refers to the following standards and documents. For all references, the latest edition of the document applies:

i. MS ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories
ii. Accreditation Policy 4 (AP 4) - Policy on The Requirements for Key Personnel of Conformity Assessment Bodies
iii. Accreditation Policy 6 (AP 6) - Policy for Participation in Proficiency Testing Activities
iv. SAMM Policy 5 (SP 5) - Policy on Measurement Uncertainty Requirements for

SAMM Testing Laboratories

v. Specific Criteria 1.2 (SC 1.2) - Specific Criteria for Accreditation in the Field of Chemical Testing
vi. Specific Criteria 1.3 (SC 1.3) - Specific Criteria for Accreditation in the Field of Microbiological Testing
vii. Specific Criteria 1.6 (SC 1.6) - Specific Criteria for Accreditation in the Field of Veterinary Testing

3 Terms and definitions

Same as MS ISO/IEC 17025.

4 General requirements

Same as MS ISO/IEC 17025.

5 Structural requirements

Same as MS ISO/IEC 17025.

6 Resource requirements

6.1 Same as MS ISO/IEC 17025

6.2 Personnel

6.2.1 In addition to MS ISO/IEC 17025 and Accreditation Policy 4 (AP 4) - Policy on The Requirements for Key Personnel of Conformity Assessment Bodies , the laboratory shall have sufficient personnel having appropriate technical knowledge and proficiency to carry out their responsibilities including experiments and analysis. The signatory(ies) shall be qualified, skilled and knowledgeable in the scope of work sought or accredited and possess the education and work experiences as per **Table 1**:

TABLE 1: Requirements for Education and Work Experience of Signatories

No.	Education	Work experience
1.	Personnel having a degree or higher in Molecular Biology or Biotechnology	i. One year or more laboratory working experience in the field of molecular testing, requires additional 3 months working experience in current laboratory; or ii. Less than one-year laboratory working experience in the field

No.	Education	Work experience
		of molecular testing, requires additional 6 months working experience in current laboratory.
2.	Personnel having a degree or higher in related science field including but not limited to the following: a) Chemist as defined in SC1.2: Specific Criteria in the Field of chemical testing if the molecular testing is carried out within the scope of chemical testing; or b) Microbiologist as defined in SC1.3: Specific Criteria in the Field of Microbiology Testing if the molecular testing is carried out within the scope of microbiology testing; or c) Veterinary surgeon/ veterinarian/ veterinary officer as defined in SC1.6: Specific Criteria in the Field of Veterinary Testing if the molecular testing is carried out within the scope of veterinary testing; or d) Gazetted/registered officer under relevant act, directives or regulations.	i. One year or more laboratory working experience in the field of molecular testing requires additional 6 months working experience in current laboratory; or ii. Less than one-year laboratory working experience in the field of molecular testing requires additional 12 months working experience in current laboratory.

6.3 Facilities and environment conditions

6.3.1 The laboratory shall have dedicated areas, equipment and facilities for specific molecular work processes in handling raw samples, processed samples, Polymerase Chain Reaction (PCR) set-up and post analysis to minimize cross-contamination and risk to personnel.

6.3.2 To minimize and prevent any chances of cross-contamination, the setup of flow-working processes in the laboratory should be established in one direction.

6.3.3 Laboratory shall comply with the applicable statutory procedures for radioactive handling and waste disposal.

6.4 Equipment

Same as MS ISO/IEC 17025.

6.5 Metrological traceability

6.5.1 In addition to MS ISO/IEC 17025, the following applies:

6.5.1.1 Appropriate record on the reference standard/material such as date of receipt, arrival condition and appropriate test condition shall be maintained. The stability of the reference standard/material under storage and test conditions shall be determined.

6.5.1.2 Reference databases, whether local or international, which are maintained for identification, comparison or interpretation purposes shall be documented and unequivocally identified. The reference database shall be from reliable and valid resources.

6.5.1.3 Reference standard/material shall be identified and stored separately from test samples.

6.6 Externally provided products and services

Same as MS ISO/IEC 17025.

7 Process requirements

7.1 Review of requests, tenders and contracts

Same as MS ISO/IEC 17025.

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

Same as MS ISO/IEC 17025.

7.2.2 Validation of methods

In addition to MS ISO/IEC 17025, the following applies:

7.2.2.1 Standard methods

Methods that have been developed, validated, collaborated, peer reviewed, published in international, regional and national standards or by a reputable technical organisation/regulatory body such as Malaysian Standard (MS), International Organization for Standardization (ISO), Codex Alimentarius Commission (CODEX), and/or European Committee for Standardization (CEN).

Where standard methods are prescribed and followed, the laboratory is expected to maintain and use the latest versions of the standard methods (reference texts). Although full validation is not required, the laboratory shall verify that it can satisfactorily perform the method and at least perform the validation/verification parameters as per **Table 2 and Table 3**.

7.2.2.2 Non-standard methods

Non-standard methods such as:

a) Methods developed by a laboratory;

b) Methods developed by a customer / manufacturer group;

c) Modified Standard test methods (e.g. change in technical requirements); and

d) Methods from scientific publications.

Validation requirements for non-standard methods shall address the minimum parameters as listed in **Table 2 and Table 3**.

7.2.2.3 Test 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 data.

Validation requirements for kits shall at least address the parameters as listed in **Table 2 and Table 3**.

Table 2: Validation/verification parameters for qualitative method

Acceptance criteria	Standard method	Non-standard method	Kits (with validated data)	Kits (without validated data)
Accuracy	√	√	√	√
Precision		√		√
Specificity		√	√	√
Selectivity		√		√
Limit of Detection (LOD)	√	√	√	√
Robustness		√		√

Table 3: Validation/verification parameters for quantitative method

Acceptance criteria	Standard method	Non-Standard method	Kits (with validated data)	Kits (without validated data)
Trueness	√	√	√	√
Precision	√	√	√	√
Specificity		√	√	√
Selectivity		√		√
Limit of Quantitation (LOQ)	√	√	√	√
Robustness		√		√

Applicability and limitations of the validated method for each defined group of products shall be established. Performance criteria, recommended by national/international organization, which are suitable for the intended purpose shall be established.

7.3 Sampling

Same as MS ISO/IEC 17025.

7.4 Handling of test and calibration items

7.4.1 In addition to MS ISO/IEC 17025, the following apply:

7.4.1.1 In order to prevent cross-contamination, there should be storage rooms and/or areas for storing of test items, reference materials and post-PCR products.

7.4.1.2 During handling of test items, all general and specific rules for preserving stability, safe transportation and prevention of contamination applies.

7.4.1.3 The traceability of all activities from receipt of test items to the reporting of results, including storage and disposal of the test items shall be documented.

7.5 Technical records

Same as MS ISO/IEC 17025.

7.6 Evaluation of measurement uncertainty

In addition to MS ISO/IEC 17025, SAMM Policy 5 (SP 5) - Policy on Measurement Uncertainty Requirements for SAMM Testing Laboratories applies.

7.7 Ensuring the validity of results

7.7.1 In addition to MS ISO/IEC 17025, the following applies:

7.7.1.1 Quality control measures shall include positive and negative controls (template free control), and extraction blank for every batch of analysis.

7.7.1.2 The laboratory shall participate in relevant Proficiency Testing programmes in accordance to AP 6.

7.7.1.3 The laboratory shall design internal quality control systems that verify the attainment of the intended validity of test results and shall document the acceptable criteria for the interpretation of the test results based on the Laboratory validation/verification data and/or related guideline.

7.8 Reporting the results

As MS ISO/IEC 17025.

7.9 Complaints

As MS ISO/IEC 17025.

7.10 Nonconforming work

As MS ISO/IEC 17025.

7.11 Control of data and information management

As MS ISO/IEC 17025.

8.0 Management system requirements

As MS ISO/IEC 17025.

APPENDIX 1
Classes of Test and Product

The areas of which accreditation is offered:

1. Genetically Modified Organism (GMO)
2. Species identification of animals, plants, microorganisms, etc.
3. Halal testing (e.g. Porcine DNA)
4. Genetic testing (e.g. paternity, disease diagnosis)
5. Others (e.g. sequencing services)

REFERENCES:

1. Biosafety Act 2007 [Act 678]
2. Food Act 1983 [Act 281]
3. Food Regulation 1985 [P.U.(A) 437/85]

ACKNOWLEDGEMENTS:

1.	Dr. Mazlan Isa	Department of Standards Malaysia (Chairman)
2.	Mr. Lim Kong Boon	Department of Standards Malaysia
3.	Ms. Faizah Puad	National Public Health Laboratory, Ministry of Health
4.	Ms. Noor Shafriza Zainal Azmi	Department of Chemistry Malaysia
5.	Ts. Laina Munid	Food Safety and Quality Laboratory (MKKM) Selangor
6.	Ms. Nor Aziah Nor Zaki	Food Safety and Quality Laboratory (MKKM) Selangor
7.	Dr. Khomaizon Abdul Kadir Pahirulzaman	Universiti Malaysia Kelantan
8.	Mr. Mohd. Hazim Mohd. Yusop	Universiti Malaysia Sabah
9.	Dr. Yuvaneswari Chandramoulee Swaran	UCSI University
10.	Ts. Nor Hamizah Md. Non	Unipeq Sdn. Bhd.
11.	Ms. Ong Swee Ling	SGS (M) Sdn. Bhd.
12.	Ms. Ruzanna Zainal	Halvec Laboratories Sdn. Bhd.
13.	Ms. Nazihah Ab. Hamid	Halvec Laboratories Sdn. Bhd.
14.	Ms. Low Yee Ping	Apical Scientific Sdn. Bhd.
15.	Ms. Aainaa Kamilah Roslee	Department of Standards Malaysia (Secretary)
16.	Ms. Nurul Shahzreenah Jam'an	Department of Standards Malaysia (Secretary)
17.	Ms. Nursyazwani Syamimi Abdul Rahman	Department of Standards Malaysia (Secretary)