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

STR 1.2 - SPECIFIC TECHNICAL REQUIREMENTS FOR ACCREDITATION OF TOXICITY TESTING LABORATORIES

Issue 4, 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 provides criteria for the assessment and accreditation of laboratories conducting toxicity testing. The laboratory shall comply with the requirements of this document and relevant statutory or legislative requirements.

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

Accreditation may be sought for toxicity testing of substances listed in but not limited to the following;

a) Chemical Substances
   Any substances that are produced synthetically or naturally that use by industry including industrial chemicals aligned with the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).

b) Cosmetic and Skin Care Products
   Chemical and natural based products in all forms as defined and listed in Guidelines for Control of Cosmetic Products in Malaysia 2017 e.g. powder, paste, liquid and aerosol.

c) Food Ingredient/Additive
   All types of food ingredient/additive intended for food preparation or for the production of food for consumption as defined in Malaysian Food Act 1983 [Act 281].

d) Medical Devices
   All types of medical devices as defined and stipulated in Medical Device [Act 737] e.g. gloves, condoms, implants, prosthetics and catheter.

e) Pharmaceutical
   Products intended for medicinal use in human or animal as stipulated in the guidance document published by National Pharmaceutical Regulatory Agency (NPRA).

f) Wastes and Environmental Samples

All types of samples taken from the environment e.g. water and waste water, river water, sediment, sludge, air, treated and untreated effluent. Other Manufactured Products.

g) All other types of natural and manufactured goods and products e.g. food packaging and toys.

2 Normative references

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

3 Terms and definitions

All terms and definitions given in MS ISO/IEC 17025 apply to this document.

3.1 Technical personnel refer to personnel who perform the scientific and technical work of the laboratory.

3.2 Technical support personnel undertake work of a repetitive nature with appropriate practical experience, specific training and with competency assessed.

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 relevant educational qualification, training, technical knowledge and experience for the assigned functions.

6.2.2 The requirements of a signatory shall be as follows;

a) a first degree in Science or equivalent discipline and at least two (2) years of experience in the field of toxicity testing; or

b) a MSc degree in Science or equivalent discipline with one (1) year experience in the field of toxicity testing; or

c) MSc degree or PhD in the field of toxicology with six (6) months experience in testing; or

d) Specific certification e.g. Diplomate of the American Board of Toxicology (DABT), Federation of European Toxicologists and European Societies of Toxicology (EUROTOX).

6.2.3 The technical personnel shall:

a) have first degree in Science or diploma with one (1) year experience or have a minimum qualification of SPM with two (2) years experience in the field of testing; and

b) have relevant competency in the area of toxicity testing he/she is involved in.

6.2.4 The technical support personnel shall:

a) have a minimum qualification of SPM with relevant experience in the field of testing; and

b) have relevant competency in the area of toxicity testing he/she is involved in.

6.2.5 Technical personnel shall participate and have performed satisfactorily in inter/intra laboratory comparison at least once a year or at any appropriate period of time.

6.2.6 The laboratory shall have a training and competency evaluation schedule for monitoring competency of its personnel.

6.3 Facilities and environmental conditions

6.3.1 The laboratory shall be of suitable size, construction and location to meet the requirements of the test and to minimize disturbance that would interfere with the validity of the test.

6.3.2 The design of the laboratory shall provide an adequate degree of separation of the different activities to assure the proper conduct of each test.

6.3.3 The laboratory shall have a sufficient number of rooms or areas to assure the isolation of test systems and the isolation of individual projects, involving hazardous substances.

6.3.4 Suitable rooms or areas shall be available for the settling in, quarantine or acclimatization, the diagnosis, treatment and control of diseases, in order to ensure that there is no unacceptable degree of deterioration of test systems.

6.3.5 There shall be storage rooms or areas as needed for supplies and equipment. Storage rooms or areas shall be separated from rooms or areas housing the test systems and shall provide adequate protection against infestation, contamination, and/or deterioration.

6.3.6 The laboratory shall monitor specific environmental condition (e.g. temperature, humidity, light, noise) that can affect the validity of the test result where the test is performed.

6.3.7 Handling and disposal of wastes shall be carried out in such a way as not to jeopardize the integrity of test. This includes provision for appropriate collection, storage and disposal facilities, and decontamination and transportation procedures.

6.4 Equipment

Same as in MS ISO/IEC 17025.

6.5 Metrological traceability

In addition to MS ISO/IEC 17025 and SAMM Policy 2 (SP2) - Policy on the Metrological Traceability of Measurement Results, testing equipment that has a significant effect on the reported results and associated uncertainties of measurement (including, where relevant, instruments used for monitoring critical environmental conditions) shall be calibrated or verified.

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 Selection and verification of methods

Laboratories may use preferred international, national, industry sourced, in-house or customer nominated methods. In all cases, the laboratory shall ensure that each particular method is adequate for its intended purpose.

However, in-house methods based on existing international or foreign established standards are accepted provided the changes are clearly described and the method validated.

Documentation shall refer to the method source and acknowledge any modifications and/or additions.

7.2.2 Validation of methods

Validation procedures vary depending on the purpose of the test. As far as is possible, the laboratory should carry out the validation exercise that can include applicability to the range of products. Validation data can also include comparison with reputable literature data including journals.

Where validation is not feasible, the laboratory must ensure every requirement of the test method is fully performed and complied with before proceeding with the actual test.

Validation data for in-house and non-standard test methods can include performance of the method on chemical substances that have been evaluated by other laboratories using the same organism.

7.2.3 Test organisms (Biological test system)

a) Organisms shall be obtained from a known/recognised source.

b) Records of source, date of receipt, arrival condition of the organism and test system shall be maintained.

c) Proper condition shall be established and maintained for the storage, housing, handling and care of organisms and test system, in order to ensure the quality of data.
d) Test organisms shall be acclimatized to the test environment for an adequate period before the first administration/application of the test or reference items.

e) All information needed to properly identify the test organisms shall appear on their housing or containers. Individual test organisms that are to be removed from their housing/container during the conduct of the test shall bear appropriate identification, whenever possible.

f) During use, housing/container for the test organisms shall be cleaned and sanitized at appropriate intervals. Any material that comes into contact with test organisms shall be free of contaminants at levels that would interfere with the test.

g) Species verification shall be carried out periodically particularly for in-bred organism e.g. fish species for ecotoxicology.

7.3 Sampling

Same as in MS ISO/IEC 17025.

7.4 Handling of test or calibration items

Same as in MS ISO/IEC 17025.

7.5 Technical records

Same as in MS ISO/IEC 17025.

7.6 Evaluation of uncertainty of measurement

Wherever applicable, laboratory shall have and shall apply for procedures of uncertainty of measurement. Estimation of uncertainty for toxicity testing methods where statistical analysis of uncertainty forms part of and is required by the method.

7.7 Ensuring the validity of results

Same as in MS ISO/IEC 17025 and SAMM Policy 4 (SP4) - Policy for Participation in Proficiency Testing Activities.

7.8 Reporting of results

Same as in 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.

8.0 Management system requirements

Same as in MS ISO/IEC 17025.

Bibliography

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

b) Global Harmonisation System Documents, e.g. Global Harmonisation System (GHS) Implementation by Country

c) Guidelines for Control of Cosmetic Products in Malaysia 2017, National Pharmaceutical Regulatory Agency

d) Laws of Malaysia, Medical Device Act 2012 [Act 737]

e) NPRA website that contain relevant guideline documents, https://www.npra.gov.my/index.php/en/classification-guideline/product-classification-guideline.html

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