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

SPECIFIC TECHNICAL REQUIREMENTS 1.2
(STR 1.2)

SPECIFIC TECHNICAL REQUIREMENTS FOR
ACCREDITATION OF TOXICITY TESTING
LABORATORIES

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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

This document provides an explanation on the application of MS ISO/IEC 17025, hereinafter referred to as “MS ISO/IEC 17025” for laboratories conducting toxicity testing and also a description of the SAMM accreditation procedures applied in this field. Laboratories that accredit their toxicity testing methods must comply with the requirements contain in this document, all clauses of MS ISO/IEC 17025, SAMM policies, and relevant legislative requirements. Technical notes issued by SAMM are also available to assist laboratories in relation to particular technical issues. This document contains only clauses of MS ISO/IEC 17025 that require further elaboration.

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

a. Chemical Products
   - All synthetic and natural products including extracts e.g. Pharmaceutical, Nutraceutical, Oil dispersant, Industrial and Household Chemical Products.

b. Manufactured Products
   - All types of manufactured goods and products e.g. food packaging and toys.

c. Cosmetic and Skin Care Products
   - Chemical and natural based products in all forms e.g. powder, paste, liquid and aerosol.

d. Medical Devices
   - All types of medical devices e.g. implants, prosthetics and catheter.

e. 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.

2 Normative references

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

3.1 Technical personnel refer to staff 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 Management requirements
As in the MS ISO/IEC 17025:2005

5 Technical requirements

5.1 General
As in the MS ISO/IEC 17025:2005

5.2 Personnel

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

5.2.1 The testing laboratories shall have sufficient personnel having the necessary training, technical knowledge and experience for the assigned functions.

5.2.2 The prerequisite of a signatory is;

i) a first degree in Science or equivalent discipline and at least 2 years of experience in the field of test; or

ii) a M Sc degree with 1 year experience or

iii) PhD with 6 months experience in the field of test.
5.2.3 The technical personnel shall:

i) First degree in Science with relevant practical training or have a minimum qualification of SPM with 2 years experience; and

ii) have passed a competency test in the area of work he/she is involved in.

5.2.4 The technical support personnel shall;

i) have a minimum qualification of SPM with relevant practical training; and

ii) have passed a competency test in the area of work he/she is involved in.

5.2.5 Technical personnel shall participate and performed satisfactorily in a PT laboratory cross check at least once a year or any appropriate period of time.

5.3 Accommodation and environmental conditions

Laboratory facilities

5.3.1 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.

5.3.2 The design of the laboratory shall provide an adequate degree of separation of the different activities to assure the proper conduct of each test.
5.3.3 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 substances or organisms known to be or suspected of being bio-hazardous.

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

5.3.5 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.

**Waste disposal**

5.3.6 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.

5.4 **Test methods and method validation**

5.4.1 **General**

Standards international methods are preferred. Laboratories may use 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.

5.4.2 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.

5.4.6 Estimation of uncertainty of measurement

Wherever possible, 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.
5.5 **Equipment**
As in MS ISO/IEC 17025.

5.6 **Measurement traceability**

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.

5.6.1 **Reference materials**

**Test Organisms**

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

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

iii) 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.

iv) Test organisms shall be acclimatized to the test environment for an adequate period before the first administration/application of the test or reference items.

v) 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.

vi) 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.

5.7 **Sampling**

As in MS ISO/IEC 17025.
5.8 Handling of test items

As in MS ISO/IEC 17025.

5.9 Assuring the quality of test results

As in MS ISO/IEC 17025.

5.10 Reporting the results

As in ISO/IEC 17025.
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9. Ms. Rohasmizah Ismail, STANDARDS MALAYSIA (Secretary)