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STANDARDS
MALAYSIA

SKIM AKREDITASI MAKMAL MALAYSIA (SAMM)
SAMM CIRCULAR 2/2019

**POLICY ON IMPLEMENTATION OF REPORTING STATEMENTS OF
CONFORMITY BASED ON MS ISO/IEC 17025:2017**

This circular provides further elaboration on implementation of clause 7.8.6 of MS ISO/IEC 17025:2017. This circular is applicable to SAMM applicant and accredited laboratories.

Implementation Date

This circular will be implemented effective immediately.

Standards Malaysia Requirements

1. The laboratory is required to establish a policy if the laboratory does not provide statement of conformity on their test report or calibration certificate.
2. The laboratory shall comply to clause 7.8.6 of MS ISO/IEC 17025 if the laboratory provides statement of conformity. The laboratory may refer to relevant latest edition of guidelines such as ILAC G8:09/2019 and JCGM 106:2012 or ISO/IEC Guide 98-4:2012.
3. Where an accredited laboratory provides statement of conformity on their test report or calibration certificate this is not regarded as being part of opinions and interpretations.
4. Based on clause 4.3 e) of SAMM Policy 1 (SP1) - Terms and Conditions Governing the Laboratory Accreditation Scheme of Malaysia, any expression of expert opinion and interpretations shall be qualified by a disclaimer that it is not under the scope of accreditation under SAMM."
5. The following scenario show examples of the different between 'statement of conformity' and 'opinions and interpretations'.
(Source: EA-INF/13 The Assessment and Accreditation of Opinions and Interpretations using ISO/IEC 17025:2005, Appendix A)

Table 1: Examples of the different between ‘statement of conformity’ and ‘opinions and interpretations’

Item	Scenario	Remarks
Statement of conformity	A sample of soil from an agricultural field has been submitted for analysis. The sampling of the soil was done by an accredited sampling facility that has demonstrated that they can take a representative sample. Analysis is carried out for levels of Nitrogen and microbiological activity in the soil which can be compared with tabulated values which indicate whether the field is fit to grow a certain crop. The laboratory compares the result with the tabulated value and the report shows that it has passed the criteria as listed in the documented table.	This part of the report is just a statement of conformity with the test requirements. Example*; Result of test: Passed – the levels of nitrogen conform to the minimum requirements of Regulation A of the Department of Agriculture (based on decision rules that agreed by the customer or inherent in the test method / regulations).
Opinion and interpretations	The report then also contains a statement from the laboratory that due to the levels of nitrogen and microbiological activity found and the use of other supporting data the field is likely to be able to support growth of the certain crop for another two years before levels are depleted and fertiliser will be required.	This part of the report is an opinions and interpretations of the result in the representative sample of that field and as such is a justified use of the opinions and interpretations clause in ISO/IEC 17025. In effect the field has been sampled and so the result is actually for the field and hence an opinion / interpretation made. It will be down to the laboratory to justify its approach to this opinions and interpretations. Example*; Result of test: The levels of nitrogen are sufficient for the growth of crop A.

*NOTE: The examples are guidance and there may well be other factors that need to be considered to ensure that the opinions and interpretations are valid.

Reference

1. MS ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories
2. ILAC-G8:09/2019, Guidelines on Decision Rules and Statements of Conformity
3. JCGM 106:2012, Evaluation of measurement data – The role of measurement uncertainty in conformity assessment.
Note: this document is also available as ISO/IEC Guide 98-4:2012
4. EA-INF/13:2015, The Assessment and Accreditation of Opinions and Interpretations using ISO/IEC 17025:2005

Approved by:

Director of Accreditation
Department of Standards Malaysia

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