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

# SAMM POLICY 10 (SP 10) – GRADING OF NON-CONFORMITIES

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**JABATAN STANDARD MALAYSIA**
**Department of Standards Malaysia**

**TABLE OF CONTENTS**

## 1 Introduction

This policy document on the grading of non-conformities and the follow-up actions that the Department of Standards Malaysia (Standards Malaysia) may need to take applies to all accredited laboratories under the *Skim Akreditasi Makmal Malaysia* (SAMM).

For non-accredited laboratories undergoing their initial assessment and laboratories seeking extension of scope, it is normal to delay accreditation until corrective actions have been effectively implemented to the full satisfaction of the assessment team. Corrective actions for all non-conformities must therefore be done before accreditation.

This policy document should be read in conjunction with other SAMM requirements.

## 2 Scope

2.1 This document outlines grading of non-conformities by determining the seriousness of the non-conformities with the actions that may need to be taken. Some examples of the various grading are listed in the Annex A.

2.2 This policy is applicable to SAMM accredited and applicant laboratories to plan and consider action to be taken according to the category of non-conformity raised.

2.3 Standards Malaysia assessors shall refer to this document for determining the grading of non-conformity.

## 3 Nature of non-conformities

3.1 For accreditation of laboratories, one aspect of the assessment is to ensure that the management system is in conformance with the standard and that staff members are following the procedures. However, the key aspect of the assessment is the determination of competence of staff and the technical validity of the operations. This assessment process requires the professional judgement of the technical assessors. Where it is considered that key technical managers or other key staff are not competent or where the technical validity of the testing or calibration work is in question, a non-conformity with one or more of the technical elements of the standard (MS ISO/IEC 17025) will need to be raised.

NOTE: For medical laboratories the applicable standard is MS ISO 15189.

3.2 There are another type of non-conformities that must also be considered. Standards Malaysia has policies and relevant requirements that the laboratories shall comply with. These may include, *inter alia,* claims of accreditation status or use of the accreditation mark. Where these requirements are not adhered to, Standards Malaysia will also raise non-conformities.

3.3 Thus for accreditation the nature of non-conformities may be:

- Documentation not conforming with the requirements of the standard;
- Staff are not following documented procedures;
- Technical managers or other key personnel not demonstrating competence in the work they are doing;
- Operational procedures such as test or measurement methods, traceability, etc., lacking technical validity;
- A breakdown in the operation of the management system of the laboratory; and/or
- The laboratory not conforming to the requirements of the Standards Malaysia.

3.4 Accreditation is primarily concerned with providing assurance to the customers of laboratories that their staff are competent and their procedures and results are technically valid, then non-conformities related to technical activities would normally be viewed as more serious than non-conformities related to the management requirements where the validity of results may not be in question (note that some elements in clause 4 of MS ISO/IEC 17025 are technical elements). However, management requirement non-conformities that jeopardise the whole management system of the laboratory would also need to be regarded as serious.

## 4 Actions taken by Standards Malaysia as a consequence of non-conformities

4.1 Assessors will all be aware that following an assessment, a significant percentage of laboratories do not conform to accreditation requirements. These laboratories are issued with Non-conformity Reports (NCRs) which define the nature of the non-conformity and which require corrective action by a specified date.

4.2 For applicant laboratories undergoing their initial assessment and laboratories seeking extension of scope, it is normal to delay accreditation until corrective actions have been effectively implemented to the full satisfaction of the assessment team. Corrective actions for all non-conformities must be done before accreditation.

4.3 For accredited laboratories, the question of seriousness of non-conformity will arise. For example, a date left off one page of a document (non-conformity in document control) should not be regarded in the same light as a series of unsatisfactory results in the proficiency testing programme, which have not been followed up, or the loss of the only SAMM approved signatory who was found to be competent by the Standards Malaysia to do that particular work.

4.4 Standards Malaysia may require that some non-conformities are corrected more urgently than others and that objective evidence of the laboratory's corrective actions are provided and that customers are advised where results are in question. If non-conformities are really serious, accreditation may need to be suspended immediately.

4.5 A typical grading of the seriousness of non-conformities, based on the actions taken by Standards Malaysia, may be:

### 4.5.1 Category 1

Where non-conformity is "very serious indeed" and the credibility of the accreditation programme is seriously threatened, the accreditation of the laboratory or the affected tests / measurements is suspended immediately. The effective date of suspension shall be the date of assessment. The lead assessor shall advise Standards Malaysia, and the Director General will issue a letter of endorsement. The letter of suspension will detail the grounds on which this action was based. Should the laboratory wish to appeal against the decision, it should do so in writing within seven (7) working days.

Should no corrective action is received and properly closed out the affected scope of accreditation is considered to have lapsed and no longer be valid after the expiry date of accreditation.

The laboratory shall be notified of the effective date of termination by letter. A laboratory with suspended / terminated accreditations shall not issue SAMM endorsed report / certificate or make reference to SAMM accreditation for those tests / calibrations for which accreditation has been suspended / terminated, and shall not make any representations to customers that imply that Standards Malaysia accreditation is current for such tests / calibrations.

Suspended scope can only be restored when all non-compliances are properly resolved. This may involve a verification visit and Standards Malaysia shall formally notify the laboratory of the reinstatement of accreditation. Laboratory with terminated scope may reapply the scope as extension of scope.

### 4.5.2 Category 2

Where non-conformity is “quite significant”, corrective action shall be submitted and closed out satisfactorily to Standards Malaysia within **three (3) months**. This includes cases whereby a number of related minor non-conformities are observed, which together, are judged to be an unacceptable quality risk without constituting an overall system failure in the area concerned. Such non-conformities may need a verification visit to ensure they have been effectively corrected especially if the validity of results or the integrity of the Standards Malaysia is threatened. However, if the assessment team agrees that the laboratory understands the issues, written assurance of corrective action and the provision of objective evidence of the measures taken may be acceptable.

Where necessary a verification visit may be made e.g. to verify the satisfactory implementation of the corrective action. Should the laboratory be unable to close out the NCR within three (3) months, Standards Malaysia shall initiate suspension as specified in clause 4.5.1 of this document.

### 4.5.3 Category 3

Where the finding is minor or isolated and does not affect test or calibration results or certificates and requiring corrective action would not improve the operations of the laboratory and could not seriously damage the relationship between the laboratory and Standards Malaysia. In such cases the non-conformity shall be raised and corrective action will be reviewed during the next assessment.

### 4.5.4 Observation

Findings which are not recorded as non-compliances are raised as “**Observation**” for some of the following reasons:

(a) an area of “concern” but unable to obtain sufficient objective evidence; and

(b) an opportunity for laboratories to consider possible improvement.

## 5 Grading of non-conformities

5.1 During the assessment team meeting, the team may have identified a number of non-conformities and their nature as described in clause 4 of this document.

5.2 Identifying the nature of a particular non-conformity may be helpful in deciding the most appropriate grading from clause 5 of this document.

5.3 For example, technical requirements non-conformities that are threatening the validity of test or measurement results would usually be regarded as at least “quite significant” and possibly “very serious indeed” (category 1 or 2 above). Similarly, a serious breakdown in the management system, such as many complaints being received but not act upon may be in the serious category.

5.4 Intentional breaching of the rules for the use of SAMM symbol or mark may also be regarded as “very serious indeed”. This would be the case particularly if the integrity of the Standards Malaysia or unfair competitive advantage against properly accredited organisations had resulted.

5.5 Some management system element non-conformities may be graded as category 2 or category 3 depending on the situation. A category 3 grading may result if the validity of results was not in question and the management system was not in jeopardy. However, there are cases where failures in elements of the management system may be serious and warrant a category 1 grading.

5.6 In some cases a series of non-conformities, each in themselves being minor may add up in combination to what is considered a serious overall problem in the laboratory.

5.7 Regardless of the nature of the non-conformities, each one should be evaluated within the circumstances presented so that a fair grading may be established and the actions taken against the laboratory will be appropriate.

5.8 It must be emphasised that apparently similar situations may result in different gradings. This is because no two circumstances are exactly the same and the consequences of the particular non-conformity may be very different.

## 6 General comments on grading of non-conformities and issuance of corrective action requests

6.1 Grading of non-conformities should be based only on the findings recorded during the assessment.

6.2 Grading decisions should be made by the lead assessor in consultation with the technical assessor(s) who were on site.

6.3 A finding should be sufficiently detailed to be able to confirm whether it was a one-time event or a general statement whose corrective action should be implemented throughout the laboratory. It is the responsibility of the laboratory to determine, through its corrective action procedure, if a one-time event may have wider implications. A corrective action request may ask the laboratory to itself determine if the finding indicates a chronic problem.

6.4 Minor non-conformities have a tendency to grow into serious non-conformities if not addressed appropriately at the time. Where non-conformity is found, the assessor(s) should evaluate its effect on the quality of the results of the laboratory. For example, an uncorrected error from the calibration of a thermometer used in a testing laboratory may have little effect on the results if that test is not particularly temperature sensitive.

6.5 In all cases of non-conformity, assessors must resist closing out non-conformities based on corrective actions presented on the day of the assessment without a proper corrective action investigation by the laboratory. Such closure may lead to the embarrassment of having to issue another NCR at the next assessment because the corrective action was not adequate.

6.6 Findings should be evaluated together with the general picture / history of the laboratory e.g. trusts ongoing improvement, staff competence, repetitive nature (from previous assessments), etc. Where urgent suspension of a laboratory is indicated after the identification of very serious non-conformities, procedures for immediate suspension are necessary.

## Annex A: Examples of guidelines on grading of non-conformities.

Many management system deficiencies are possible but these are usually addressed during the initial assessment and must be corrected and closed out prior to accreditation being granted. Such non-conformities are not included in the examples below as they are seldom an issue for a laboratory already accredited.

### 1 Category 1 - Non-conformities that could lead to immediate suspension of accreditation or of the affected scope of accreditation.

1.1 The laboratory has lost its sole approved signatory for particular work and no longer has competent staff doing that work. They continue to issue test reports / calibration certificates in that field. They did not advise Standards Malaysia nor did they self suspend their accreditation.

*Result:* Suspension for that particular work until a new approved signatory has been found to be competent by Standards Malaysia e.g. interviewed by a technical assessor.

1.2 After two previous warnings the laboratory is still issuing test reports / calibration certificates endorsed with the SAMM symbol with results (not marked accordingly) which are outside the scope of its accreditation.

*Result*: Withdrawal or general suspension until there is a serious commitment to comply with SAMM requirements and monitoring are implemented, which convince Standards Malaysia that it will not happen again. (SAMM Policy 3 - *Policy on the Use of SAMM Accreditation Symbol and Combined ILAC MRA Mark or Reference to SAMM Accreditation*)

1.3 Key equipment for particular work has failed and cannot be fixed or replaced in the immediate future. The laboratory is not subcontracting the work to another acceptable laboratory and is issuing test reports / calibration certificates even though the alternative equipment being used is not technically valid.

*Result*: Suspension for that particular work until suitable equipment is commissioned to the satisfaction of Standards Malaysia or the work is temporarily sub-contracted to another laboratory accredited for such work.

1.4 The accommodation is such that it is impossible for laboratory staff to prevent serious cross contamination of samples.

*Result*: Suspension of that testing until an on-site visit confirms that accommodation has been altered to resolve the problem and a monitoring programme has been established to demonstrate that its facilities remain under control.

1.5 The laboratory has identified a serious error in a calibration record that impacts on test results. This has not been corrected and customers have not been notified of erroneous results, which they have received.

*Result*: This part of the laboratory's work is suspended until the equipment has been properly recalibrated and commissioned and earlier work that was affected has been recalled and dealt with. (If the error can be corrected directly, suspension may not be necessary but a cause analysis would be appropriate to prevent recurrence.)

1.6 There are no current dates of calibration of equipment in the equipment records and therefore it is impossible to verify the calibration status of the equipment. Further, the maintenance programme and maintenance records cannot be located. In addition there are no records of which reference materials / standards were used for particular equipment calibrations.

*Result*: The laboratory would be suspended immediately. Such a situation would indicate that something had gone seriously wrong since the last assessment.

1.7 There are no records of action taken on an unsatisfactory result of a proficiency testing. There are no records of any corrective actions. There was speculation amongst laboratory staff that an incorrect standard was used but this was not followed through. It appears that other QC data is not monitored or acted upon.

*Result*: The laboratory is immediately suspended for this particular work until a proper investigation has been completed and suitable corrective action taken to demonstrate that the test is under control, and records of this properly kept.

1.8 The laboratory has no measurement uncertainty budget for a particular calibration, which it has implemented since the last assessment and has been claiming accreditation status.

*Result*: This work would be suspended immediately until Standards Malaysia was satisfied that a proper measurement uncertainty budget has been presented. The laboratory would also receive a serious warning about the misuse of its accreditation status.

1.9 The laboratory cannot locate its list of its reference standards and it is not clear which items are being used as reference standards.

*Result*: The laboratory is suspended until evidence is forthcoming that it has sorted out its reference items and has proper records of the whole measurement traceability process.

1.10 A new in-house procedure has been developed for one particular accredited test. The procedure has not been validated and there is no evidence that it is giving the same results as the reference method. The laboratory is claiming accreditation for this procedure.

*Result*: The accreditation for that test is immediately suspended until full method validation is completed to the satisfaction of Standards Malaysia.

1.11 There is significant evidence that the management system is seriously failing. The laboratory has not conducted an internal audit for over 18 months (just before the last assessment, which is not according its own procedure). Also staff members indicate that many customer complaints are being received by telephone and sent to the appropriate person by e-mail but there are not recorded in the complaints file, and they are not acted upon.

*Result*: The laboratory's accreditation is suspended until there has been an internal audit and a management review and a further on-site assessment indicates that the system is again in effective operation.

## 2 Category 2 - non-conformities that would require proof of implementation of corrective action within 3 months

2.1 Some critical equipment has passed its scheduled calibration date and has not been recalibrated. Daily or as used checks indicate that the equipment continues to meet specifications.

2.2 A recent proficiency testing result was an unsatisfactory and corrective action has not yet identified or effectively corrected the problem.

2.3 A standard method has been altered without the customer's prior approval and without validation of the alteration. (More information would be needed to determine the significance of this that may be more serious than indicated)

2.4 An advertisement is implying accreditation for a wider range of work than is covered in the scope.

2.5 The internal audit programme is two months overdue. Two items from the most recent one have not been followed up or closed out.

2.6 The laboratory has not conducted a management review for over twelve (12) months.

2.7 Some items of volumetric glassware and one thermometer have not been calibrated. (The significance of this will depend on the contribution these measurements make to the uncertainty of the results).

2.8 There are some errors in the transcription of the standard method to the laboratory methods manual.

2.9 Competency records of some technical staff do not confirm that they are competent to do what they are doing in relation to accredited work. (If this is more than a records problem it may be more serious than indicated.)

2.10 Procedures as specified in MS ISO/IEC 17025 and other applicable documents are not available.

NOTE: For medical laboratories the applicable standard is MS ISO 15189.

2.11 Some of the procedures or operations for document control, for updating the quality manual, for distribution of changed test and calibration methods or amending documents are not being followed.

2.12 The laboratory has no record of delivery of last year's training programme. Also, there is no evidence of last year's performance appraisals and training needs identification. The internal audit did not identify these problems.

2.13 The measurement uncertainty budget is not fully in line with ISO GUM or equivalent but the calculated values of the measurement uncertainty are not smaller than expected values.

2.14 In one procedure there was a requirement for the engineer to visually check the cubes for defects but no criteria were given for rejecting them.

## 3 Category 3- non-conformities that would require proof of implementation of corrective action during next assessment.

3.1 The 'Quality Manager' and 'Technical Manager' are not clearly identified in Laboratory Quality Manual (LQM).

3.2 There was no documented evidence to indicate that when equipment goes outside the direct control of laboratory, their function and calibration status are checked before being returned to services.

3.3 A master list or equivalent document control procedure identifying the current revision status and distribution relating to system procedures and test methods was not available.

3.4 Records relevant to the person authorised to sign laboratory test reports were not maintained in the laboratory.

3.5 Training records of technicians who operate new equipment were not updated.

3.6 Original observation was not recorded for example witnessing of COD determination, no evidence that the original burette readings were recorded.

3.7 There was no evidence of record of review before samples were accepted for testing.

3.8 Review of the internal audit report showed that not all elements of management system are addressed.

3.9 No training schedule/programme was available.

**4 Observation - observations are reported in the observation forms and will be followed up at the next assessment.**

Some of the following examples, although apparently minor, may indicate wider underlying problems, which need to be addressed.

4.1 One customer complaint had been acted upon but not been closed out.

4.2 One staff member had no job personal description although there was a generic description for those in that position in the manual.

4.3 The document control procedure of the laboratory requires that every page of each procedure manual is to be signed off by the technical manager. The team finds two pages of one procedure that have not been signed off. Other pages appear to have been correctly signed.

4.4 A new technician tells an assessor that she had one customer complaint about the fact that a report was one day late. She told her supervisor but did not fill out the appropriate corrective action form as she considered the complaint to be frivolous. Other complaints seem to be recorded and acted upon properly.

4.5 In the back of a cupboard full of volumetric glassware, an assessor finds one standard flask that has not been calibrated. It has dust on it indicating that it has not been used for some time as others nearer the

front are all sparkling clean. Other volumetric glassware in the laboratory appears to be in order.

4.6 A label has fallen of a standard stock solution and is lying beside the bottle in the cupboard. The record of its standardization is in order assuming that the label matches the bottle. Other labels are intact.

4.7 One of the dates in the sample reception notebook was incomplete in that only the month and year were recorded.

4.8 Additional equipment, that does not significantly influence the measurement results or the uncertainty, is being used but is not listed in the equipment records of the laboratory.

4.9 The value of a measurement uncertainty is written using “ppm” rather than $10^{-6}$ in the calibration records (but not in the calibration certificate).

4.10 The accommodation is not being kept sufficiently clean and tidy for the detailed or trace or micro work being done. However, quality control data or environmental monitoring indicates that test results should not have been affected to date.