



**STANDARDS**  
MALAYSIA

**MALAYSIA INSPECTION BODIES ACCREDITATION SCHEME  
(MIBAS)**

**MIBAS POLICY 3 (MP3) – POLICY ON GRADING OF NON-  
CONFORMITIES**

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**JABATAN STANDARD MALAYSIA  
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## **1 Introduction**

This policy document on the grading of non-conformities and the follow-up actions that the Department of Standards Malaysia (Standards Malaysia) shall be applied to all accredited inspection bodies under the Malaysia Inspection Bodies Accreditation Scheme (MIBAS).

For non-accredited inspection bodies undergoing their initial assessment and inspection bodies 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 MIBAS requirements.

## **2 Scope**

- 2.1 This document outlines Standards Malaysia's approach to grading non-conformities, through linking the seriousness of the nonconformity with the actions that the Standards Malaysia may need to take. Some examples of the various grading are listed in the Annex A.
- 2.2 This policy is applicable to MIBAS accredited and applicant inspection bodies 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**

For accreditation of inspection bodies, 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 and validity of technical operations. This assessment process requires the professional judgement of the technical assessors. Where it is considered that aspects of technical activities are not in compliance with accreditation requirements that are based on the applicable standard(s) and/or regulation(s), one or more non-conformities will need to be raised.

Thus for accreditation the nature of non-conformity may include:

- documentation not conforming with the requirements of accreditation criteria;

- staff are not following documented procedures;
- operational procedures lacking technical validity;
- a breakdown in the operation of the inspection body; and/or
- the inspection body not conforming to the requirements of the Standards Malaysia.

#### **4 Grading of non-conformities and actions taken by Standards Malaysia**

##### **4.1 General comments on grading of non-conformities and issuing of corrective action requests.**

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 to ensure the actions taken against the inspection body will be appropriate.

It is emphasized 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 nonconformity may be very different.

Where a grading decision is marginal, the track record of the inspection body with its accreditation and the degree to which the Standards Malaysia trusts the body to take prompt and effective corrective action may result in the downgrading of the seriousness of the non-conformity.

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

Grading decisions should be made by the team leader in consultation with the technical assessor(s) who were on site, where possible. They should be made before the assessment team leaves the site.

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 inspection body. It is the responsibility of the inspection body to determine, through its corrective action procedure, if a one-time event may have wider implications. A corrective action request may ask the inspection body to itself determine if the finding indicates a chronic problem.

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 inspection body.

In all cases of non-conformity, assessors must resist “approving” proposed corrective actions presented on the day of the assessment without a proper corrective action investigation by the inspection body. Such approvals may lead to the embarrassment of having to issue another non-conformity at the next assessment because the “approved” corrective action was not adequate.

Where urgent suspension of a inspection body is indicated after the identification of very serious non-conformities, immediate suspension are necessary.

Where the nonconformities are raised by the Standards Malaysia assessment team, the inspection body shall take necessary corrective actions within the specified time frame to resolve the nonconformities. The inspection body is required to provide the following information to Standards Malaysia through e-Accreditation system:

- i. the analysis of the extent and cause (root cause analysis);
- ii. the description the specific actions taken; and
- iii. the evidence of corrective actions taken.

## 4.2 Category of non-conformities

Standards Malaysia will consider the nature of non-conformities, as well as assessment findings and categorise as follows:

### 4.2.1 Category 1

Where non-conformity is “very serious indeed” the accreditation of the inspection body is **suspended immediately**. The effective date of suspension shall be the date of assessment. The team leader shall advise Standards Malaysia, and the Director General may approve the suspension. Subsequently Standards Malaysia will issue a suspension letter to the inspection body. Should the inspection body wish to appeal against the decision, it should do so in writing within seven (7) working days.

If the suspended scope results in very serious impact on the customer, the inspection body should take appropriate action.

Should no corrective action and root cause analysis of the nonconformities are received, and the nonconformities remained unresolved, the affected scope of accreditation is considered lapsed and no longer be valid after the expiry date of accreditation.

The inspection body shall be notified of the effective date of termination in writing. A inspection body with suspended/terminated accreditations shall not issue MIBAS endorsed certificate/report or make reference to MIBAS accreditation for those inspection activities 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 inspections.

Suspended scope can only be restored when all non-conformities are properly resolved. This may involve a verification assessment.

#### 4.2.2 Category 2

Where non-conformity is “quite significant”, corrective action and root cause analysis of the nonconformities shall be submitted to Standards Malaysia and closed out satisfactorily 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 assessment 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 inspection body understands the issues, written assurance of corrective action and the provision of objective evidence of the measures taken may be acceptable.

Should the nonconformity be unable to be closed out within three (3) months, Standards Malaysia may initiate suspension of the inspection body’s accreditation.

#### 4.2.3 Category 3

Where the finding is minor or isolated and does not affect inspection reports/certificate. In such cases the non-conformity shall be raised and corrective action and root cause analysis of the nonconformities shall be submitted and closed out satisfactorily to Standards Malaysia within **three (3) months**. Should the nonconformity be unable to be closed out within three (3) months, Standards Malaysia may initiate suspension of the inspection body’s accreditation.

#### 4.2.4 Category 4 - Observation

Findings which are not recorded as non-conformities 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 inspection bodies to consider possible improvement.

## **Examples of guidelines on grading of non-conformities.**

Many quality 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 inspection body already accredited.

### **1 Category 1**

- 1.1 The inspection body has lost its key technical manager(s) for particular work and no longer has competent staff doing that work. They continue to issue inspection reports in that field. They did not advise the Standards Malaysia nor did they self-suspend their accreditation.

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

- 1.2 After two previous warnings the inspection body is still issuing inspection reports endorsed with the MIBAS 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 following accreditation rules and a procedure and monitoring are implemented, which convince the Standards Malaysia that it will not happen again. (MIBAS Policy 2 - *Policy on the Use of MIBAS Accreditation Symbol and Combined ILAC MRA Mark or Reference to MIBAS Accreditation*)

- 1.3 Key equipment for particular work has failed and cannot be fixed or replaced in the immediate future. The inspection body is not subcontracting the work to another acceptable inspection body and is issuing inspection reports 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 the Standards Malaysia or the work is temporarily sub-contracted to another inspection body accredited for such work.

- 1.4 The inspection body has identified a serious error in a calibration record that impacts on inspection results. This has not been corrected and clients have not been notified of erroneous results, which they have received.

*Result:* This part of the inspection body'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.)

- 1.5 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 inspection body would be suspended immediately. Such a situation would indicate that something had gone seriously wrong since the last assessment.

- 1.6 The inspection body cannot locate its list of its reference standards and it is not clear which items are being used as reference standards.

*Result:* The inspection body is suspended until evidence is forthcoming that it has sorted out its reference items and has proper records of the whole measurement trace-ability process.

- 1.7 There is significant evidence that the quality management system is seriously failing. The inspection body 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 inspection body'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.

- 1.8 Intentional breaching of the rules for the use of MIBAS symbol or ILAC MRA Mark may also be regarded as "very serious indeed". This would be the case particularly if the integrity of the Standards Malaysia had been jeopardised or if an unfair competitive advantage against properly accredited organisations had resulted.



*Result:* Withdrawal or general suspension until there is a serious commitment to comply with MIBAS requirements and monitoring are implemented, which convince Standards Malaysia that it will not happen again. (MIBAS Policy 2 - *Policy on the Use of MIBAS Accreditation Symbol and Combined ILAC MRA Mark or Reference to MIBAS Accreditation*)

## **2 Category 2**

- 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 outlier and corrective action has not yet identified or effectively corrected the problem.
- 2.3 A standard method has been altered without the client's prior approval and without verification 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 without apparent reason. Two items from the most recent one have not been followed up or closed out.
- 2.6 This year's management review has not been done.
- 2.7 There are some errors in the transcription of the standard method to the inspection body methods manual.
- 2.8 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.)
- 2.9 Procedures as specified in MS ISO/IEC 17020 and other applicable documents are not available.
- 2.10 Some of the procedures or operations for document control, for updating the quality manual, for distribution of changed inspection methods or amending documents are not being followed.

- 2.11 The inspection body 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.

### **3 Category 3**

- 3.1 The 'Quality Manager' and 'Technical Manager' are not clearly identified in Inspection Body Quality Manual (IQM).
- 3.2 There was no documented evidence to indicate that when equipment goes outside the direct control of inspection body, their function and calibration status are checked before being returned to services.
- 3.3 The organisation chart included in the quality manual is not up-to-date. Discussion with staff members confirms that they are aware of the current organisation structure.
- 3.4 A master list or equivalent document control procedure identifying the current revision status and distribution relating to system procedures and inspection methods was not available. Further investigation shows that operation is carried out in accordance with current versions of documents.
- 3.5 There are no review records for a significant portion of requests for work. Those work requests are within the capability of the organisation.
- 3.6 Records relevant to the person authorized to sign inspection reports were not maintained in the inspection body.
- 3.7 Competence records of a few inspectors do not confirm that they are competent to perform the accredited activities they have assigned. Observation and discussion with the operators confirm that they are competent.
- 3.8 The documented procedure for conducting internal audits does not reflect the auditing practice. Checking of records shows that internal audits are acceptable.

### **4 Observation**

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