



**STANDARDS**  
MALAYSIA

**MALAYSIA PROFICIENCY TESTING PROVIDER  
ACCREDITATION SCHEME (MyPTP)**

**MyPTP POLICY 3 (PP3) -  
GRADING OF NON-CONFORMITIES**

*Issue 2, 8 October 2019*



**MS ISO/IEC 17043**

**JABATAN STANDARD MALAYSIA  
Department of Standards 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) may need to take applies to all accredited proficiency testing providers under the MyPTP scheme.

For non-accredited proficiency testing providers undergoing their initial assessment and proficiency testing providers 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.

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

## 2 Purpose

This document outlines Standards Malaysia approach to grading non-conformities, through linking the seriousness of the nonconformity with the actions that the Standards Malaysia may need to take.

This policy document should be read in conjunction with other MyPTP policy documents.

## 3 Nature of non-conformities

3.1 For accreditation of proficiency testing providers, 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 and / or experts. Where it is considered that key technical managers or other key staff are not competent or calibration work is in question, a non-conformity with one or more of the technical elements of the standard (MS ISO/IEC 17043) will need to be raised.

3.2 Thus for accreditation the nature of non-conformities 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 proficiency testing provider; and/or
- The proficiency testing provider 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 proficiency testing provider will be appropriate.

It is 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.

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. 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 proficiency testing provider. It is the responsibility of the proficiency testing provider to determine, through its corrective action procedure, if a one-time event may have wider implications. A corrective action request may ask the proficiency testing provider 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 proficiency testing provider. For example, an uncorrected error from the calibration of a thermometer used in a testing carried out by a proficiency testing provider during a sample preparation may have little effect on the results if that test is not particularly temperature sensitive.

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 proficiency testing provider. Such approvals may lead to the embarrassment of having to issue another NCR at the next assessment because the “approved” corrective action was not adequate.

Where urgent suspension of a proficiency testing provider 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 proficiency testing provider shall take necessary corrective actions within the specified time frame to resolve the nonconformities. The proficiency testing provider 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” and the credibility of the accreditation programme is seriously threatened, the accreditation of the proficiency testing provider or the affected proficiency testing scheme 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 proficiency testing provider. Should the proficiency testing provider wish to appeal against the decision, it should do so in writing within 7 working days.

Should no corrective action is received 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 proficiency testing provider shall be notified of the effective date of termination in writing. A proficiency testing provider with suspended/terminated accreditations must not issue MyPTP endorsed report or make reference to MyPTP accreditation for those proficiency testing scheme for which accreditation has been suspended/terminated, and must make no representations to clients that imply that Standards Malaysia accreditation is current for such proficiency testing scheme.

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 integrity of the Standards Malaysia is threatened. However, if the assessment team agrees that the proficiency testing provider 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 proficiency testing provider’s accreditation.

#### 4.2.3 Category 3

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

#### 4.2.4 Observation

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

- (i) an area of “concern” but unable to obtain sufficient objective evidence
- (ii) an opportunity for proficiency testing providers to consider possible improvement.