Grading of Nonconformities

1 Nature of nonconformities

For accreditation of laboratories and inspection bodies, one aspect of the assessment is to ensure that the management system is in conformance with the standard and that personnel are following the procedures. However, the key aspect of the assessment is the determination of competence of personnel and the technical validity of the operations. This assessment process requires the professional judgment of the technical assessors and/or experts. Where it is considered that key technical managers or other key personnel are not competent or where the technical validity of the testing, calibration or inspection work is in question, non-conformity with one or more of the technical elements of the standards (i.e. ISO/IEC 17025, ISO/IEC 17020, ISO 15189, *ISO/IEC 17043)* will need to be raised.

Aside from international standards that the laboratory/inspection body complied with, the PAB has established additional requirements for each specific field (i.e. chemical testing, biological testing, calibration, etc.) for the laboratory/inspection body/inspection body to comply.

Nonconformities may have different natures. For example:

- Non-fulfillment of international standards (i.e. ISO/IEC 17025, ISO/IEC 17020, ISO 15189, *ISO/IEC 17043*) and PAB supplementary requirements
- Documentation not conforming *to* the requirements of the standard and supplementary requirements
- Documented procedures not followed
- Personnel not demonstrating competence in performing the work assigned.
- Operational procedures such as test or measurement methods lacking technical validity
- Lack of or doubtful measurement traceability
- Ineffective quality assurance/control procedures
- Breakdown in the operation of the quality management system of the laboratory/inspection body
- The applicant/accredited laboratory/inspection body not conforming to the accreditation regulations

Definitions:

- ***Highly Significant Nonconformity*** *– a non-conformity where the credibility of the accreditation is seriously threatened resulting to immediate suspension of affected scope of accreditation of a PAB accredited laboratory or inspection body.*

- ***Significant Nonconformity*** *– A non-conformity which directly affects the test/calibration/inspection results and/or non-fulfilment of standard requirements.*

- ***Minor Nonconformity*** *– a non-conformity which is isolated and does not affect test, calibration or inspection results or certificates.*

In deciding which nonconformities are so serious as to require immediate suspension, which are serious enough to require prompt attention and the presentation of objective evidence to PAB, and which are minor and may be checked out at the next assessment, the PAB will need to take into account the nature of those nonconformities.

Because accreditation is primarily concerned with providing assurance to the customers of laboratories/inspection bodies that their staff are competent and their procedures and results are technically valid, then nonconformities related to technical activities would

normally be viewed as more serious than nonconformities related to the management requirements where the validity of results may not be in question. However, management requirements nonconformities that jeopardize the whole quality system of the laboratory/inspection body would also need to be regarded as serious.

The following outlines the approach to grading nonconformities, from more to less serious, through linking the seriousness of the non-conformity with the actions that the PAB may need to take.

2 Grading the nonconformities

During the assessment team meeting, team members may have identified a number of nonconformities and their nature as described in Section 1.

Identifying the nature of a particular nonconformity may be helpful in deciding the most appropriate grading of nonconformity.

For example, nonconformities *on technical requirements* that are threatening the validity of test or measurement results would usually be graded at a minimum “significant”, and possibly “highly significant”. Similarly, a serious breakdown in the quality management system, such as many complaints being received but not .acted upon, may be *graded as* “highly significant”.

Intentional *nonfulfillment of requirements* of the LA/SR03 (PAB Requirements for the Use of PAB Laboratory and Inspection Body Accreditation Symbols) may also be *graded* as “highly significant”. This would be the case particularly if the integrity of the PAB is threatened or *there is an* unfair competitive advantage *to an* accredited organizations.

Some nonconformities *on management system* may be graded as “significant” or “minor” depending on the *assessment findings.* A minor grading may result if the validity of results was not in question and the management system was not in jeopardy. However, *when there is a failure in management system, this will be graded as* “highly significant”

In some cases a series of nonconformities, each in themselves being minor, may add up in combination to what was considered a serious overall problem in the laboratory/inspection body.

Regardless of the nature of the nonconformities, each one should be evaluated within the circumstances presented so that a fair grading may be established and the actions taken against the laboratory/inspection body will be appropriate.

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

3 Notes on grading of nonconformities and issuing nonconformity reports

Grading of nonconformities should be based only on the findings recorded during the assessment.

Grading decisions are made by the assessor and team leader/lead assessor on site. The nonconformity finding with the grading is presented to the auditee/assessee. If any grading issue arises and cannot be resolved, it shall be elevated to PAB.

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 *conformity assessment* body. It is the responsibility of the *conformity assessment* body to determine, through its corrective action, if a one-time event may have wider implications.

Minor nonconformities, which are to be checked *on* the next assessment, shall also be reported *to* the *conformity assessment* body.

Minor nonconformities have a tendency to be *elevated* to significant nonconformities if not addressed appropriately at the time.

In all cases of nonconformity, assessors must resist "approving" proposed corrective actions presented on the day of the assessment without a proper corrective action investigation by the *conformity assessment* body.

Findings should be evaluated together with *proper investigation* of the *conformity assessment* body e.g. trust, ongoing improvement, staff competence, repetitive nature (from previous assessments), etc.

Where *immediate* suspension of a *conformity assessment* body is indicated after the identification of highly significant nonconformities *during the closing meeting, PAB shall issue suspension letter upon the evaluation of final assessment report.*

4 Actions taken by PAB as a consequence of nonconformities

Assessors will all be aware that following an assessment, a significant percentage of *conformity assessment* bodies fall short of (do not conform with) accreditation requirements. These *conformity assessment* bodies are issued with Assessment Findings (AF) which define the nature of the non-conformity and which require corrective action on a specified date.

The PAB require that all nonconformities are corrected, and that objective evidence/s of the *conformity assessment* body's corrective actions is/are provided and that customers are advised where results are in question. If nonconformities are really serious, accreditation may need to be suspended immediately.

These varying consequential actions of the PAB amount to grading of nonconformities.

Based on the actions to be taken by PAB, the grading of the seriousness of nonconformities is as follows:

a. Where nonconformity *is* "highly significant" and the credibility of the accreditation is seriously threatened resulting in immediate suspension of affected scope of accreditation of a PAB accredited laboratory or inspection body. (Note: this category is not applicable for initial assessment)

b. Where nonconformity *is* "significant" and directly affects the test/calibration/inspection results and/*or* nonfulfillment of standard requirements. Corrective actions must be completed within specified interval before accreditation is granted or to avoid suspension of accreditation if already accredited. Such nonconformities may need a follow-up on-site assessment to ensure they have been effectively corrected especially if the validity of results or the integrity of the PAB is threatened. However, if the assessment team agrees that the

laboratory/inspection body understands the issues, written assurance of corrective action and the provision of objective evidence of the measures taken may be acceptable.

c. Where the nonconformity *is* “minor” and is isolated and does not directly affect test, calibration or inspection results or certificates. In such cases the nonconformity could be noted in the assessment notes, for checking at the next assessment.

d. Observations are other comments not classified as nonconformity but could be areas for improvement valuable or value-adding practices in the operations of the *conformity assessment* body.

ANNEX A

Examples of nonconformities which may be allocated to the various gradings.

It must be emphasized that had more detailed information been available to the PAB about the real situation, a different grading may well have been given.

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 nonconformities are not included in the examples below as they seldom an issue for a *conformity assessment* body already accredited.

1 Highly significant - nonconformities that could lead to immediate suspension of accreditation or of the affected scope of accreditation.

1.1 The *conformity assessment* body has lost its key technical manager(s) *or approved* signatory for a particular work *or scope* and no longer has competent staff and continue to issue reports in that field. The *conformity assessment* body did not notify the PAB nor did it self-*suspension to* its accreditation *or scope of accreditation.*

Result: Suspension *of accreditation and scope of accreditation* until *a* new technical manager *or approved signatory* has been *assessed and recommended* by the PAB.

1.2 After two previous warnings the *conformity assessment* body is still issuing reports ~~endorsed~~ with the PAB logo with results (not marked accordingly) which are outside the scope of its accreditation.

Result: Withdrawal or suspension until there is a serious commitment to following accreditation rules and a procedure and monitoring are implemented, which convince the PAB that it will not happen again. (see LA/SR 03 PAB Requirements for the Use of PAB *conformity assessment* body Accreditation and Inspection Body Accreditation Symbols).

1.3 Key equipment for particular work has failed and cannot be fixed or replaced and the laboratory/inspection body is not subcontracting the work to another acceptable *conformity assessment* body and is issuing reports even though the alternative equipment being used is not technically valid.

Result: Suspension for the particular work until suitable equipment is commissioned to the satisfaction of the PAB or the work is temporarily sub- contracted to another *conformity assessment* body accredited for such work.

1.4 The accommodation is such that is impossible for *conformity assessment* body staff to prevent serious cross contamination of samples.

Result: Suspension of that testing until an 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 *conformity assessment* body has identified a serious error in a calibration record that impacts on test results. This has not been corrected and clients have not been notified of the erroneous results, which they have received.

Result: This part of the *conformity assessment* body's work is suspended until the equipment has been properly recalibrated and commissioned and that the *affected* earlier work 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 *conformity assessment* body 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 outlying result of a proficiency test. There are no records of any corrective actions. There was a speculation amongst laboratory/inspection body 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 *conformity assessment* body 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 *conformity assessment* body has no uncertainty budget for a particular calibration, which it has implemented since the last assessment and has been claiming accreditation for.

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

1.9 The results of a calibration inter laboratory comparison shows an En value greater than 1 and there is no record or explanation of the laboratory having followed up on this potential problem.

Result: The *conformity assessment* body is immediately suspended for this particular calibration work until effective follow-up action has been demonstrated.

1.10 The *conformity assessment* body cannot locate its list of its reference standards and it is not clear which items are being used as reference standards.

Results: The *conformity assessment* body is suspended until evidence is presented that it has sorted out its reference items and has proper records of the whole measurement traceability process.

1.11 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 conformity assessment body 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 the PAB.

1.12 There is no significant evidence that the quality management system is seriously failing. The *conformity assessment* 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 the telephone and sent to the appropriate person by e-mail but there are none recorded in the complaints file, and they are not acted upon.

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

2.0 Significant nonconformities that would require proof of implementation of corrective action within a specified time interval.

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 validation of the alteration. (More information would be needed to determine the significance of this which may be more serious than indicated)

2.4 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 indicate that test results should not have been affected to date.

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

2.6 The internal auditing programme is two months overdue. Two items from most recent one *has* not been followed up or close out.

2.7 This year's management review has not been done.

2.8 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).

2.9 There are some errors in the transcription of the standard method to the *conformity assessment* body*'s* methods manual.

2.10 Competency records of some technical staff *does not confirm the competency* to *their* accredited work. (If this is more than a records problem it maybe more serious than indicated.)

2.11 There is no procedure for control of nonconforming work (or recall of incorrect reports).

2.12 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 complete and / or are not being followed.

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

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

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

3.0 Minor nonconformities that are reported as such and will be followed up at the next assessment

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

3.1 A photocopy of an obsolete procedure was found in the drawer of one of the analysts *which is against the policy of the conformity assessment body.*

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

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

3.4 The document control procedure of the *conformity assessmen*t 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.

3.5 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 not serious. Other complaints seem to be recorded and acted upon properly.

3.6 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 *conformity assessment* body appears to be in order.

3.7 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.

3.8 One of the dates in the sample reception notebook was incomplete in that only the month and year were recorded. *(More information would be needed to determine the significance of this which may be more serious than indicated)*

3.9 A reference standard was not calibrated by the due date but no calibrations had been performed based on this item, after that date and until it was again recalibrated.

3.10 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 *conformity assessment* body.

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