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) 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) and PAB supplementary requirements
- Documentation not conforming with 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

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 non- conformities and their nature as described in Section 1.

Identifying the nature of a particular non-conformity may be helpful in deciding the most appropriate grading of non-conformity.

For example, technical requirements nonconformities 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 in the “highly significant” category.

Intentional breaching of the LA/SR03 (PAB Requirements for the Use of PAB Laboratory and Inspection Body Accreditation Symbols) may also be regarded as “highly significant”. This would be the case particularly if the integrity of the PAB is threatened or unfair competitive advantage against properly accredited organizations had resulted.

Some management system element nonconformities may be graded as “significant” or “minor” depending on the situation. A minor 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 “highly significant” grading.

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 laboratory/inspection body with its accreditation and the degree to which the PAB trusts the laboratory/inspection body to take prompt and effective corrective action may result in the downgrading of the seriousness of the non-conformity.

3 Notes on grading of nonconformities and issuing non-conformity 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 on site, 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 laboratory/inspection body. It is the responsibility of the laboratory/inspection body to determine, through its corrective action procedure, if a one-time event may have wider implications. A non-conformity report may ask the laboratory/inspection body to itself determine if the finding indicates a chronic problem.

Minor nonconformities, which are to be checked at the next assessment, shall also be reported so that the laboratory/inspection body manager understands that they will be checked during the next assessment.

Minor nonconformities have a tendency to grow into significant nonconformities 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/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 laboratory/inspection body.

Findings should be evaluated together with the general picture/history of the laboratory/inspection body e.g. trust, ongoing improvement, staff competence, repetitive nature (from previous assessments), etc.

Where urgent suspension of a laboratory/inspection body is indicated after the identification of highly significant nonconformities, procedures for immediate suspension are necessary rather than awaiting the next meeting of a committee.

4 Actions taken by PAB as a consequence of nonconformities

Assessors will all be aware that following an assessment, a significant percentage of laboratories/inspection bodies fall short of (do not conform with) accreditation requirements. These laboratories/inspection bodies are issued with On-Site Assessment Findings (OAF) 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 laboratory/inspection 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 non-conformities is as follows:

a. Where non-conformity are "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 non-conformity are "significant" and directly affects the test/calibration/inspection results and non-fulfillment 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 non-conformity are “minor” and is isolated and does not directly affect test, calibration or inspection results or certificates. In such cases the non-conformity 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 laboratory or inspection 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 laboratory/inspection 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 laboratory/inspection body has lost its key technical manager(s) for particular work and no longer has competent staff doing that work and continue to issue test / calibration reports in that field. The laboratory/inspection body did not advise the PAB nor did it self- suspend its accreditation.

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

1.2 After two previous warnings the laboratory/inspection body is still issuing test / calibration reports endorsed with the PAB logo 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 PAB that it will not happen again. (see LA/SR 03 PAB Requirements for the Use of PAB Laboratory/inspection 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 laboratory/inspection body and is issuing test / calibration 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 laboratory/inspection body accredited for such work.

1.4 The accommodation is such that is impossible for laboratory/inspection body 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/inspection 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 erroneous results, which they have received.

Result: This part of the laboratory/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.)

1.6 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/inspection 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 laboratory/inspection 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 laboratory/inspection 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 laboratory/inspection body would also receive a serious warning about the misuse of its accreditation status.

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

Result: The laboratory/inspection body is immediately suspended for this particular calibration work until effective follow-up action has been demonstrated.

1.10 The calibration / testing laboratory/inspection body cannot locate its list of its reference standards and it is not clear which items are being used as reference standards.

Results: The laboratory/inspection 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 laboratory/inspection 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 Laboratory/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 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 laboratory/inspection body's accreditation is suspended until there has been internal audit and management review and a further on site-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 have 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 laboratory/inspection body methods manual.

2.10 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 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 laboratory/inspection 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 was a requirement for the engineer to visually check the cubes for defects but no criteria were 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 needed to be addressed.

3.1 A photocopy of an obsolete procedure was found in the drawer of one of the analysts.

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 laboratory/inspection body requires that every page of each procedure manual is to be signed off by the technical manager. The team finds two page 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 laboratory/inspection 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

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 laboratory/inspection 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).