Guidelines on Grading of Non-conformities

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PREAMBLE

A new work item, which was approved at the 1998 ILAC General Assembly, was to investigate the question of the grading of non-conformities of laboratories by accreditation bodies. Dr Max Robertson was asked to lead the enquiry that was to be aimed at determining the degree of consistency amongst accreditation bodies and, if necessary due to lack of consistency, to prepare an ILAC guidance document on the subject.

A questionnaire was prepared and approved at the ILAC Technical Accreditation Issues Committee (TAIC) meeting in mid 1999 and was sent out to ILAC members. All those that replied except one had some form of grading although many grading systems related to the various actions that the accreditation body would take to correct the various non-conformities rather than clearly defined categories of grading. Only one accreditation body had clearly defined A, B, C etc grading categories. There was no obvious consistency in grading amongst the various replies. The one without any grading considered that all nonconformities were serious.

At the October 1999 meeting of the TAIC the decision was, “Given the responses to the enquiry, it is clear that this subject needs attention. It is concluded that a guidance paper should be prepared with the aim of harmonising the grading of nonconformities. The 1999 ILAC General Assembly decided, “TAIC is requested to further develop guidelines for dealing with non-conformities.”

The guidance in this document is based on the methods of grading of the majority of accreditation bodies. However, when judging whether an individual laboratory or its staff members are competent, the personal professional judgement of the technical assessors, supported by quality control results such as reference material results or proficiency testing results, will determine the seriousness of any particular non-conformity and the actions which the accredited laboratory should take.

PURPOSE

This document outlines one approach to grading non-conformities, from more to less serious, through linking the seriousness of the nonconformity with the actions that the accreditation body may need to take. Some examples of the various gradings are listed.

AUTHORSHIP

This document has been produced by the ILAC Technical Accreditation Issues Committee.

1 NATURE OF NON-CONFORMITIES

For quality management system certification, the specified standard defines what is required. If during an audit, requirements in the standard are found to be not in place in the documentation, then non-conformity has occurred and a corrective action request will be raised. Further, if the laboratory staff members are not performing their tasks in accordance with the documented procedures this will also be regarded as a non-conformity. These decisions are usually quite objective.

For accreditation of laboratories, one aspect of the assessment is to ensure, as with certification, 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 (not audit) 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 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 (ISO/IEC 17025) will need to be raised.

For accredited laboratories there is another type of non-conformity that must also be considered. The accreditation body will have rules and requirements that its accredited laboratories must follow. These rules may include, inter alia, claims of accreditation status or use of the accreditation mark. Where these rules have been broken, the accreditation body will also raise a nonconformity.

Thus for accreditation the nature of nonconformity may be:

- documentation not conforming with the requirements of the standard
- staff are not following documented procedures
- technical managers or other key staff 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 quality management system of the laboratory
- the laboratory not conforming to the rules of the accreditation body.

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

Because 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 nonconformities related to the management requirements where the validity of results may not be in question (note that some elements in section 4 of ISO/IEC 17025 are technical elements). However, management requirement non-conformities that jeopardise the whole quality system of the laboratory would also need to be regarded as serious.

The following outlines one approach to grading non-conformities, from more to less serious, through linking the seriousness of the non-conformity with the actions that the accreditation body may need to take. Some examples of the various gradings are listed.

2 ACTIONS TAKEN BY ACCREDITATION BODIES AS A CONSEQUENCE OF NON-CONFORMITIES

Laboratory assessors will all be aware that following an assessment, a significant percentage of laboratories fall short of (do not conform with) accreditation requirements. These laboratories are issued with Non-conformity Notices or Corrective Action Requests (CARs) which define the nature of the non-conformity and which request / require corrective action by a specified date.

For non-accredited laboratories undergoing their initial assessment it is normal to delay accreditation until corrective actions have been effectively implemented to the full satisfaction of the assessment team. However the assessment team may propose that CARs based on minor non-conformities may be cleared after the accreditation. Corrective actions based on serious nonconformities must be done before accreditation.

For laboratories already accredited, the question of seriousness of non-conformity will arise. For example, should a date left off one page of a document (nonconformity in document control) be regarded in the same light as a series of significant outliers in the proficiency-testing programme, which have not been followed up, or as the loss of the only staff member (signatory) who was found to be competent by the accreditation body to do that particular work?

The accreditation body 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 clients are advised where results are in question. If non-conformities are really serious, accreditation may need to be suspended immediately.

These varying consequential actions of the accreditation body amount to grading of non-conformities.

A typical grading of the seriousness of nonconformities, based on the actions taken by the accreditation body, may be:

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.

2) Where non-conformity is "quite significant", corrective action must be completed within the specified time interval to avoid suspension. Such non-conformities may well 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 accreditation body 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.

3) Where the non-conformity is minor or isolated and does not affect test or calibration results or certificates, requiring corrective action would not improve the operations of the laboratory and could seriously damage the relationship between the laboratory and the accreditation body. In such cases the non-conformity could be noted in the assessment notes, for checking at the next assessment but no request for corrective action should be made.

By starting with the actions that the accreditation body requires of the laboratory, when it identifies a non-conformity, we have defined three grading categories for nonconformities.

Forms of grading similar to this but with various numbers of categories were the most common for accreditation bodies that replied to the ILAC enquiry.

3 GRADING THE NON-CONFORMITIES

During the private analysis meeting of the assessment team, they may have identified a number of non-conformities and their nature as described in Section 2.

Identifying the nature of a particular nonconformity may be helpful in deciding the most appropriate grading from Section 3.

For example, technical requirements nonconformities that are threatening the validity of test or measurement results would usually be regarded as at least “quite significant” and possibly “very serious indeed” (grades 1 or 2 above). Similarly, a serious breakdown in the quality management system, such as many complaints being received but none actioned, may be in the serious category.

Apparently intentional breaching of the rules for the use of accreditation body logo or mark may also be regarded as “very serious indeed”. This would be the case particularly if the integrity of the accreditation body or unfair competitive advantage against properly accredited organisations had resulted.

Some management system element nonconformities may be graded as 2 or 3 depending on the situation. A 3 grading may result if the validity of results were 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 1 grading.

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

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 will be appropriate.

To maximise the usefulness of this document, ILAC members have provided examples of non-conformities that may lead to each particular grading. These are presented in the appendix. The suggested gradings are for guidance only. Had the full circumstances been presented, a different grading may have been more appropriate.

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.

Because the evaluation of staff competence or technical validity is not entirely objective, different gradings may result in similar situations. The accreditation body should take all steps possible to minimise these inconsistent outcomes.

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

4 GENERAL COMMENTS ON GRADING OF NON-CONFORMITIES AND ISSUING OF CORRECTIVE ACTION REQUESTS

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

Grading decisions should be made by the assessor and lead assessor who were on site. They should be made at or soon after the visit.

A finding should be sufficiently detailed to be able to confirm whether it was a onetime 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.

Minor non-conformities, which are to be checked at the next assessment, may be reported verbally to the laboratory, may perhaps be included in the report and should be recorded in the assessment notes, so that the laboratory manager understands that they will be checked during the next assessment.

Minor non-conformities have a tendency to grow into significant non-conformities if not addressed appropriately at the time.

Where a non-conformity is found, the assessor(s) should evaluate its affect 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.

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

Findings should be evaluated together with the general picture / history of the laboratory e.g. trust, 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 rather than awaiting the next meeting of a committee.

APPENDIX: Examples of Non-conformities which may be Allocated to the Various Gradings

It must be emphasised that had more detailed information been available to the authors of this paper 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 are seldom an issue for a laboratory already accredited.

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 key technical manager(s) for particular work and no longer has competent staff doing that work. They continue to issue test / calibration reports in that field. They did not advise the accreditation body 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 accreditation body e.g. interviewed by a technical assessor.

1.2 After two previous warnings the laboratory is still issuing test / calibration reports endorsed with the accreditation body 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 accreditation body that it will not happen again. (see ILAC G 14:2000 on use of accreditation body logos)

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 / calibration 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 accreditation body 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 clients 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 outlying result of a proficiency test. 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 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 the accreditation body was satisfied that a proper uncertainty budget has been presented. The laboratory 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 laboratory is immediately suspended for this particular calibration work until effective follow-up action has been demonstrated.

1.10 The calibration / testing 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.

1.11 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 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 accreditation body.

1.12 There is significant evidence that the quality 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 none 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 Non-conformities 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 the most recent one have not been followed up or closed 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 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 may be 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 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.

2.14 The uncertainty budget is not fully in line with EA 4/02 or 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 Minor non-conformities that:

- are reported as such and will be followed up at the next assessment or
- are indicated to the laboratory and are not reported in the written report but they are noted in the files for checking at the next assessment.

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

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 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 standardisation 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.

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).