Purpose

DPA explain to the assessors working with DPA, its policy for the grading of the nonconformities found during the assessment of CAB against the requirements of relevant accreditation standards. This policy outlines one approach to the classification of nonconformity, from most important to least serious, through linking the seriousness of nonconformities and actions DPA deems necessary to undertake. Several examples of nonconformities gradings are listed in the document.

References

The standard ISO/IEC 17011:2017, point 7.6.6, "General Requirements on accreditation organizations which accredit the conformity assessment bodies".
Procedure DA-PT-001 "Procedure for accreditation, surveillance and renewal of accreditation"

Scope

This policy is implemented on all the nonconformities found during the assessment of CAB in accreditation procedure.

1. THE NATURE OF THE NONCONFORMITIES

For certification of quality management systems of an organization, the relevant standard defines the requirements.

For accreditation of CABs, one aspect of the evaluation is to ensure, as well as certification, that the management system is in conformance with the standard and that staff follow the procedures.
However, the key aspect of the evaluation is to determine the competence of the staff and technical validity of their actions.

For this assessment process (not audit), DPA requires professional opinion of the assessors and technical experts.

Where it is considered that key technical or their assisstants are not competent or where the technical validity of calibration and tests is questionable, signaling of a nonconformity is done based on one or more of the technical and reference standard S SH ISO / IEC 17025, S SH ISO / IEC 17020, ISO 17065, ISO 17021, ISO 17024, etc.

For accredited CABs there is another type of non-conformity that shall be taken into consideration. DPA has rules and requirements that CAB shall have to follow. These rules include, among others, request for accreditation status and the use of its symbol. When these rules are violated, the DPA considers this a nonconformity.

For these reasons, for the accreditation the nature of nonconformity would be:

- Documentation is not conforming to the requirements of the standard.

- Staff is not following documented procedures.

- Technical managers, Quality Manager or other key staff is not demonstrating competence in the work they are doing

- Operational procedures such as test or measurement methods, traceability, etc., have lacking of technical validity.

- Breakdown in the operation of the quality management system of the CAB.

- The CAB is not conforming to the accreditation rules.

In deciding which nonconformities are very important to seek immediate suspension, or important to seek a swift action and the presentation of objective evidence to the DPA, or which are less important and can be checked at next assessment, DPA takes into account the nature of these nonconformities.

DPA has as a priority to provide customers CABs that staff is competent and the procedures and results of analysis sheets and certificates are technically valid, then nonconformities related to technical activities normally are considered as serious compared to those dealing with management requirements, where the validity of the results may not harmed. Nonconformities of managerial aspects, scattered around a quality system CAB should also be considered as serious.
To understand better this classification we will show nonconformities, from the most serious to less serious, describing the relation between the importance of nonconformity with the action that the DPA shall undertake.

2. **ACTIONS UNDERTAKEN BY DPA AS RESULT OF NONCONFORMITIES**

A significant percentage of CABs fail (are not conform) to accreditation requirements. These CABs were communicated nonconformities and / or requiring corrective action, which determine the nature of the nonconformity and within which date should solve them.

For the non-accredited CAB, in which the first initial assessment are conducted, accreditation may be delayed until corrective actions have been effectively undertaken and with the completion of the assessment team requirements.

The assessment team may propose that corrective actions related to unimportant nonconformities be cleared after accreditation.

Corrective actions associated with serious nonconformities, will be carried out before granting accreditation.

DPA may require that some of the nonconformities are corrected more urgently than others and that objective evidence of corrective actions carried out by CAB are given to DPA and clients to be notified that the results of testing / calibration are suspicious and should be repeated.
If nonconformities are really serious, the mediate suspension of accreditation is necessary.

Consequently, the character of subsequent actions imposed by the DPA is in the proportion with grading of nonconformities.

Classification of the seriousness of nonconformities, based on the actions undertaken by DPA, can be:

1. Nonconformity is "very serious" when accreditation program reliability is seriously threatened, the accreditation of CABs that, or violated testing / calibration are interrupted immediately.
2. Nonconformity is "important", corrective actions shall be completed within a specified time interval to avoid suspension of accreditation.

These nonconformities (1 and 2) could require another assessment visit to the CAB to ensure that are corrected efficiently, especially if the validity of results or reliability of the DPA are threatened. However, if the assessment team is convinced that the CAB has understood the issue, written guarantee of corrective actions and demonstration on objective evidence of the measures undertaken, may be acceptable.

3. Nonconformity is "minor or isolated" and does not influence the results of the testing and calibration certificates. Requiring corrective action would not improve the operations of the CAB-that and could seriously damage the relationship between the CAB and DPA. In these cases, nonconformity may be involved in different evaluation notes, to be controlled in the next assessment.

Referring to the type of measure, DPA requires by a CAB when identifies a nonconformity, three categories for classification of nonconformities are defined.

3. CLASIFICATION OF NON-CONFORMITIES

Classification of nonconformity shall be based on the nature of action, that DPA will undertake relating to the nonconformity.

Class 1: nonconformity 'major' will be, a very serious nonconformity, nonconformities of technical character, threatening the tests results validity that requires immediate interruption of accreditation. Similarly, a serious lack in quality management system, such as many complaints received but no action is taken, can be considered as a major non conformity.

Manifestation of a violation in the rules of use of the accreditation body's symbol, when the integrity of the DPA is compromised or has resulted in unfair competitive advantage versus correctly accredited organizations can be considered major nonconformity.

- For non accredited CAB undergoing their first assessment, the accreditation is delayed until corrective actions are taken and effectively implemented within five months.
- For accredited CAB undergoing their surveillance, and the non- conformities affecting specific area in the scope of the accreditation or the whole scope, in this case the CAB has to correct such nonconformities immediately otherwise the lead assessor shall immediately inform the DPA relevant staff for immediate action regarding the accreditation of the CAB which shall be suspended immediately, or shall not be granted before closure of such nonconformities.

Example:

1.1 *The body has lost its technical inspection for particular work and has not competent personnel to perform the work, and yet continue to issue certificates in this sector. Not notified the fact the accreditation body nor did they self suspend their accreditation.*

Result: Suspension for that particular sector until a new technical manager to be considered competent by the accreditation body e.g interviews by a technical assessor.

1.2 Once it has received two warnings, the inspection body is still issuing test or calibration, the symbol of the accreditation body, containing results of measurements (without proper records) that are outside the scope of accreditation.

Result: Suspension or withdrawn of accreditation until there is a serious commitment to uniform rules of accreditation and monitoring procedures are implemented to convince the accreditation body that fact will not happen again.

1.3 Key equipment for a particular sector of the measurements are broken and not repaired or replaced in the near future (immediate). CAB not change the

calibration path to another level and issue appropriate certificates although alternative instruments used are not technically valid.

Result: Suspension for that particular sector until equipment is not considered to be appropriate by the accreditation body or subcontracted work temporarily in another CAB accredited for that job.

1.4 The layout) of the CAB is such that it is impossible for the staff to prevent contamination of samples in test

Result: Suspension of those testing until an onsite visit to confirm that the plan was changed to solve the problem and a monitoring program to demonstrate that plants are under control.

Class 2: "Medium" nonconformities will be a serious nonconformity when DPA requires that corective actions shall be carried out within a specified time interval to avoid suspension and then the withdrawal of accreditation.
DPA requires that actions shall be taken within the time agreed as follows.

- Within (5) months, deviations arising from the first onsite assessment shall be closed.
- Within (2) months, deviations arising from the supplementary assessment and surveillance visits shall be closed.

When all non-conformities are not closed, the applicant is required to take new corrective action and to close all non-conformities within (1) month, and if the applicant or accredited CAB has not closed properly and in agreed time the non-conformities, the lead assessor requires starting of the accreditation refusal procedure or in the case of surveillance, starting of accreditation suspension.
These kind of non-conformities need to be followed through onsite assments to ensure that they are effectively corrected especially when affected the validity and integrity of the DPA.

EXAMPLES
2.1 Some critical equipment passed the validity period of calibration and are not re-calibrated. Daily assessments conducted show that they continue to meet specifications.

2.2 The results of a recent proficiency test was an isolated and corrective action has not yet been identified or corrected the problem.

2.3 A standard method was changed without prior approval of the client and without validity (validation) of change (would have been needed more information to determine the significance of this modification, which could be more serious than stated) .

2.4 The premises are not kept clean and adequately adjusted for more precision work carried out in them. However, the data quality control or environmental monitoring indicate that test results could not be influenced by that point.

2.5 There are some errors in the transcription of the standard method to manual methods of inspection body

Class 3: 'small' is a nonconformity isolated and does not affect the results of the testing, calibration certificates, inspection reports etc.

Examples:

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

3.2 The complaint was lodged by consumers but was not resolved.

3.3 A staff member had no job description, although there was a general description in the manual for that position.

3.4 "Quality Manager" and "Technical Manager" are not clearly identified in the Body Quality Manual Inspektiues

3.5 There was no documented evidence to show that when the machine is off direct control of the inspection body, their function and calibration status check before returning to service.

3.6 The organizational chart included in the quality manual is not updated. Discussion with staff members confirmed that they are aware of the current organizational structure.

The assessment grup's observation on areas for possible improvement may also be presented to conformity assessment body during the closing meeting or to be included in assessment report. The assessment group shall be careful in formulation of observations for possible improvement in order to avoid reccomendations and specific solutions. Regarding the observations for possible improvements, the CAB is not obliged to take corrective actions, but they will be assessed in the next visits as possibility for improvements.

NONCONFORMITIES OF MANAGEMENT SYSTEM.

Some nonconformities in management system aspects can be classified as 2 or 3 after the concrete situation. A class 3, can be given if the validity of the measurement results is not in question and the management system was not compromised in many aspects.

However, as mentioned in the above, there are cases where failures in the management system may be serious and make it possible to classify the nonconformities of class 1.

In some cases, a series of nonconformities even if in themselves are not serious nature, can provide a combination that can be considered serious for the CAB-in.

Regardless of the nature of the nonconformity, each should be evaluated by calculating the circumstances in which it is estimated, in such a way that the classification can be fair and impartial manner and that the actions taken against CAB has been adopted.

4. GENERAL COMMENTS ON NONCONFORMITIES CLASSIFICATION

Classification of nonconformities shall be based only on recorded outcomes during the assessment visit in CAB.

Grading decisions will be taken by the evaluators present in CAB, imediately or directly after the assessment visit.

A finding should be sufficiently detailed, in order to confirm whether it was a random event or a general statement whose corrective action should be implemented by the CAB's.

CAB has the responsibility to determine, through the opening of its corrective action if an event may have wider implications.

Minor nonconformities, which must be checked in the next assessment, may be reported verbally to CAB's, could possibly be involved in and register in the check list, so that the CAB's responsibility to understand, they will be checked the next visit

Where there is a nonconformity, the assessors will need to assess its effect on the quality of measurement results. For example, a thermometer can have an effect not suggestible to measurement results if the results are not sensitive to temperature in particular.

Findings should be evaluated together with an overview of the CAB and its history, taking into account, for example, a degree of confidence, scheduled upgrades, technical staff competence, repetitive nature (the raport from previous assessments) , etc.

Date:08.06.2022 **General Director**

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