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Accreditation Services

SCC Guidelines and Procedures for Laboratories with Serious and Critical Nonconformities

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PREFACE

The document *SCC Guidelines and Procedures for Laboratories with Serious and Critical Nonconformities* replaces *CAN-P-1625 - PALCAN Policy on Guidelines and Procedures for Laboratories with Serious and Critical Nonconformities - November 2006*.

1. OBJECTIVES

1.1 To provide SCC assessment teams with guidelines and procedures for:

- the course of action to take when serious and critical nonconformities are identified during laboratory assessment activities;
- determining when the nonconformities become so critical that the tests/calibrations cannot be accredited;
- determining if increased surveillance activities/visits should be recommended.

1.2 To present a decision process to assist teams in the selection of the appropriate course of action.

1.3 To make teams aware that SCC must be provided with a Team recommendation whenever serious and critical nonconformities are encountered.

2. SCOPE AND APPLICATION

2.1 These guidelines apply to all assessments and reassessments conducted on behalf of SCC. To alleviate the text, the term « assessment » has been used for both assessment and reassessment.

2.2 These guidelines apply whenever:

a) a team member is not confident in the laboratory's ability to manage the Management System (MS) and/or competence to conduct the accredited tests or calibrations;
b) the number of the nonconformities are such that the team or a team member cannot comfortably form an overall impression of conformance;
c) the nature of the nonconformities are such that they cast serious doubt on the overall ability of the laboratory to perform the accredited tests or calibrations.

2.3 Specific accreditation requirements and criteria are outside the scope of these guidelines and are defined in SCC Requirements and Guidance documents. Refer to these documents to determine the requirements that apply to the subject laboratory.

3. DEFINITIONS

3.1 Nonconformity: Non-fulfillment of a requirement

3.2 Serious Nonconformities: One or a series of nonconformities for which documentation alone cannot provide confidence in the effectiveness of their resolution.

Note 1: *Examples include:*

- *several un-documented management system procedures, but practices are generally suitable;*
- *some key procedures or processes not implemented;*
- *assessor(s) cannot state with confidence that the lab is able to produce competent test/calibration results.*

Note 2: *Failure can be one critical system or a general system failure leading to a lack of evidence to demonstrate the competence of the laboratory.*

Note 3: *Serious nonconformities related to the management system alone will normally require additional time for the laboratory to fully resolve, particularly with regard to providing objective evidence demonstrating implementation.*

3.3 Critical Nonconformities: One or a series of nonconformities that affect test/calibration results or that render the management system ineffective. Their complete resolution will require considerably more time than the SCC assessment visit process allows.

Note 1: *Examples include a combination of:*

- *several key procedures or processes not implemented;*
- *general lack of monitoring critical management systems elements;*
- *absence of commitment to the management systems;*
- *lack of resources (equipment, staff) to conduct test(s)/calibration(s);*
- *evidence that test/calibration results have been compromised.*

Note 2: *Immediate action is needed to mitigate the impact of the critical nonconformities on the accredited activities when the laboratory will not be able to address the failure in a timely manner. Credibility of the accreditation program is threatened.*

3.4 Extraordinary Assessment Visit: On-site visit to a laboratory that can be conducted at any time to ensure compliance with the accreditation criteria. Extraordinary Assessments are conducted to assess the continued effective implementation of the Management System and or technical activities of the laboratory. The duration of these visits are generally no more than one (1) day on-site and is in addition to the biennial surveillance questionnaire.

Note 1: *Extraordinary Assessment visits can be conducted by a full team or individual team members depending on the nature of the nonconformities and/or the experience of the team members.*

4. GUIDELINES FOR THE ASSESSMENT OF LABORATORIES WITH SERIOUS OR CRITICAL NONCONFORMITIES

4.1 Nonconformities are identified by assessment teams when accreditation requirements are not fulfilled (when nonconformities occur). The laboratory will usually respond by providing documented evidence of the measures taken to correct the nonconformities. Teams will then evaluate the documentation and upon acceptance, forward a recommendation to SCC for accreditation or maintenance of accreditation.

However, there are instances when it may not be practical to proceed in this manner, or when a review of the documented evidence alone may not definitely provide the confidence that the corrective measures are effective (refer to paragraph 2.2). In these instances and when serious or critical nonconformities have been identified (refer to paragraph 3.2 and 3.3), teams must consider if:

- accreditation can be granted or maintained and/or;
- there is a need for more extensive surveillance of the laboratory.

4.2 While on site, each team member must advise the Lead Assessor (LA) as early as possible if there is evidence of serious or critical nonconformities. The team should meet as soon as possible to determine the extent of the potential problem and document the findings. The SCC Account Manager should be contacted to discuss options.

4.3 If at all possible, teams faced with serious or critical nonconformities should continue with the current assessment. Section 5 and Annexes A to E provide additional details and guidelines. Teams should consider the following when applicable:

a) For applicant laboratories: consider recommending a reduction of the proposed scope or conducting a Gap Analysis;

b) For accredited laboratories: consider recommending immediate full or partial suspension or the formulation of a request from the laboratory to voluntarily suspend or withdraw affected tests/calibrations from the scope of accreditation (Refer to Annex B);
c) For Accredited laboratories when the problem is generalized: consider not recommending any requested scope extension. When the problem is localized, consider not recommending scope extensions in the affected area (refer to Annex B);
d) Teams should recommend an Extraordinary Assessment visit when the review of the supporting documentation alone may not definitely provide the confidence that the corrective measures are effective. (Refer to Annex C)
e) Teams should recommend an Extraordinary Assessment visit before the next reassessment to obtain evidence that the corrective action undertaken to eliminate the serious or critical QMS nonconformity has been successfully implemented. Teams should consider recommending an Extraordinary Assessment visit to assess the continued effective implementation of the QMS or when there are concerns that a laboratory will be capable to effectively maintain the corrective action assessed at a Extraordinary Assessment visit. (Refer to Annex C, item 4.3f and item 4.4.)
f) The possibility of conducting the next reassessment in advance of the scheduled date should also be considered. Specific conditions related to the areas affected by the serious or critical nonconformities require consideration for this recommendation. (Refer to Annex D and item 4.4 below).
g) Surveillance activities can be compounded when different aspects of the laboratory technical and management system have identified serious or critical nonconformities. (Refer to Section 5 and Annex E)

4.4 An additional or early visit (Extraordinary Assessment or advancing the next reassessment) is deemed necessary when the team judges that the situation is such that:

- fully mastering the newly implemented process will take time; or
- the team is concerned about recurrence due to the magnitude of the change or due to a lack of sufficient evidence to determine that the problem will not reoccur (for example: to confirm that a new quality manager is working out, newly trained analyst has mastered a critical new technique, general breakdown is fully addressed).

4.5 Where Proficiency Testing results are available for the affected activities these must be reviewed and considered in the evaluation of the competence of the laboratory for performing specific tests/calibrations.

4.6 As soon as possible, the LA must inform the Laboratory Management and Senior Management of the situation and proposed options, and proceed with the current visit as agreed to with the Laboratory.

4.7 The LA is responsible for evaluating the overall report of findings to determine if the accumulation of required actions constitutes serious or critical nonconformities. The LA is also responsible for recording the options agreed to by the team.

4.8 When the management and analysis of the responses is expected to be considerably more extensive than usual, Lead Assessors can request additional time/fees for this activity. The laboratory and the Account Manager must be informed and Lead Assessor call-up modified accordingly. An estimate will be provided to the laboratory. (Refer to Annex A)

4.9 The findings report should identify any recommendation for Extraordinary Assessment visits as well as additional time foreseen for the review of responses to required actions. The Account Manager should be informed immediately after the visit whenever such a recommendation has been made.

4.10 Additional fees for any visits or additional activities will apply and an estimate will be provided to the laboratory. Additional fees will include but not be limited to: Lead Assessor and/or technical assessor professional fees, travel and accommodation.

4.11 As is the case with any visit findings, the laboratory can file a complaint challenging the team recommendation/finding for additional visits or activities within (10) days from the conclusion of the visit. Refer to the findings report.

5. REFERENCES AND BIBLIOGRAPHY

1) Accreditation Program Overview

ANNEX A: GUIDELINES FOR EVALUATING THE NEED FOR SUPPLEMENTAL DOCUMENT REVIEW

A.1 When the list of required actions is extensive and the LA perceives that it should take more than one day to fully review the management responses and coordinate the responses of the technical areas, consideration should be given to requesting supplemental time for response review.

A.2 The LA is responsible for determining if the collective responses have maintained a coherent management system or if the individual responses could have impacted the documentation of the system in such a manner that the system has become fragmented or contradictory.

A.3. When the LA has concerns that the system has become fragmented or contradictory, the LA must recommend and conduct a supplemental documentation review. The supplemental documentation review is a complete review/assessment of the management system as a whole rather than separately evaluating each original response.

ANNEX B: GUIDELINES FOR RECOMMENDING PARTIAL OR FULL SUSPENSION OR WITHDRAWAL OF ACCREDITED TESTS/CALIBRATIONS

B.1 Full or partial suspension or withdrawals should be considered when critical technical nonconformities are encountered.

B.2 The team should meet in private to determine the extent of the affected areas, if only a specific technical area is affected and if the team can recommend accreditation for a portion of the scope. Teams must consider the accreditation requirements, the impact to the laboratory's clients' needs and the apparent ability of the laboratory to resolve the nonconformities within the allowable time frames. When the overall technical operation is affected, consideration could be given to the possibility of reducing the scope to retain only critical tests/calibrations in order to allow the laboratory to focus only on a limited area and thus have more possibility to regain control in a timelier manner.

B.3 The LA should inform the laboratory immediately of the team concerns that have led to the consideration for immediate suspension. As soon as possible, the LA should also document the justification of the recommendation for immediate suspension to the Laboratory Management and Senior Management.

B.4 The LA should also advise the laboratory that they can request voluntary suspension or withdrawal of the affected tests/calibrations from the scope by formulating and forwarding a written request to the Account Manager immediately following the visit. Such a request can even be considered during the assessment.

B.5 Suspensions or withdrawals are conducted in accordance with the SCC Accreditation Program Overview and the Suspensions and Withdrawals SOP.

B.6 The Laboratory can apply for a scope extension of the tests/calibrations that were withdrawn or apply at a later date for a reinstatement of the tests/calibrations that were suspended.

ANNEX C: GUIDELINES FOR RECOMMENDING An Extraordinary Assessment VISIT

C.1 The focus of such a visit is to evaluate the ability of the laboratory to maintain the effectiveness of corrective actions proposed in the responses to required actions Group A from the previous visit. The team normally consists of the LA and may also include technical assessors under special circumstances (refer to C.3). The LA should preferably be, but not necessarily, the LA of the previous visit. Such visits usually last one day on site.

C.2 A Extraordinary Assessment visit should be considered in addition to the surveillance questionnaire whenever a reassessment identifies serious management system nonconformities.

C.3 A Extraordinary Assessment visit should also be considered in addition to a surveillance questionnaire as a follow up to an Extraordinary Assessment visit when assessors from an Extraordinary Assessment visit (technical or QMS) are concerned about the ability of the laboratory to sustain the corrective action(s) that were deemed acceptable.

This is generally the type of Extraordinary Assessment visit where Technical Experts are required.

C.4 When it is determined that more time is required or that most or all of the team is needed, a full reassessment visit should be considered instead (Refer to Annex D). Areas reviewed during Extraordinary Assessment visits are related to the findings of the previous visit and the progress made by the laboratory which may include:

a) Review of any newly developed documentation or changes to documentation
b) Review of the implementation of previously developed documentation.

C.5 Extraordinary Assessment visits are planned and conducted in accordance with SCC Accreditation Program Overview.

ANNEX D: GUIDELINES FOR RECOMMENDING CHANGING THE REASSESSMENT SCHEDULE

D.1 Changing the reassessment cycle rather than conducting an Extraordinary Assessment visit or sending a surveillance questionnaire should be considered when there is a combination of serious technical nonconformities and serious or critical QMS nonconformities or the conditions in section C.4 have occurred. The change in reassessment schedule (advancement of the next and subsequent scheduled reassessment visits) is in addition to any immediate Extraordinary Assessment visits. When significant areas remain that could not be fully assessed in the current visit due to serious or critical nonconformities, changing the reassessment schedule should be considered.

The change in reassessment schedule should also be considered when the Extraordinary Assessment activities would require more than one day or when most of the technical team will be required.

D.2 The LA forwards a recommendation to the Account Manager after the reassessment visit, Extraordinary Assessment visit or when the report is being forwarded for approval. The Account Manager will consider the recommendation and upon approval forward the recommendation to the Vice President, Accreditation Services.

D.3 Upon approval by the VP, the Account Manager will notify the laboratory of the change in schedule.

D.4 A change in the reassessment visit schedule may also be considered when it is more cost effective to conduct the next reassessment in advance in lieu of an Extraordinary Assessment visit. The proximity of the next scheduled reassessment should be considered.

ANNEX E: COMPOUNDING OF SURVEILLANCE ACTIVITIES

Suspension, withdrawal and surveillance activities required as a result of serious or critical nonconformities can be compounded. A laboratory with critical technical nonconformities in one area and serious technical nonconformities in another area and serious QMS nonconformities can be subject to scope reduction, and Extraordinary Assessment visit.

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