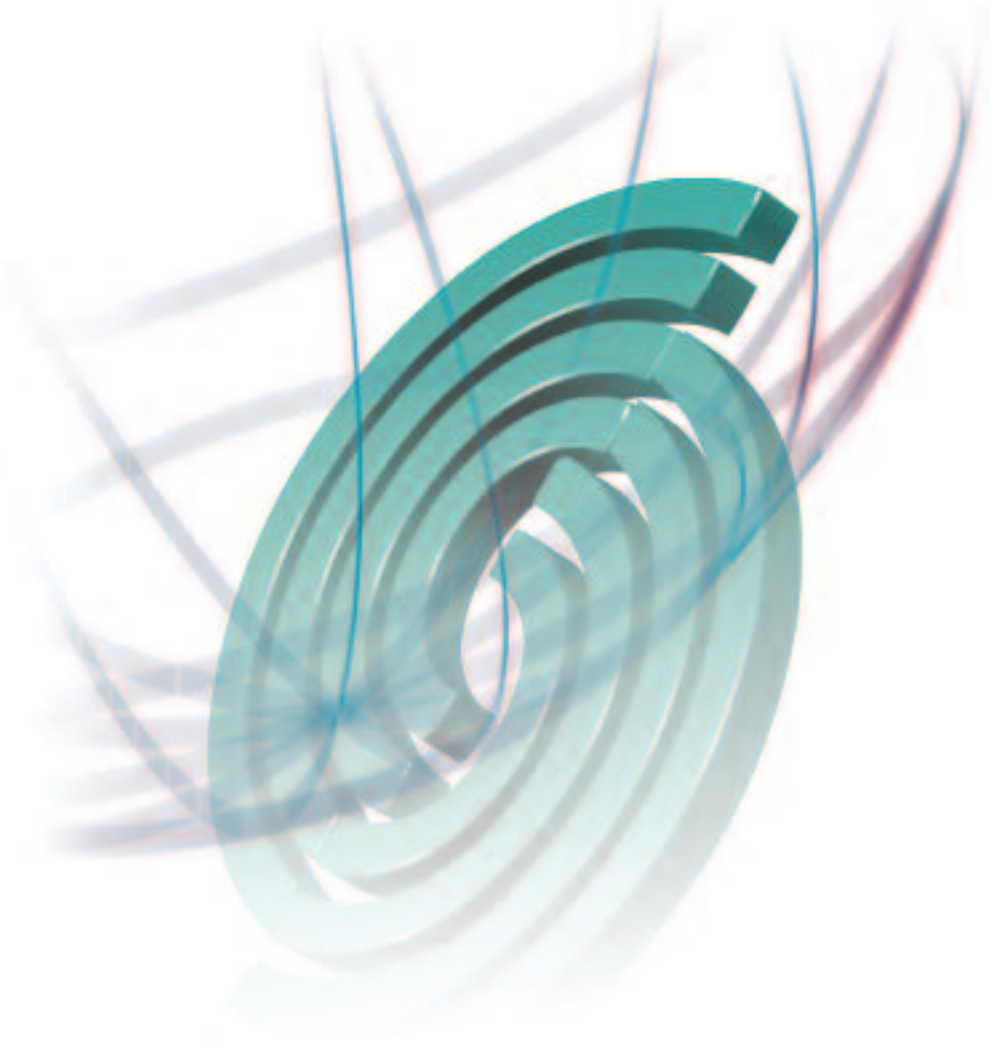


Standards Council of Canada
Conseil canadien des normes

PALCAN Policy on Guidelines and Procedures for Laboratories with Serious and Critical Non-Conformities

CAN-P-1625
November 2006

Canada

PALCAN POLICY ON GUIDELINES AND PROCEDURES FOR LABORATORIES WITH SERIOUS AND CRITICAL NON-CONFORMITIES

POLITIQUE DU PALCAN LIGNES DIRECTRICES ET PROCÉDURES RELATIVES AUX LABORATOIRES AYANT DES NON-CONFORMITÉS GRAVES ET CRITIQUES

CAN-P-1625
November 2006

Standards Council of Canada
270 Albert Street, Suite 200
Ottawa, Ontario
K1P 6N7
Canada
Tel.: (613) 238-3222
Fax.: (613) 569-7808
Email: info@scc.ca
Website : www.scc.ca

NOTE : A French version of this document is available from the:

Standards Council of Canada
270 Albert Street, Suite 200,
OTTAWA, Ontario
K1P 6N7
Tel.: (613) 238-3222
Fax.: (613) 569-7808
Email: info.palcan@scc.ca
Website: www.ccn.ca

NOTE: On peut obtenir un exemplaire français de ce document en écrivant au:

Conseil canadien des normes
270 rue Albert, bureau 200
OTTAWA (Ontario)
K1P 6N7
Tél.: (613) 238-3222
Fax.: (613) 569-7808
Courriel: info.palcan@scc.ca
Site web: www.ccn.ca

TABLE OF CONTENTS

FOREWORD

The Standards Council of Canada ("Council") is a crown corporation established by an Act of Parliament in 1970, amended in 1996, to foster and promote efficient and effective voluntary standardization in Canada. It is independent of government in its policies and operations, although it is financed partially by Parliamentary appropriation. The Council consists of members from government and the private sectors.

The mandate of the Council is to promote the participation of Canadians in voluntary standards activities, promote public-private sector cooperation in relation to voluntary standardization in Canada, coordinate and oversee the efforts of the persons and organizations involved in the National Standards System, foster quality, performance and technological innovation in Canadian goods and services through standards-related activities, and develop standards-related strategies and long-term objectives.

In essence, the Council promotes efficient and effective voluntary standardization in Canada in order to advance the national economy, support sustainable development, benefit the health, safety and welfare of workers and the public, assist and protect consumers, facilitate domestic and international trade and further international cooperation in relation to standardization.

In addition, the Council serves as the government's focal point for voluntary standardization and represents Canada in international standardization activities, sets out policies and procedures for the development of National Standards of Canada, and for the accreditation of standards development organizations, of product certification bodies,, of testing and calibration laboratories, of quality and environmental management systems registration bodies and of quality management systems and environmental auditor certifiers and training course providers, and promotes and supports the principle of recognition of accreditation or equivalent systems as a means of decreasing the number of multiple assessments and audits, both in Canada and with Canada's trading partners.
This document is one of several issued by the Standards Council of Canada to define the policies, plans, and procedures established by the Council to help achieve its mandate.

Requests for clarification and recommendations for amendment of this document, or requests for additional copies should be addressed to the publisher directly.

1 OBJECTIVES

1.1 To provide PALCAN, SCC and Partner Organizations assessment teams with guidelines and procedures for:

- the course of action to take when serious and critical non-conformities are identified during laboratory assessment activities;
- determining when the non-conformities 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 non-conformities are encountered.

2 SCOPE AND APPLICATION

2.1 These guidelines apply to all assessments and reassessments conducted on behalf of SCC PALCAN. 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 non-conformities are such that the team or a team member cannot comfortably form an overall impression of conformance;

c) the nature of the non-conformities 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 PALCAN and Partner Organization specific documents. Refer to these documents to determine the requirements that apply to the subject laboratory.

3 DEFINITIONS

3.1 **Non-conformity**: Non-fulfillment of a requirement (*ISO 9000-2000 Fundamentals and vocabulary 3.6.2*).

3.2 **Serious Non-Conformities**: One or a series of non-conformities 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 non-conformities 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 Non-conformities**: One or a series of non-conformities 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 non-conformities 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 **Surveillance Visit**: On-site visit to a laboratory that can be conducted at anytime to ensure compliance with the accreditation criteria. Surveillance visits 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.

3.5 **Verification Visit**: On-site visit that is part of an on-going assessment process to determine that the responses to the required actions are effective.

Note 1: Surveillance and verification visits can be conducted by a full team or individual team members depending on the nature of the non-conformities and/or the experience of the team members.

4 GUIDELINES FOR THE ASSESSMENT OF LABORATORIES WITH SERIOUS OR CRITICAL NON-CONFORMITIES

4.1 Required Actions (Group A and B) are identified by assessment teams when accreditation requirements are not fulfilled (when non-conformities occur). The laboratory will usually respond by providing documented evidence of the measures taken to correct the non-conformities. 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 non-conformities 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 Team Leader (TL) as early as possible if there is evidence of serious or critical non-conformities. The team should meet as soon as possible to determine the extent of the potential problem and document the findings. The SCC SPO should be contacted to discuss options.

4.3 If at all possible, teams faced with serious or critical non-conformities should continue with the current assessment. Section 5 and Annexes A to F 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 a verification 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 a surveillance visit before the next reassessment to obtain evidence that the corrective action undertaken to eliminate the serious or critical QMS non-conformity has been successfully implemented. Teams should consider recommending a surveillance 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 verification visit. (Refer to Annex D, 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 non-conformities require consideration for this recommendation. (Refer to Annex E 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 non-conformities. (Refer to Section 5 and Annex F)

4.4 An additional or early visit (Surveillance 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 TL 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 TL is responsible for evaluating the overall report of findings to determine if the accumulation of required actions constitutes serious or critical non-conformities. The TL is also responsible for recording the options agreed to by the team (refer to chart section 5)

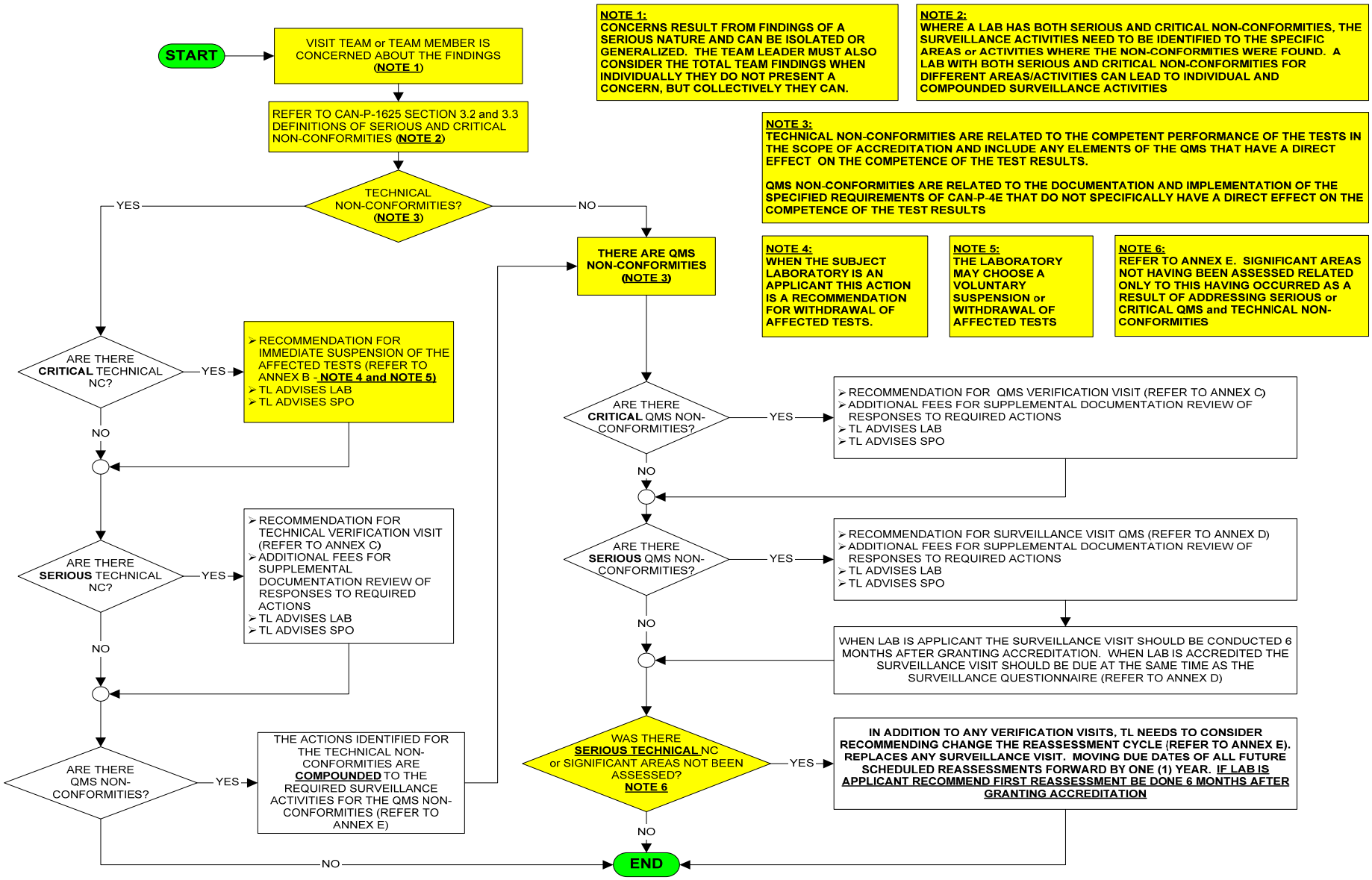
4.8 When the management and analysis of the responses is expected to be considerably more extensive than usual, Team Leaders can request additional time/fees for this activity. The laboratory and the SPO must be informed and Team Leader assignment form modified accordingly. An estimate will be provided to the laboratory. (Refer to Annex A)

4.9 The site visit report (form L1580) should identify any recommendation for verification or surveillance visits as well as additional time foreseen for the review of responses to required actions. The SCC SPO or Partner Organization 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: Team Leader and/or technical assessor professional fees, travel and accommodation and additional SPO time.

4.11 As is the case with any visit findings, team recommendation/finding for additional visits or activities can be appealed within (10) days from the conclusion of the visit. Refer to the L1580 visit report.

5 DECISION PROCESS FOR THE SELECTION OF COURSE OF ACTION TO ADDRESS SERIOUS or CRITICAL NC



6 REFERENCES AND BIBLIOGRAPHY

1) CAN-P-15, *Accreditation Programs Requirements and Procedures for Suspension and Withdrawal, Complaints, Appeals, and Hearings*

2) CAN-P-1570 PALCAN Handbook

3) *ILAC G20:2002 - Guidelines On Grading Of Non-conformities*

4) L1580 PALCAN Letter, *Observations and Summary of Responses*

ANNEX A

GUIDELINES FOR EVALUATING THE NEED FOR SUPPLEMENTAL DOCUMENT REVIEW

A.1 When the list of required actions is extensive and the TL 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 TL 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 TL has concerns that the system has become fragmented or contradictory, the TL 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 non-conformities 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 non-conformities 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 more timely manner.

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

B.4 The TL 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 SPO immediately following the visit. Such a request can even be considered during the assessment.

B.5 Suspensions or withdrawals are conducted in accordance with TP92.11 – Suspensions and Withdrawals. TP92.11 is an internal PALCAN process document, available upon request to laboratories affected by the process. Contact the SPO to obtain a copy.

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 A VERIFICATION VISIT

C.1 A verification visit should be considered whenever an assessment identifies serious technical non-conformities or critical management system non-conformities. These non-conformities are such that documentation alone may not demonstrate that the response to a required action will be effective.

C.2 Verification visits should also be considered when there is an extensive list of required actions or to determine if the laboratory fully understands critical corrective measure(s) that are new to them.

C.3 It is important to note that during verification visits no additional required actions should be identified; the mandate of the visit is limited to the verification of the effectiveness of the response to the original finding.

C.4 Verification visits usually take one to two days on site depending on the extent of the affected areas. During the verification visit, the original report of findings (L1580) is annotated with the team findings: response is either acceptable or the detail of the additional information/action is added.

C.5 Verification visits are planned and conducted in accordance with TP92.12 – Verification Visit. TP92.12 is an internal PALCAN process document, available upon request to laboratories affected by the process. Contact the SPO to obtain a copy.

ANNEX D

GUIDELINES FOR RECOMMENDING A SURVEILLANCE VISIT

D.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 TL and may also include technical assessors under special circumstances (refer to D.3). The TL should preferably be, but not necessarily, the TL of the previous visit. Such visits usually last one day on site.

D.2 A surveillance visit should be considered in addition to the surveillance questionnaire whenever a reassessment identifies serious management system non-conformities.

D.3 A surveillance visit should also be considered in addition to a surveillance questionnaire as a follow up to a verification visit when assessors from a verification 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 surveillance visit where Technical Assessors are required.

D.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 E). Areas reviewed during surveillance 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.

D.5 Surveillance visit are planned and conducted in accordance with TP92.13 – Surveillance Visit. TP92.13 is an internal PALCAN process document, available upon request to laboratories affected by the process. Contact the SPO to obtain a copy.

ANNEX E

GUIDELINES FOR RECOMMENDING CHANGING THE REASSESSMENT SCHEDULE

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

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

E.2 The TL forwards a recommendation to the SPO after the reassessment visit, verification visit or when the report is being forwarded for approval. The SPO will consider the recommendation and upon approval forward the recommendation to the Manager, Laboratory Accreditation.

E.3 Upon approval by the Manager, the SPO will notify the laboratory of the change in schedule.

E.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 a surveillance visit. The proximity of the next scheduled reassessment should be considered.

ANNEX F

COMPOUNDING OF SURVEILLANCE ACTIVITIES

Suspension, withdrawal and surveillance activities (verification and surveillance visits) required as a result of serious or critical non-conformities can be compounded. A laboratory with critical technical non-conformities in one area and serious technical non-conformities in another area and serious QMS non-conformities can be subject to scope reduction, verification visit and surveillance visit. (Refer to section 5).