Centre d'expertise en analyse environnementale du Québec

Analytical Laboratory Accreditation Program

TERMS AND CONDITIONS OF ACCREDITATION

DR-12-SCA-05-ENG

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FOREWORD

As a branch of the Ministère du Développement durable, de l'Environnement et de la Lutte contre les Changements climatiques, the Centre d'expertise en analyse environnementale du Québec (CEAEQ) administers the Analytical Laboratory Accreditation Program – *Programme d'accréditation des laboratoires d'analyse* (PALA). The Ministère de l'Agriculture, des Pêcheries et de l'Alimentation du Québec (MAPAQ) contributes to the CEAEQ by overseeing the technical component reserved for analytical laboratories serving the agricultural sector. Similarly, the Institut de recherche Robert-Sauvé en santé et en sécurité du travail (IRSST – Robert-Sauvé research institute in occupational health and safety) provides technical support in the air microbiology sector.

To ensure the uniform application of this program for all accredited analytical laboratories, the present document describes the provisions, conditions and particulars accompanying the requirements for laboratory accreditation.

CONTENTS

INTRODUCTION

This document describes the operating procedures of the Analytical Laboratory Accreditation Program (PALA) for the granting, maintenance, renewal, suspension, withdrawal and abandonment of accreditation, and for extending the scope of accreditation.

Operating under the Direction de l'accréditation et de la qualité [Office of accreditation and quality] of the CEAEQ, the Division des programmes d'accréditation [Accreditation programs division] is responsible for ensuring the application of these Terms and Conditions of Accreditation.

Recommendations concerning all of these actions are made by the Accreditation Committee to the Minister of Sustainable Development, Environment and the Fight against Climate Change, for analyses required under the *Environment Quality Act (EQA)*.

For analyses not governed by the EQA, the Accreditation Committee presents its recommendations to the appropriate authorities.

The various fees for laboratory accreditation are described in the document entitled *Tarification relative au Programme d'accréditation des laboratoires d'analyse*, DR-12-TARIF [Fee schedule for the Analytical Laboratory Accreditation Program].

1 GRANTING

1.1 Initial application for accreditation

When a laboratory makes its first application, provisional accreditation is granted for up to two years if the laboratory meets the following conditions:

- formal commitment by the laboratory to respect the requirements and operating rules of the Analytical Laboratory Accreditation Program
- on-site assessment confirming the laboratory's compliance with program requirements
- proficiency test demonstrating analytical performance in line with program requirements (the test may be repeated up to two times)

The minimum scores that must be obtained on proficiency tests are as follows:

- in toxicology, environmental chemistry (except families of organic compounds) and agricultural chemistry:
  - 60% for each parameter
  - 75% for the domain as a whole

- in environmental chemistry (for families of organic compounds):
  - 60% for at least 80% of the various parameters of the same family
  - 75% for the domain as a whole

- in microbiology:
  - 75% for enumeration parameters in microbiology
  - 75% for all identification parameters for bacteria and molds in air microbiology
  - 100% for all parameters using presence/absence methods

If a laboratory cannot demonstrate that it meets the requirements for a given domain, even after repeating the proficiency test a maximum of twice, the applicant is informed that its application file is closed and must apply again for accreditation in that domain.

Once a laboratory has demonstrated that it meets the requirements for accreditation, the file is sent for recommendation to the Accreditation Committee.

If the Committee's recommendation is positive, the file is submitted for the approval of the Minister, in the case of accreditations governed by the EQA. For accreditations involving air microbiology, the file is submitted to the Chief Executive Officer of the IRSST and the Managing Director of the CEAEQ.

Finally, if approved by the Minister or the Chief Executive Officer of the IRSST and the Managing Director of the CEAEQ, a provisional accreditation certificate is issued. Accreditation comes into force on the effective date shown on the certificate.

1.2 Application to extend the scope of accreditation

When a laboratory files an application to extend its scope of accreditation, an on-site assessment specific to the application may be carried out. The laboratory must also pass a proficiency test, which can be repeated up to two times. If it meets the conditions set out in section 1.1, its application is sent for recommendation to the Accreditation Committee. Upon favourable recommendation and the approval of the authorities, an extension of the accreditation is granted for up to five years

1.3 Closing an application for accreditation

If the CEAEQ sends a request to a laboratory in connection with an application for accreditation (or one to extend the scope of accreditation) and does not receive a written response, the application will be considered inactive. An application that remains inactive for more than sixty days will be closed; however, fifteen days before that deadline the laboratory will be notified of the imminent closing of its application file. If there is still no response, the closure will be confirmed in writing after the period prescribed. The fees paid on submitting the application will not be reimbursed.

Thereafter, to obtain accreditation the laboratory must submit a completely new application and pay the applicable fees.

2 MAINTENANCE

2.1 On-site assessment

2.1.1 General information

Maintenance of accreditation is conditional on the laboratory's compliance with program requirements. That compliance is verified by on-site assessments conducted every two years. In the case of newly accredited laboratories, a follow-up on-site assessment is performed about twelve months after the effective date of the first provisional accreditation certificate.

Within thirty days of receiving the on-site assessment report, if any non-compliance was identified the laboratory must either correct it (and provide documentation of the corrections made) or present an acceptable correction plan.

After review of the correction report, the laboratory may be granted sixty additional days in which to demonstrate compliance with the program. At the end of that period, if the laboratory's response is still incomplete or inadequate, the CEAEQ will take steps toward suspending the laboratory's accreditation for the domain concerned. Before a suspension can be lifted, a follow-up on-site assessment must be performed, with a favourable conclusion from the lead assessor.

2.1.2 Planning on-site assessments

With its first accreditation, the laboratory will be given an anniversary date for on-site assessments. The latter are planned by the CEAEQ to take place every two years, within approximately six weeks of the anniversary date. If the laboratory cannot receive the on-site assessment team on the scheduled date, its scope of accreditation could be suspended.

2.1.2.1 Modification of the anniversary date

The laboratory may send a written request to its program officer to modify the anniversary date, under the following conditions:

- To advance the anniversary date, the request must be made at least three months before the proposed new date.
- To put back the anniversary date (by a maximum of three months), the request must be made at least three months before the existing anniversary date.

Once the new date is approved, subsequent requests to modify the anniversary date will be relative to the new date. Only one such request will be approved in any five-year period.

2.1.3 Follow-up on-site assessment

When on-site assessment clearly shows that the laboratory's management system is failing or that the guidelines for analytical work are not being respected, a follow-up on-site assessment is done within twelve months to verify whether the laboratory has taken effective corrective measures. Follow-up on-site assessment may also be performed when called for by particular circumstances. A follow-up assessment may or may not be announced beforehand.

Within thirty days of receiving the follow-up on-site assessment report, any non-compliance identified must be corrected, with documentation of the corrections made. If the laboratory's response is incomplete or inadequate, its scope of accreditation may be suspended for the domain concerned. To lift the suspension, an additional follow-up on-site assessment must be performed, with a favourable conclusion from the lead assessor.

2.1.4 Specific on-site assessment

Particular circumstances, such as a customer complaint, major reorganization of the laboratory, or an application to extend the scope of accreditation, may result in a specific on-site assessment being performed.

Within thirty days after receiving the specific on-site assessment report, any non-compliance identified must be corrected, with documentation of the corrections made. In the case of a customer complaint, if the laboratory's response is incomplete or inadequate, its scope of accreditation could be suspended for the domain concerned. To lift that suspension, a follow-up on-site assessment must be performed, with a favourable conclusion from the lead assessor. For other situations, the procedure outlined in section 2.1.1 is applied.

2.1.5 Questionnaire

In years when no on-site assessment is planned, accredited laboratories must complete a questionnaire to confirm that their management system is still operational and to report any changes in staff or facilities. Information must also be provided on their most recent internal audit and management review. A laboratory that fails to return the questionnaire within fifteen working days may be subject to specific on-site assessment at its own expense.

2.2 Proficiency tests

Maintenance of accreditation is conditional on successfully passing all proficiency tests scheduled for each accredited domain. When a laboratory obtains accreditation it is immediately included in the annual scheduling of proficiency tests.

A laboratory that fails to submit the results of a scheduled mandatory proficiency test will be notified that, as stipulated in its signed commitment, it must subcontract the parameters concerned until it has repeated the test and demonstrated that it meets program requirements. This must be done within six months, otherwise the Accreditation Committee

will be asked to recommend to the appropriate authority that it suspend or withdraw the laboratory's accreditation for the domain(s) concerned.

In proficiency tests for inorganic chemistry and toxicology, a laboratory must score at least 60% for all parameters. For families of compounds in organic chemistry, a laboratory must score at least 60% in more than 80% of the family's compounds. For enumeration and identification parameters in microbiology the passing score is 75% per parameter. For presence/absence methods in microbiology, the passing score is 100% for each parameter.

In each domain, a laboratory must always score at least 75%, except for presence/absence methods in microbiology, where the score must be 100%.

Table 1: Minimum Performance Requirements

Field	Score by parameter (%)	Score by domain (%)
Inorganic Chemistry, Toxicology	60	75
Organic Chemistry	60 (in more than 80% of the family's compounds)	75
Microbiology (enumeration and identification)	75	75
Microbiology (presence/absence)	100	100

When proficiency tests are not available from the CEAEQ, after prior authorization from its program officer a laboratory may obtain performance samples from an ISO/IEC 17043 accredited proficiency test provider. The laboratory must send the report of its results to the program officer, who will review it on the basis of program criteria.

2.2.1 Rules applied in the event of failure

Appendix I presents the decision-making process applied to proficiency tests.

2.3 Correction report

If the score for any parameter is less than 75%, the laboratory must submit a correction report within thirty days.

The correction report must explain the causes of the failure, describe the corrective measures taken subsequent to the test, and indicate what follow-up will be done to avoid repeating the situation observed.

For proficiency tests in microbiology, the confirmation results, the expression of results, the analytical conditions and the equipment data provided on the information form will all be reviewed. Subsequently, a correction report or additional documents (such as work sheets) may be requested, even if the laboratory's results are over 75%.

After reception of the complete correction report, proficiency tests are repeated for any parameters where a problem was identified. Proficiency tests are not repeated if the score for a parameter was over 60%, unless the score for the domain was less than 75%. In that event the proficiency test is repeated for all the domain's parameters, except in microbiology, where performance is assessed on a parameter basis. For the microbiology sector then, the proficiency test is only repeated for parameters that were problematic. For families of compounds in organic chemistry, the proficiency test is repeated for the domain as a whole. For the presence/absence parameter in microbiology, proficiency tests are repeated if the score for the domain was less than 100%.

2.4 Subcontracting

When a laboratory performs below the standards set out in section 2.2, it must subcontract the parameter or domain concerned, as stipulated in its signed commitment. For families of organic compounds, the entire domain must be subcontracted if the laboratory fails to obtain 60% for at least 80% of parameters. For presence/absence methods in microbiology, the domain must be subcontracted if the laboratory fails to obtain 100%.

When a laboratory is sent a subcontract notice, it is also informed that it must produce a correction report within thirty days. After reception of that report, if approved by the program officer, the proficiency tests are repeated. If a repeated test is successful, the laboratory is informed that it may resume analyses for the parameter or domain concerned. Otherwise, the laboratory must continue subcontracting and produce a new correction report showing that it has mastered analysis for that parameter or domain. It is then sent a new proficiency test for a second repeat. If that test is successful the laboratory is notified that it may resume analyses, otherwise the Accreditation Committee will be asked to recommend suspension or withdrawal of the laboratory's accreditation for the domain concerned.

Subcontracting required after failing a proficiency test may continue for a maximum of six months. After that, the Accreditation Committee will be asked to recommend the suspension of accreditation for the domains concerned.

2.5 Voluntary accreditation not subject to Québec regulations

In cases of voluntary accreditation, e.g. if a laboratory is located outside of Canada or accreditation is not required under the *Environment Quality Act*, subcontracting is recommended after a performance failure. Also, failure of a proficiency test will result in the laboratory having to submit a correction report and repeat the test successfully to be in compliance with program rules.

If for technical reasons the laboratory is unable to perform analyses in the appropriate manner, it must voluntarily subcontract the work concerned until it has corrected the situation and regained mastery of the techniques required. As mentioned in section 3.2, the laboratory must inform its program officer of such actions.

2.6 Infrequent analysis

For a laboratory to maintain its accreditation, samples must be analyzed for accredited parameters at least twice per year. Samples analyzed for the annual proficiency test are counted for this requirement.

3 SUBCONTRACT RECOMMENDATION NOTICE

3.1 Notice sent by the Ministry

A laboratory may be sent a complete or partial scope subcontract recommendation notice if on-site assessment shows that its management system is failing or that it no longer meets the requirements of the guidelines for analytical work. It could also be subject to complete or partial suspension, or withdrawal of its accreditation, if so decided by the Minister.

A subcontract notice may also be sent if major difficulties arise due to changes affecting the activities or management of the laboratory, e.g. in terms of staff, premises, equipment, analytical methods or quality controls. The same applies when a complaint or information of any kind indicates, after review, that a laboratory no longer satisfies program requirements (including the payment of program fees). The laboratory's scope may then be placed under subcontract.

Subcontracting applies for a maximum of thirty days. If by the end of that time corrective measures have not been taken, or are deemed inadequate, the Accreditation Committee is asked to recommend suspension for up to six months, as specified in section 5. If the laboratory is unable to resolve its difficulties within that period, its accreditation may be withdrawn for the domains concerned.

At all times, the accreditation fees listed in the document *Tarification relative au Programme d'accréditation des laboratoires d'analyse*, DR-12-TARIF [Fee schedule for the Analytical Laboratory Accreditation Program], are maintained.

3.2 Voluntary subcontracting by a laboratory

A laboratory may decide to subcontract part of the analytical work for which it is accredited. For example, it may wish to do so because of technical problems in its analytical operations. In such situations, the laboratory must notify its program officer that it has begun voluntary subcontracting, specifying the date and explaining the reasons for that action, and must do the same when it ceases voluntary subcontracting. Voluntary subcontracting may not be done for more than six months, otherwise the Accreditation Committee will be asked to consider recommending suspension or withdrawal of the domains of accreditation concerned.

Voluntary subcontracting for any reason other than analytical problems will be evaluated by the CEAEQ.

Furthermore a laboratory may not engage in voluntary subcontracting to avoid its supervisory obligations in domains of accreditation related to the *Regulation respecting the quality of drinking water*.

3.3 Client notification

In accordance with PALA and section 4.5.2 of ISO/IEC 17025, laboratories are obligated to inform their clients if any part of their work is subcontracted. Also, information on the subcontracting of domains or parameters by accredited laboratories may be published externally by the CEAEQ, on the Internet for example.

4 RENEWAL

When a laboratory's accreditation certificate is approaching expiry, the CEAEQ produces a report with a summary of the laboratory's analytical performance and the results of its on-site assessments. This report is presented to the Accreditation Committee for evaluation. The file is then submitted to the authorities concerned. If their decision is favourable, the laboratory is issued a new accreditation certificate, valid for up to five years.

If the laboratory fails to meet PALA requirements, or if there is reason to believe that it would fail to do so if the certificate were renewed, renewal may be denied. In some cases, further verification may be done before a decision is made. If the decision is negative, the authority responsible sends the laboratory an explanation for why renewal was denied.

5 SUSPENSION

A laboratory's accreditation may be suspended if on-site assessment reveals that it has lost control of its management system or that it fails to meet PALA requirements. Suspension may also be applied in whole or in part to its scope of accreditation if a laboratory fails to satisfy the minimum requirements after twice repeating the proficiency tests, if it fails to respect its signed commitments, or if major difficulties arise due to changes affecting the activities or management of the laboratory, e.g. in terms of staff, premises, equipment, analytical methods or quality controls. The same applies if a complaint or information of any kind indicates, after review, that a

laboratory no longer meets program requirements (including the payment of program fees and respecting the anniversary date for on-site assessment, as described in section 2.1).

In such event the laboratory's file is submitted for review to the Accreditation Committee, which makes a recommendation to the authorities concerned. The laboratory may then be notified of the suspension, for a set period, of one or more domains or even the entirety of its scope of accreditation.

A suspension may be applied for up to six months, during which suspended domains are temporarily withdrawn from the laboratory's scope in the official list of accredited laboratories and on the CEAEQ's website. If the laboratory is unable to resolve its difficulties within that period, its accreditation for the domains concerned may be withdrawn. Accreditation fees cannot be reimbursed, as indicated in the document *Tarification relative au Programme d'accréditation des laboratoires d'analyse*, DR-12-TARIF [Fee schedule for the Analytical Laboratory Accreditation Program].

For a suspension to be lifted, the laboratory must prove that it has resolved its difficulties. This can be done through a further on-site assessment or by passing a proficiency test. The laboratory's file will be submitted for review to the Accreditation Committee, which will make a recommendation to the authorities concerned.

6 WITHDRAWAL

If a laboratory fails to achieve the minimum standards for proficiency tests, or if on-site assessment, a complaint or information of any kind indicates, after review, that it no longer satisfies program requirements, it may be subject to partial or even complete withdrawal of its scope of accreditation. In that event, prior written notice is sent to the laboratory. The laboratory will then have a set period in which to submit observations, in writing. When a notice of withdrawal is issued, the domains in question are withdrawn from the laboratory's scope on the official list of accredited laboratories. Partial or complete withdrawal may also be published on the CEAEQ's website.

A laboratory whose accreditation is withdrawn must return its accreditation certificates to the CEAEQ. If the withdrawal only concerns a particular domain, only the certificate for that domain must be returned. The CEAEQ's website will be updated accordingly.

A laboratory whose accreditation has been withdrawn, whether partly or completely, may seek accreditation again if it believes that it can meet the requirements.

7 ABANDONMENT

A laboratory that wishes to abandon its accreditation, in whole or in part, may do so by sending written notice to its program officer. It must then return to the CEAEQ the original accreditation certificates concerned and pay the fees indicated in the document *Tarification relative au Programme d'accréditation des laboratoires d'analyse*, DR-12-TARIF [Fee schedule for the Analytical Laboratory Accreditation Program]. Complete abandonment takes effect on the date of reception of the notice of abandonment. For partial abandonment, since a new certificate of

accreditation must be issued, the abandonment takes effect on the effective date of the new certificate. Partial or complete abandonment may be published on the CEAEQ's website.

8 SPECIAL SITUATIONS

8.1 New facilities or change of premises

When planning a move (into new facilities or a change of premises), a laboratory must comply with the following obligations:

- Notice of the moving date, with a floor plan of the new facilities, must be submitted at least one month before the moving date.
- The laboratory must be able to give a precise date for the resumption of analytical services following the move.
- A specific on-site assessment must be done within three months after the date of the move. A laboratory that refuses an on-site assessment may have its scope of accreditation suspended until such assessment takes place.

8.2 Change of ownership

When the ownership of a laboratory is transferred, written confirmation of that change must be provided by the manager to the program officer, along with documents certifying the new ownership including its listing in the *Registre des entreprises du Québec*. The new manager must sign the commitment form.

If necessary, a specific on-site assessment will be conducted.

8.3 Accreditation covering multiple sites

A laboratory whose accreditation covers multiple sites may apply to transfer an accredited activity from one site to another. For the location to which an activity is transferred, the rules applied are similar to those for extending the scope of accreditation.

If the domains or parameters transferred are in keeping with the activities of the receiving laboratory, or are technically compatible with domains and parameters for which it is already accredited, the following rules apply:

- The program officer must be sent documentation of the analytical method used and the validation data produced at the new physical location, including with any equipment that was transferred. Note that in Chapter III of PALA, section 5.5.2 stipulates that before entering service, such equipment must be calibrated or verified to establish that it meets the laboratory's requirements and complies with the relevant standards. It must be checked or calibrated before use (section 5.6).

- If necessary, a specific on-site assessment is performed (e.g. depending on the type, number and complexity of parameters transferred).
- If applicable, a provisional proficiency test is performed.
- A certificate of accreditation is issued.

If the domains or parameters transferred are not in keeping with the activities of the receiving laboratory, or are incompatible for technical reasons (equipment, facilities, staff qualifications, etc.), in addition to the rules above a specific on-site assessment is mandatory, not optional.

REFERENCES

CENTRE D'EXPERTISE EN ANALYSE ENVIRONNEMENTALE DU QUÉBEC. *Programme d'accréditation des laboratoires d'analyse: Normes et exigences*, DR-12-PALA, Ministère du Développement durable, de l'Environnement et des Parcs, March 6, 2012.

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APPENDIX I – DECISION-MAKING PROCESS APPLIED TO PROFICIENCY TESTS

Sector	Score by domain (%)	Score by parameter (%)	Correction report	Proficiency tests repeated – domain	Proficiency tests repeated – parameter	Subcontracting
Microbiology (enumeration and identification)	N/A	between 60 and <75	yes	-	yes	no
		< 60	yes	-	yes	yes
Microbiology (presence/absence)	N/A	< 100	yes	-	yes	yes
Inorganic Chemistry	≥ 75	between 60 and <75	yes	-	-	no
		< 60	yes	-	yes	yes
	< 75	between 60 and <75	yes	yes	all	no
		< 60	yes	yes	all	yes
Organic Chemistry	≥ 75	< 60	yes	yes**	all	yes**
	< 75	≥ 60*	yes	yes	all	no
		< 60	yes	yes	all	yes**
Toxicology	≥ 75	between 60 and <75	yes	-	-	no
		< 60	yes	-	yes	yes
	< 75	≥ 75	yes	yes	-	no
		between 60 and <75	yes	yes	-	no
		< 60	yes	yes	yes	yes

*** for more than 80% of parameters in domain**

**** when 20% or more of the domain's various parameters of the same family are < 60%**

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