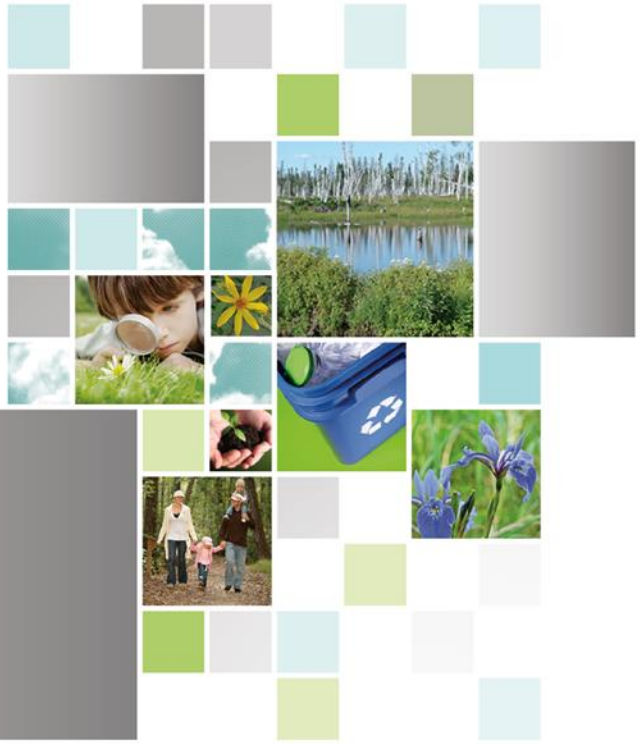

ANALYTICAL LABORATORY ACCREDITATION PROGRAM

INSTRUCTIONS
APPLICATION FOR ACCREDITATION
(DR-12-01-01-ENG)

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Québec

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INSTRUCTIONS

1. GENERAL

To obtain accreditation, a laboratory or **company** must meet the standards and requirements set out in the document entitled *Programme d'accréditation des laboratoires d'analyse* [Analytical Laboratory Accreditation Program] (DR-12-PALA).

When applying for accreditation, the **company** or laboratory must demonstrate that it has the necessary skills to perform the specified analyses. The company or laboratory must also agree to comply with the conditions set out in the Program and meet all requirements specified in the documents mentioned in the Program **(see Tables 1 and 2).**

Table 1: Program requirements applicable to all fields of accreditation

Name and number of document	Subject
Exigences relatives à la qualification du personnel [Requirements regarding staff qualifications] (DR-12-PER)	Requirements pertaining to the training and experience of staff in the capacity of supervisor, authorized signatory, laboratory, chemistry, microbiology or toxicology technician, sampling technician, scientific officer for drinking water sampling**, or technician and scientific officer for the operation of air quality monitoring stations**.
Protocole pour les essais d'aptitude des laboratoires d'analyse [Protocol for proficiency testing of analytical laboratories] (DR-12-SCA-04)	Description of the proficiency testing process, including planning, preparation, performance, information processing, data interpretation, report, and follow-up.
Modalités d'accréditation [Terms and conditions of accreditation] (DR-12-SCA-05)	Provisions, conditions, and particulars of requirements with regard to the granting, maintenance, extension, renewal, suspension, and withdrawal of accreditation.
Exigences applicables à la déclaration de l'accréditation [Requirements regarding the statement of accreditation] (DR-12-SCA-06)	Description of the terms and conditions regarding advertising and the statement of accreditation as well as of the rules regarding the use of electronic data management systems (LIMS).
Lignes directrices concernant l'échantillonnage de l'eau potable [Guidelines concerning the sampling of drinking water] (DR-12-SCA-07)	Requirements regarding drinking water sampling.

Table 2: Program requirements according to the field for which accreditation is requested

Field of accreditation	Name and number of document	Subject
Chemistry	*Lignes directrices concernant les travaux analytiques en chimie* [Guidelines concerning analytical work in chemistry] (DR-12-SCA-01)	Requirements regarding quality assurance and control for accreditation in chemistry.
	Protocole pour la validation d'une méthode d'analyse en chimie [Protocol for the validation of an analytical method in chemistry] (DR-12-VMC)	Requirements for the validation of an analytical method in chemistry.
	Directive sur la validation des méthodes d'analyse en chimie [Directive on the validation of analytical methods in chemistry] (DR-12-VAL)	Details on the types of materials to use for validating analytical methods in chemistry.
	Guide d'estimation de l'incertitude des mesures pour les analyses chimiques [Guide for estimation of measurement uncertainty in chemical analyses] (DR-12-INC)	Procedure for estimating the uncertainty of analytical methods in chemistry.
Water and solid matter microbiology	*Lignes directrices concernant les travaux analytiques en microbiologie* [Guidelines concerning analytical work in microbiology] (DR-12-SCA-02)	Requirements regarding quality assurance and control for accreditation in microbiology.
	Protocole pour la validation et la vérification d'une méthode d'analyse en microbiologie [Protocol for the validation and verification of an analytical method in microbiology] (DR-12-VMM)	Requirements for the validation and verification of an analytical method in microbiology.

Field of accreditation	Name and number of document	Subject
Air microbiology	*Lignes directrices concernant les travaux analytiques en microbiologie de l'air* [Guidelines concerning analytical work in air microbiology] (DR-12-SCA-08)	Requirements regarding quality assurance and control for accreditation in air microbiology.
Toxicology	*Lignes directrices concernant les travaux analytiques en toxicologie* [Guidelines concerning analytical work in toxicology] (DR-12-SCA-03)	Requirements regarding quality assurance and control for accreditation in toxicology.
Air quality monitoring stations	*Lignes directrices concernant les stations de surveillance de la qualité de l'air* [Guidelines concerning air quality monitoring stations] (DR-12-SCA-09)	Technical requirements regarding the accreditation of air quality monitoring stations.

These documents are available on the website of the Centre d'expertise en analyse environnementale du Québec (CEAEQ) of the Ministère de l'Environnement et de la Lutte contre les changements climatiques (MELCC), at the following address: www.ceaeq.gouv.qc.ca.

2. INSTRUCTIONS FOR FILING AN APPLICATION FOR ACCREDITATION

Applicants should consult the requirements of the program to which they are applying, making sure that they understand the scope of the requirements and are in compliance with them.

All information received is treated confidentially in accordance with the provisions of the Act respecting access to documents held by public bodies and the Protection of personal information (CQLR c A-2.1). The CEAEQ's Direction de l'accréditation et de la qualité ensures the confidentiality of information pertaining to all applications for accreditation.

The information provided in the documents submitted by the applicant is used to:

- **Ensure that the laboratory or company has examined each of the requirements and is in compliance with them;**
- **Detect any potential non-compliance;**
- **Verify the conformity of elements stated by the laboratory during the on-site assessment.**

The application for accreditation must be accompanied by the "Statement of the applicant or holder" containing the information required under section 115.8 of the Environment

Quality Act (CQLR, chapter Q-2). All required documents must also be attached and sent to the CEAEQ via email at ceaeq@environnement.gouv.qc.ca or by mail at the following address:

Direction de l'accréditation et de la qualité
Centre d'expertise en analyse environnementale du Québec
Ministère de l'Environnement
et de la Lutte contre les changements climatiques
2700, rue Einstein, bureau D.2.325
Québec (Québec) G1P 3W8

3. DOCUMENTS REQUIRED FOR FILING AN APPLICATION FOR ACCREDITATION OR A SCOPE EXTENSION

3.1. Initial application for accreditation

For a first-time application for accreditation, the applicant must provide the following documents:

- **The completed *Demande d'accréditation* form [Application for Accreditation] (FO-12-01-02) indicating the scope of the accreditation requested.**

  This form must be approved by the manager with the authority to commit the laboratory or company to comply with the accreditation program's operating rules and requirements.

- **The completed *Renseignements généraux* form [General Information] (FO-12-01-03) with copies of all of required documents.**

  If copies of documents such as organizational charts, legal authentication documents, curricula vitae, or diplomas are required, they should be appended to the application for accreditation, even if they are already included in the quality manual, in order to facilitate processing the file.

  The laboratory's commitment in section 8 of form FO-12-01-03 must be approved and signed by the manager with the authority to commit the laboratory or company to comply with the accreditation program's operating rules and requirements.

- **The completed *Grille de conformité* [Compliance Chart] (DR-12-GCA).**

  The applicant should complete the *Compliance Chart*, referencing the corresponding section and pages of the laboratory's quality manual or any other relevant documents that the applicant attached, making sure to address each item on the chart. If the applicant deems an item to be irrelevant, "N.A." (not applicable) may be entered. The staff, equipment, policies, procedures, and tests referred to must pertain to the activities associated with the application for accreditation.

- The quality manual and any other documents pertaining to the *Compliance Chart*, including the quality management system procedures.

- **Copies of the analytical methods or sampling protocol, if applicable:**
  - **The methods must be based on recognized reference methods;**
  - **The elements concerning the conservation and preparation of samples, the analytical conditions, and quality controls relevant to the associated acceptability criteria must be submitted.**
- **The validation data and calibration curves, if applicable, that meet the requirements of the PALA:**
  - **The laboratory's validation protocol must be consistent with DR-12-VMC, DR-12-VMM, DR-12-SCA-08 or DR-12-SCA-03, as appropriate;**
  - **The quantification limits of the in-laboratory analytical methods must be equal to or less than the minima specified in the document *Critères de variation relatifs* [Relative difference criteria] (DR-12-CVR);**
  - **The materials used for the validation of methods in chemistry must be consistent with the *Directive on the validation of analytical methods in chemistry* (DR-12-VAL).**

3.2. Extension of the scope of accreditation

If applying for an extension of the scope of accreditation, the applicant must submit the following documents:

- **The completed *Application for Accreditation* (FO-12-01-02), indicating the domains concerned by the extension of the scope of accreditation (see section 3.1).**
- **Relevant sections of the *General Information* form (FO-12-01-03) duly completed in order to update the accreditation file, if applicable, along with copies of all required documents (see section 3.1).**
- **Copies of the analytical methods or sampling protocol that include the same information that is required for an initial application.**

4. DOCUMENTS REQUIRED ACCORDING TO THE FIELD FOR WHICH ACCREDITATION IS REQUESTED

4.1. Chemistry

For chemistry applications, laboratories must also include the following items: the validation of methods in accordance with the *Protocol for the validation and verification of an analytical method in chemistry* (DR-12-VMC), calibration curves for the parameters of the domains indicated in the application, and a copy of the analytical methods used by the laboratory.

4.2. Water and solid matter microbiology

For water and solid matter microbiology applications, laboratories must also include the following items: the validation of methods in accordance with the *Protocol for the*

validation and verification of an analytical method in microbiology (DR-12-VMM) and a copy of the analytical methods used by the laboratory.

4.3. Toxicology

For toxicology applications, laboratories must also include validation data for the methods that pertain to the application.

4.4. Air microbiology

For air microbiology applications, laboratories must also include validation data for the methods that pertain to the application.

4.5. Air quality monitoring stations

For applications concerning air quality monitoring stations, companies must also include information on the objective of the monitoring station(s), a description of the station(s), and a list of its/their equipment.

5. REVIEW OF THE APPLICATION FOR ACCREDITATION OR SCOPE EXTENSION

5.1. Receipt of the application

Upon receipt of the application, the program officer designated by the CEAEQ ensures that the information received is complete and, if needed, contacts the applicant to obtain any other additional information. The officer then fully examines the laboratory's documentation. This analysis is intended to ensure that the documentation complies with accreditation requirements. If needed, a review report on the documentation indicating missing or incomplete items is sent to the applicant.

5.2. Steps in processing applications

The steps subsequent to the documentation review are as follows:

- For initial applications, an on-site assessment is scheduled to confirm compliance with accreditation requirements. **For applications to extend the scope of accreditation, an on-site assessment may also be carried out.**
- When available, a preliminary proficiency test is carried out to demonstrate the laboratory's analytical performance.
- A report is sent to the Accreditation Committee for recommendation.
- The committee members examine the report and, on the basis of the file's compliance with requirements in force, agree to recommend accreditation to the minister.
- **For an initial application for accreditation, a two-year provisional accreditation certificate may be granted by the minister. For an extension of the scope, a certificate may be issued by the minister for a five-year period.**

The provisions, conditions, and particulars accompanying the accreditation requirements are described in the document entitled *Terms and Conditions of Accreditation* (DR-12-SCA-05-ENG).

6. FEES

Application fees are payable to the order of the Minister of Finance upon receipt of the invoice, in accordance with the document entitled *Tarification relative aux programmes d'accréditation des laboratoires d'analyse* [Fee schedule for the Analytical Laboratory Accreditation Program] (DR-12-TARIF).

A laboratory or company that has not paid the application fees or that is in default of payment of any other accreditation fees cannot obtain accreditation until all amounts due have been paid.

APPENDIX

Application Filing Checklist

	Initial application	**Application for extension**
Statement of applicant or holder.	☐	☐
Completed *Application for Accreditation* form (FO-12-01-02) indicating the scope of accreditation requested.	☐	☐
Completed *General Information* form (FO-12-01-03), accompanied by copies of all required documents.	☐	Relevant sections ☐
Completed *Compliance Chart* (DR-12-GCA).	☐	N/A
The quality manual and any other documents pertaining to the *Compliance Chart* (DR-12-GCA), including quality management system procedures.	☐	N/A
Copies of the analytical methods or sampling protocol.	☐	☐
Validation data and calibration curves that comply with PALA requirements, if applicable.	☐	☐

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