

LAB-CIL REF 02 COFRAC NEW STANDARD FOR ORGANISERS OF INTERLABORATORY COMPARISONS ACCREDITATION

COFRAC stands for "Comité Français d'Accréditation". It is the French body for accreditation that installed LAB-CIL REF 02. This standard applies solely to organisations organising interlaboratory comparisons (ILC). It defines the technical and the quality assurance management requirements to which organisers of ILC have to comply with. The accreditation process is described in this article.

1 - Accreditation context of ILC organisers

Work began in 1998 on request from organisms organising interlaboratory assays and desiring a COFRAC recognition. An Accreditation Technical Commission (ATC) began work on that topic. In 2001, an ILC-ATC continued the work.

● ILC ATC missions

- to update and install a standard for ILC organisers' accreditation (ILCO)
- to put forward a proposition about ILCO
- to examine technical experts' competence
- to take into account other ACT's wishes and needs in ILCO matter.

This work led to the July 2002 standard named "LAB CIL REF 02" that defines requirements to be met by ILCO to be accredited. It is based upon "ILAC Guide 13" which defines the requirements laboratories have to comply with to have their competences acknowledged. For the technical part, it takes the main requirements from "ISO / CEI 43-1 Guide". For the quality management part, it takes the main requirements from ISO / CEI 17025 standard. It applies to ILC aiming at evaluating laboratories competences. Currently, it does not apply to ILC having other aims such as method validation, material characteristics determination, or in the calibrating field.

● ILC aims

- to determine participating laboratories' competence
- to evaluate methods
- to determine material's characteristics (metrology or other) that might be adopted later on as reference material.

Shortly, COFRAC is going to extend these aims to methods and reference material evaluation.

2 - Standard

As described earlier, the standard is made up of two parts, but unlike the ISO 17025, the first part describes the technical requirements and the second part the requirements linked to quality management.

● List of technical requirements :

- ILCO staff and potential subcontractors' competences
- the way the ILCO conceives, organises and leads the ILC campaign (homogeneity, stability of samples subjected to assay, reference values, instructions to participants ...). To define its requirements the ILCO may get help from statisticians or a consultative technical experts group

- data analysis and results interpretation (recording of results, statistical model used)
- ways to avoid collusion, falsification of results
- way to produce an ILC campaign report

● List of quality management requirements :

- organisation's management, quality management system
- control of quality documentation and records
- way of carrying out requests review, calls for tenders, contracts
- requirements voiced when turning to subcontractors
- way of defining services and supplies purchasing
- feedback from clients
- control of non-conforming work
- corrective and preventive actions
- way to carry out an internal audit
- management review

● Differences between ISO 17025 standard and LAB-CIL REF 02 standard at the quality management level

ISO 17025 standard defines requirements applying to a laboratory to have its competence recognised. While LAB CIL REF 02 standard defines requirements applying to an ILCO to have its competence recognised.

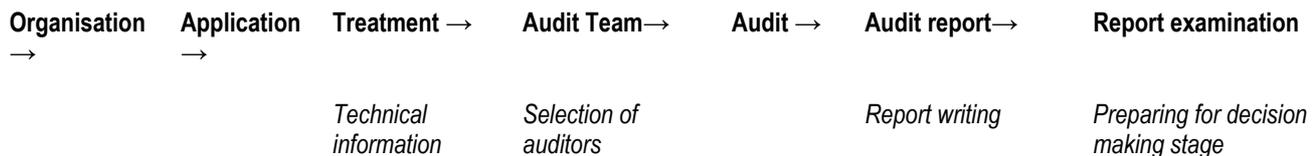
A laboratory quality insurance system defines the way to competently carry out assays or calibrations.

An ILCO quality assurance system defines its organisation to satisfy to its own aim, i.e. to competently carry out interlaboratory comparisons.

The focus is set, for example, on confidentiality, on ways to barr collusion of participants or falsification of results, on the turning to competent subcontractors.

3- Accreditation process

Treatment of the application constitutes the first step along the path towards accreditation. COFRAC conducts an investigation into the case file asking the applying organism, if need be, complementary technical information. Supplied with this information, the COFRAC accreditation manager selects an audit team and assigns it in the organism to be audited. At the end of the audit, auditors write an audit report, which is then examined by reporters, either by the ATC or by an internal commission, in case of renewal without major change in competence. Then comes the decision stage when the COFRAC head pronounces in favour or against ILCO accreditation.



Treatment of an accreditation application

● **ATC composition**

The ATC is made up of 19 members representing laboratories, authorities and other bodies.

● **Accreditation process**

The accreditation manager makes the conducting of investigation into the application file with the ATC.

The elements to supply are :

- quality documents and special procedures
- scope of the accreditation application
- list of possible subcontractors

For each field of competence, the applicant defines the scope of the accreditation's application. The organiser indicates :

- the date from which it has carried out interlaboratory comparisons
- the number of campaigns organised
- the number of participants in the campaigns
- the time and frequency of the campaigns

Example of an accreditation's application extend

(Definitions : LAB CIL REF 05)

Activity sector **Food industry - multi products**

Type of product Milk products (dry milk)

Assays field

Analysis of milk product components

Assays

- Dry matter content
- Fat content (etherochlorhydric method)
- Protein matter content
- Urea and ammonium hydroxyde content (enzymatic method)

● **Accreditation cycle for Organisers of ILC**

In the initial audit, the audit head is an expert quality specialist. A technical expert - according to the field - and a statistics technician expert assist him or her.

Accreditation is granted for a 57 month period with supervision phases every 15 months. Renewal time intervenes at the end of this initial phase of 4 years and 9 months. Then, the organism enters a 5 year accreditation cycle with a supervision phase every 15 months.

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Abbreviations :

ATC : Accreditation Technical Commission
COFRAC (COmité FRançais d'Accréditation) : French Committee for Accreditation
ILAC : International Laboratory Accreditation Cooperation

ILC : InterLaboratory Comparisons
ILCO : InterLaboratory Comparisons Organiser

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