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Quality in Testing Laboratories: A Real Case in a Spanish Fuel Laboratory

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Abstract

Quality management is the chosen option by those organizations that maintain a strong commitment to excellence in their products, services, and processes. The technical competence of a testing laboratory is essential to provide confidence in the results issued to its clients: administrations, companies, or individuals who request their services. The implementation of a quality system, with international recognition, facilitates and enables laboratory projection in national and international forums. The study shows the steps followed by a fuel laboratory (R + D + i), integrated in a Spanish university, to implement the quality standards established in ISO/IEC 17025 and ISO 9001. Despite its small size, the laboratory maintains high-quality standards. Obtaining ISO/IEC 17025 accreditation has allowed the laboratory to recognize its technical competence at a national and international level, greater visibility, and better positioning among laboratories that offer the same services, which has increased the number of customers and has achieved their loyalty.

Keywords: testing laboratory, ISO/IEC 17025, ISO 9001, technical competence, integrated quality

1. Introduction

Practically all fields of science are moving forward at an increasingly rapid rate thanks to the results obtained from laboratories.

A laboratory [1] is a place equipped with all of the resources needed to carry out scientific, technological, or technical research, experiments, practices, and works, with the appropriate level of rigor:

- It ensures that foreign influences, other than those specifically set out, do not occur and alter the result of experiment or measurement.
- It guarantees the repeatability of the experiment or measurement, i.e., any other laboratory could repeat the process and obtain the same result.

How can we ensure the confidence of the results of the tests carried out by the laboratory?

Accreditation is the internationally established tool to build trust on the performance of a very specific type of organizations, named, in such a way, Conformity Assessment Organizations (CAO) (**Figure 1**), including testing laboratories, calibration laboratories, inspection agencies, certification bodies, and environmental verifiers [2].

The main objective of the Conformity Assessment Organizations (CAO) is to demonstrate the society (administration, companies, and consumers at large) that the products and services made available comply with certain requirements related to quality and security. These requirements can be set by law, and therefore have a regulatory nature, or can be specified by standards, specifications, or other voluntary documents.

Accreditation arouses both controversy and interest; multiple studies try to deepen in the subject from different perspectives [3–7].

1.1 The benefits of accreditation

1.1.1 For accredited organizations

- Builds organization recognition.
- Competitive advantage: accreditation provides independent assurance that your staff is competent.
- Market access: accreditation is recognized and accepted in over 90 countries worldwide.
- Fosters a continuous improvement dynamic within the organization.
- Facilitates access to government contracting: accreditation has increasingly become an important criterion in the public procurement procedures.

1.1.2 For government

Accredited bodies, both public and private, are already being used by governments as an effective market-led tool for delivering policy more efficiently, resulting in a substantial reduction in costs as well as best practice.



Figure 1.
Conformity assessment organizations.



Figure 2.
 Accreditation organizations of different countries.

1.1.3 For business

By selecting an accredited body, businesses:

- Reduce downtime and control costs.
- Minimize risks.
- Increase its customer confidence.
- Increase its product acceptance in other markets.
- Open up opportunities for competent supplier selection.
- Reduce the risk of failures.

Accreditation organizations of different countries (**Figure 2**) perform their task pursuant to the same international criteria, using equivalent and transparent assessment methods, providing the necessary confidence to allow the mutual acceptance of results.

The ISO/IEC 17025 Standard was designed to be used by testing and calibration laboratories in the development of their quality, administrative, and technical management systems.

Working under the standards of ISO/IEC 17025, the technical competence of the laboratory and the validity of its results are recognized, responding to the requirements of the organizations or entities that contract it and offering credibility to its clients [8].

2. State of the art

Product or service quality is the consumer's perception of it and should be defined within the context under review.

From a value-added perspective, quality means bring value to the customer, i.e., offer product or service conditions of use superior to those that the customer expects to receive and at an accessible price.

For good product or service quality [9], there are three very important points which we need to bear in mind:

- **Technical dimension:** it encompasses scientific and technological aspects that affect the product or service.

- **Human dimension:** it attends to relations between customers and organizations.
- **Economic dimension:** it attempts to minimize costs both for the customer and the organization.

In 1957 and 1988, respectively, the European Organization for Quality (EOQ) and the European Foundation for Quality Management (EFQM) are founded in Europe to promote total quality management; among the most important European quality infrastructure organizations are testing laboratories.

When you commission a laboratory to test products, to determine its characteristics, as part of the quality control or to determine compliance with particular requirements of standards or specifications, it is necessary to be sure that they supply you with accurate and reliable results. In other words, this is a laboratory technically competent.

In order to ensure the reliability of its products or services, minimize risks, and increase customer confidence and product acceptance in other markets, it is essential for the organizations to call on a laboratory with the highest degree of technical competence.

2.1 The normative evolution

The first version of Standard ISO/IEC 17025 dates from 1999. The ISO/IEC 17025:2017 Standard on General Requirements for the Competence of Testing and Calibration Laboratories is currently in force, but it has had a long way before it arrived here from that first version in 1999.

The ISO/IEC 17025:1999 Standard replaced the ISO/IEC 25:1990 former guide (General Requirements for the Competence of Calibration and Testing Laboratories) and the European EN 45001:1989 Standard (General Criteria for the Operation of Testing Laboratories), introducing new requirements in relation to responsibilities and commitment of upper management and giving greater emphasis to continuous improvement according to Deming method or PDCA (plan-do-check-act) (**Figure 3**) and to dialog with the customer.

The ISO/IEC 17025 Standard emerged in 1999 as a reference generic guideline for Testing or Calibration Laboratories; the existence and evolution of the quality

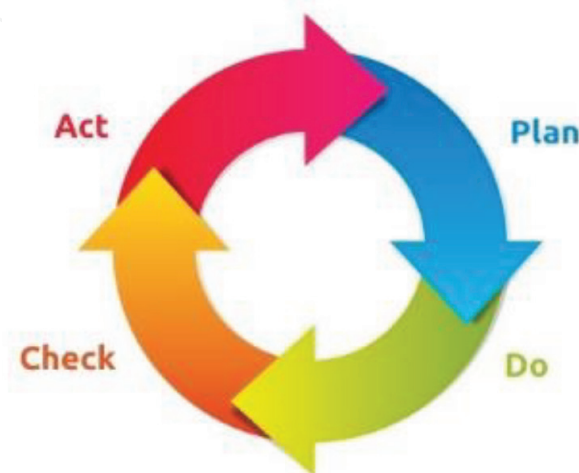


Figure 3.
Deming cycle.

management regulation stipulated in ISO 9001 Standard led to a revision to determine their alignment with the ISO 9001:2000 Standard in 2005 (**Figure 4**).

In 2017, to adjust its form to the structure of the rest of 17,000 Series Standards and with the objective of adapting to the latest changes in the laboratories sphere and to the new information technologies applied to work practices, the ISO/IEC 17025 Standard was once again reviewed. The revised standard is in line with ISO terminology, with a set of terms and definitions common to all the standards related to conformity assessment (**Figure 5**).

The ISO/IEC 17025 [10] goes to show that laboratories that implement this standard:

- Operate an effective quality management system based on ongoing improvement

The laboratory implements a quality management system to administer and use its documentation, both in management and in technical areas.

- Are technically competent

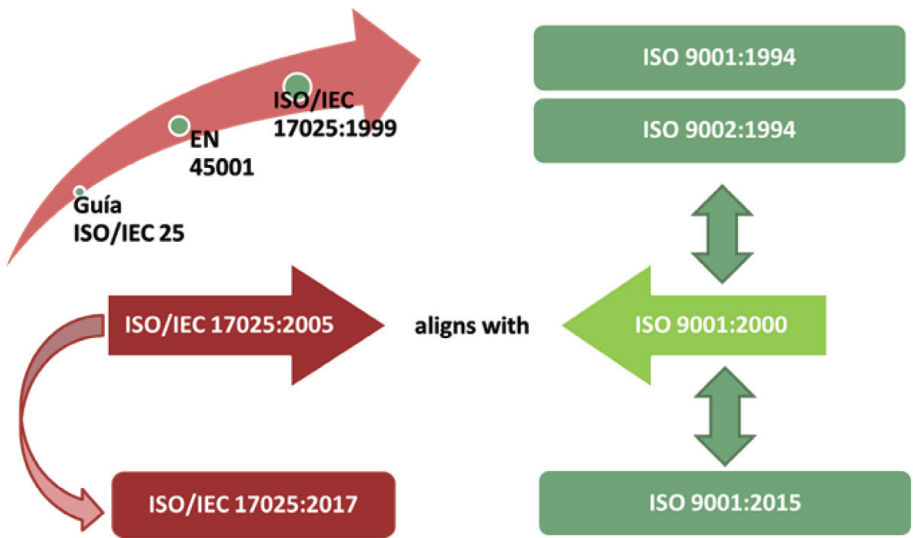


Figure 4.
Chronological evolution ISO/IEC 17025.

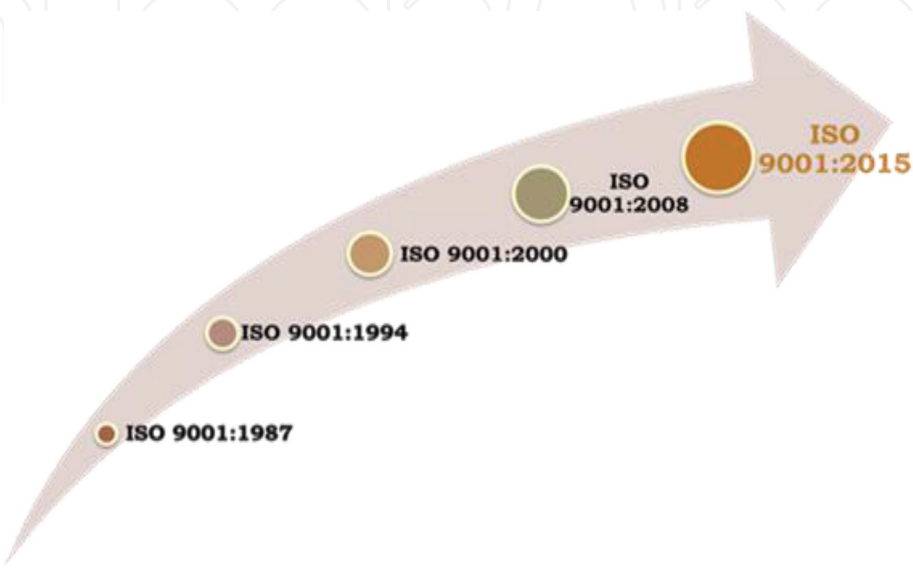


Figure 5.
Chronological evolution ISO 9001.

The laboratory demonstrates technical competence of staff, appropriate facilities and environmental conditions, validity of test methods, reliable test equipment, and reference standard materials with traceability to the international system of units.

- Are capable of producing testing or calibration reliable results

The laboratory implements quality assurance programs, which generate technically valid results.

The ISO 17025 Standard introduces two types of requirements:

- Management requirements

These requirements are related to the laboratory quality management. Requirements analogous to those set out in the ISO 9001 Standard.

- Technical requirements

These requirements are related to aspects with direct influence over the testing result.

We should bear in mind that conformity with the scope defined in the ISO/IEC 17025 Standard does not mean that the laboratory quality management system meets all the requirements of the ISO 9001 Standard. Likewise, conformity of the laboratory quality management system with standard ISO 9001 requirements alone is no guarantee of the laboratory competence to generate theoretically valid data and results (**Figure 6**).

The laboratory certification guarantees compliance with requirements of the ISO 9001 Standard; the laboratory accreditation guarantees the technical competence for testing activities (**Figures 7 and 8**).

According to data from the ENAC, in Spain in 2010, there were 1040 accredited testing laboratories, and their number has soared to over 1138 in 2013. In 2014,

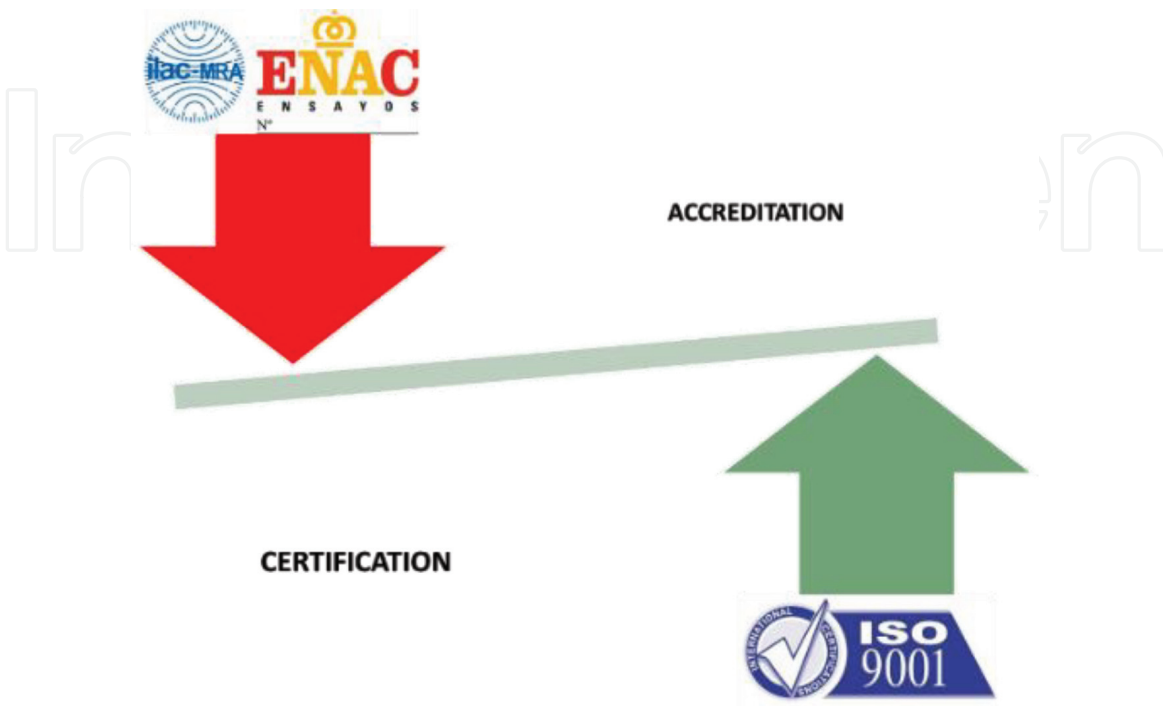


Figure 6.
ISO/IEC 17025 versus ISO 9001.

due to the financial crisis, the number of accredited laboratories decreased significantly to 1043: some temporarily suspended accreditation while others even go out of business. Since 2015, is noted a constant and moderate growth; at the end 2017, there were already 1081 laboratories accredited (**Figure 9**).

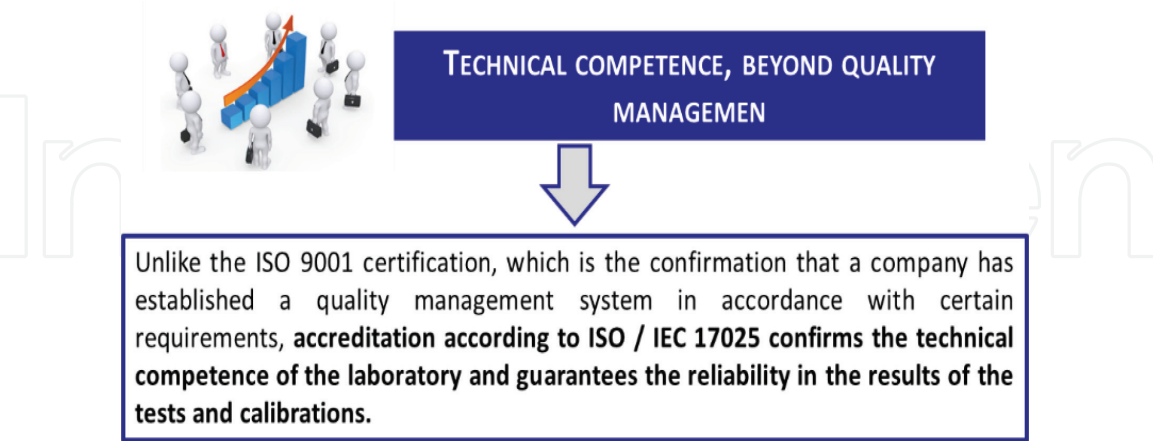


Figure 7.
Technical competence beyond quality management.

STANDARDS	ISO/IEC 17025	ISO 9001
Scope	Testing and Calibration Laboratory	Company
Maim facets	Management and technical competence	Management
Auditig entity	ENAC, UKAS, EMA...	Certification entities (AENOR, SGS...)
Status of the audited entity	Accredited Laboratory	Certified company
Guarantee	✓ It has a system quality management ✓ Produce theoretically valid data and results	✓ It has a system quality management

Figure 8.
Relationship between the standards ISO/IEC 17025 and ISO 9001.

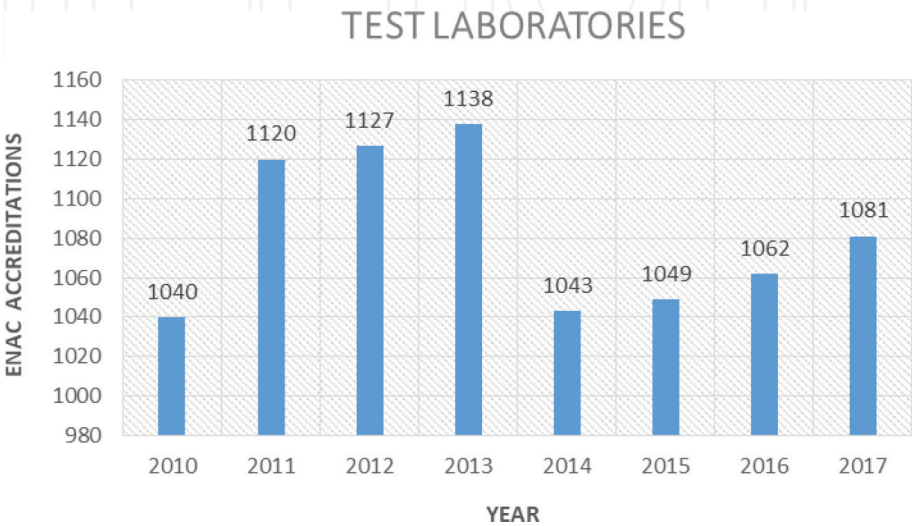


Figure 9.
ENAC accreditations of testing laboratories (2010–2017).

3. Case study: LABCOMB accreditation

The small size of a laboratory is not an impediment to the implementation of the ISO/IEC 17025 Standard; but the size and the laboratory characteristics have to take it into account to design the proper quality management system, trying to simplify.

3.1 Objective

A Fuel's laboratory (R + D + i) accreditation. The laboratory is a member of a research center at a Spanish university.

To establish the procedure to be followed, the path to the system established by the ENAC (National Accreditation Entity—Spain) to accredit a testing laboratory, LABCOMB, under internationally established criteria.

3.2 Preparation of documentation

The accreditation is a declaration of the technical competence of the laboratory to perform the activities included in the scope of the accreditation. This competence is established through the evaluation of laboratory compliance with the requirements established to that effect in international standards.

The accreditation system for testing laboratories establishes the accreditation requirements to be met by the laboratories, as well as the accreditation framework and procedure. The accreditation granted is valid and is fully accepted in Spain and internationally.

The accreditation does not imply in any case the acceptance or validation by the ENAC of the results of each test, nor does it exempt the laboratory from its responsibility in case of erroneous results.

3.2.1 Documentation prepared by LABCOMB according to the general criteria for accreditation

The ISO/IEC 17025 Standard establishes the general requirements related to the technical competence of the testing laboratories that ENAC uses as criteria for accreditation.

The laboratory identifies in its Quality Manual: MC/LABCOMB, the legal personality that assumes its legal responsibilities, defines its quality policy, and records all the documentation prepared in order to meet the criteria established in the ISO/IEC 17025 Standard:

- Management requirements
- Technical requirements

The documentary structure of LABCOMB's quality management system consists of:

- The Quality Manual:

MC/LABCOMB, Quality Manual ISO 17025

- General procedures:

P/LABCOMB/01	Staff skills
P/LABCOMB/02	Internal staff training program
P/LABCOMB/03	Document and record control
P/LABCOMB/04	Procurement management and subcontracting
P/LABCOMB/05	Supplier evaluation
P/LABCOMB/06	Complaint handling
P/LABCOMB/07	Development of testing procedures
P/LABCOMB/08	Validation procedures
P/LABCOMB/09	Uncertainty calculation
P/LABCOMB/10	Test process
P/LABCOMB/11	Equipment and reagent management
P/LABCOMB/12	Regulation and legislation review
P/LABCOMB/13	Internal audits
P/LABCOMB/14	Nonconformity treatment
P/LABCOMB/15	Corrective and preventive action management
P/LABCOMB/16	Revision of the system by the general direction



FORMATS OF GENERAL PROCEDURES



RECORDS

- Technical procedures: test procedures (PE) and calibration procedures (PC)

PE/LABCOMB/01	Determination of flash point, Pensky-Martens method
PE/LABCOMB/02	Determination of cold filter plugging point (CFPP)
PE/LABCOMB/03	Determination of cloud point
PE/LABCOMB/04	Determination of distillation characteristics at atmospheric pressure
PE/LABCOMB/05	Determination of sulfur content for UVF method
PE/LABCOMB/06	Calculation of cetane index by the four-variable equation
PE/LABCOMB/07	Determination of density by the hydrometer method
PE/LABCOMB/08	Determination of sulfur content for UVF method (<3 ppm)
PE/LABCOMB/09	Determination of water, Karl-Fischer method
PE/LABCOMB/10	Determination of water, Karl-Fischer method (>1%)
PE/LABCOMB/11	Determination of kinematic viscosity
PE/LABCOMB/12	Determination of flash and fire points, Cleveland method
PE/LABCOMB/13	Determination of combustion heat
PE/LABCOMB/14	Determination of water by distillation

PE/LABCOMB/15	Determination of sulfur content, XRF method
PE/LABCOMB/16	Determination of nickel and vanadium content, RXF method
PE/LABCOMB/17	Determination of ash
PE/LABCOMB/18	Determination of sulfated ash
PE/LABCOMB/19	Determination of free water and particulate contamination
PE/LABCOMB/20	Determination of water and sediments by the centrifuge method
PE/LABCOMB/21	Corrosiveness to copper. Copper strip test
PE/LABCOMB/22	Commercial butane and propane. Analysis by GC
PE/LABCOMB/23	Determination of ASTM color of petroleum products
PE/LABCOMB/24	Estimation of net and gross heat of combustion
PE/LABCOMB/25	Determination of total sulfur content. Method of elemental analysis
PE/LABCOMB/26	Determination of pour point
PE/LABCOMB/27	Natural Gas. Analysis by GC



FORMATS OF TECHNICAL PROCEDURES



RECORDS

PC/LABCOMB/01	Calibration of thermal equipment
PC/LABCOMB/02	Calibration of volumetric material
PC/LABCOMB/03	Calibration of thermometers
PC/LABCOMB/04	Calibration of stopwatches
PC/LABCOMB/05	Calibration of hydrometers
PC/LABCOMB/06	Calibration of viscometers
PC/LABCOMB/07	Calibration of thermostatic baths



FORMATS OF TECHNICAL PROCEDURES



RECORDS

3.2.2 Scope

The laboratory is not accredited to perform all the tests included in its offer. Accredited tests are included in the Scope.

The accreditation scope describes the technical competence declared by LABCOMB (**Figure 10**) in order to be assessed by the ENAC. It finally constitutes the Technical Annex to the “Accreditation Certification,” and it should, therefore,



Acreditación nº 814/LE1688
Anexo Técnico Rev. 6
Fecha: 28/07/2017
Hoja 1 de 3

ANEXO TÉCNICO
ACREDITACIÓN Nº 814/LE1688

Entidad: LABORATORIO DE COMBUSTIBLES. CENTRO DE INVESTIGACIONES TECNOLÓGICAS DE LA UNIVERSIDADE DA CORUÑA

Dirección: Centro de Investigaciones Tecnológicas. Campus de Esteiro; 15403 Ferrol (A Coruña)

Norma de referencia: UNE-EN ISO/IEC 17025:2005

Ensayos en la siguiente área:

Combustibles y productos petrolíferos 1

Combustibles y productos petrolíferos

Categoría 0 (Ensayos en el laboratorio permanente)

PRODUCTO/MATERIAL A ENSAYAR	ENSAYO	NORMA/PROCEDIMIENTO DE ENSAYO
Productos Petrolíferos	Densidad mediante aerómetro (0,70 - 1,00 g/ml)	UNE-EN ISO 3675:1999 UNE-EN ISO 3675:1999 ERRATUM:2011
	Viscosidad cinemática a 40 y 50 ºC (7 - 500 mm ² /s)	UNE-EN ISO 3104:1996 UNE-EN ISO 3104:1996 ERRATUM UNE-EN ISO 3104/AC:1999
	Agua por destilación (0,05 - 25 %v/v)	UNE 51027:1978 ASTM D95-13e1
	Corrosión a la tira de cobre a 50 ºC	UNE-EN ISO 2160:1999
	Color ASTM	ASTM D1500-12
	Agua y sedimentos por centrifugación	UNE 51028:1965
Gasóleos y gasolinas	Destilación a presión atmosférica (20 ºC a 370 ºC)	UNE-EN ISO 3405: 2011
	Azufre total por fluorescencia ultravioleta (3 a 50 mg/Kg)	UNE-EN ISO 20846:2005



Figure 10.
LABCOMB present scope (sheet 1).

LABCOMB is responsible for establishing the accreditation scope, although ENAC establishes the type of information that should be included to ensure its proper definition.

LABCOMB accredited tests include:

PE/LABCOMB/01	Determination of flash point, Pensky-Martens method
PE/LABCOMB/02	Determination of cold filter plugging point (CFPP)
PE/LABCOMB/03	Determination of cloud point
PE/LABCOMB/04	Determination of distillation characteristics at atmospheric pressure
PE/LABCOMB/05	Determination of sulfur content for UVF method
PE/LABCOMB/06	Calculation of cetane index by the four-variable equation

PE/LABCOMB/07	Determination of density by the hydrometer method
PE/LABCOMB/11	Determination of kinematic viscosity
PE/LABCOMB/14	Determination of water by distillation
PE/LABCOMB/19	Determination of free water and particulate contamination
PE/LABCOMB/20	Determination of water and sediments by the centrifuge method
PE/LABCOMB/21	Corrosiveness to copper. Copper strip test
PE/LABCOMB/23	Determination of ASTM color of petroleum products

3.3 Accreditation request

3.3.1 File opening

The accreditation process begins with the opening of the file in March 2010. ENAC understands that when applying for accreditation, LABCOMB complies with all the legally established requirements to carry out the activity for which accreditation is requested.

If at any time during the accreditation process it becomes clear that this is not the case, ENAC proceeds to stop the process until the laboratory provides evidence that the detected problem has been adequately resolved.

ENAC can request evidence of compliance with these legal requirements before initiating the accreditation process.

The information received by ENAC, both in the application and throughout the entire accreditation process, will be considered as CONFIDENTIAL for all purposes with the following limitations:

- Those established, as the case may be, by law.
- In activities that take place in the regulated field or in those in which the laboratory operates with an administrative authorization, ENAC may, at the request of the competent administration, inform the latter of the results of the evaluations.
- If the laboratory is accredited by other accreditors, ENAC can exchange information with them, in accordance with what is established by the cross-border accreditation procedures established by international accrediting organizations.

3.3.2 Acceptance of the request

ENAC acknowledges receipt of the application and reviews the documentation provided in order to verify that the activity is susceptible to be accredited. Inform LABCOMB of the ENAC technician responsible for the follow-up of your file. If there is any legal, statutory, or other reason that prevents accreditation, it is communicated to the laboratory.

ENAC evaluates whether the activity corresponds to the accreditation scheme under which it is requested, if the scope is clearly defined and the documentation is complete and adequate. ENAC can request, at this time or in subsequent phases of the process, additional information to ensure the correct execution of the accreditation process.

Within any of the phases of the accreditation process, if more than 1 year passes without a response from the laboratory to a request for information, ENAC will consider the annulment of the file.

ENAC may consider the convenience of making a preliminary visit to the laboratory, in order to prepare the following stages of the accreditation process so that it can be carried out as efficiently as possible.

3.3.3 Appointment of the audit team

ENAC appoints, from its auditors and qualified experts, the members of the audit team that will carry out the evaluation process.

The number of members of the audit team is a function of the scope of accreditation requested but in any case, with a chief auditor, and as many technicians as necessary in the tests for which the laboratory requests accreditation.

The laboratory is informed in advance of the names of the members of the audit team and, if appropriate, of the organization to which they belong. The laboratory could recuse them in writing, providing that the reasons that they understand could compromise their independence and impartiality. In this case ENAC will analyze the reasons given and will communicate its decision to the applicant.

3.4 The audit process

3.4.1 Study of the technical documentation

The accreditation process begins with the study of the documentation by the auditors appointed to evaluate the adequacy of the procedures within the scope of accreditation requested. If the result of that documentary study is satisfactory, the audit will proceed.

3.4.2 Audit

On the date agreed with the laboratory, the designated audit team conducts an audit visit, the purpose of which is to verify compliance with the accreditation criteria. Prior to the visit, the chief auditor sends the audit plan to the laboratory.

The audit takes place in three phases:

1. Initial meeting: it takes place between the representatives of LABCOMB and the audit team. During this initial meeting, the appropriate presentations are made, the audit plan and the scope of the audit are confirmed, and the system to be followed is indicated.

2. Development of the audit: the audit team proceeds to observe the operation of the laboratory and to assess compliance with the accreditation requirements.

The realization of some tests, of those included in the scope to be evaluated, to verify the correct performance of them is requested.

3. Final meeting: its main purpose is to present to the laboratory managers a summary of the results of the investigation.

3.4.3 Audit team report

The audit team, within a period of no more than 15 business days from the date of the audit, prepares a report with the results and information gathered during the audit, which is sent to the laboratory for its information.

The report of this audit has a validity period of 6 months from its date of issue. After this period it may be necessary to carry out a new audit to decide on the accreditation of the laboratory.

3.4.4 Laboratory response

Once the audit report is received, LABCOMB acts as indicated in Operational Note NO-11 “Deviations, classification, and treatment,” responding to the possible “nonconformities” and “observations” raised in the report. The laboratory can claim those extremes of the report with which it is dissatisfied.

The decision of accreditation must be made within the validity period of the audit report; to ensure that the decision can be made within that period, the laboratory sends the response before the prescribed period is met.

3.5 Accreditation decision

To grant accreditation, the Accreditation Commission must rely on the technical competence of LABCOMB to carry out the activities for which it requests accreditation and must trust that the accreditation requirements are met and the deviations detected in its case have been adequately addressed.

The Accreditation Commission analyzes the information generated during the evaluation process and based on this adopts the decision of “grant accreditation” in July 2010.

3.5.1 Certificate of accreditation

After a favorable decision and once LABCOMB pays the corresponding costs, ENAC issues a Certificate of Accreditation, which attests to the granting of accreditation in favor of the laboratory.

3.6 Use of the ENAC trademark

Once accredited, the laboratory has the right to make use of the ENAC trademark or reference to its accredited status under the conditions established in document CEA-ENAC-01 “Criteria for the use of the ENAC trademark or reference to the status of accredited.”

3.7 Validity of the accreditation

Laboratory accreditation is considered valid as long as LABCOMB continues to meet the criteria established by ENAC and the obligations resulting from its accreditation.

The laboratory may, at any time, request a voluntary temporary suspension of all or part of the scope of accreditation. The voluntary temporary suspension implies the temporary prohibition of the use of the ENAC trademark or reference to the status of accredited as established in document CEA-ENAC-01.

3.8 Maintenance of accreditation

The maintenance of the accreditation is structured in a first cycle of 4 years and subsequent cycles not exceeding 5 years in which LABCOMB was submitted by ENAC to the following activities:

- Follow-up audits between reevaluation periods
- Reassessment audits: 2014 and 2018

In order to maintain accreditation, the Accreditation Commission must trust that the laboratory maintains its technical competence for the activities included in its accreditation scope, the accreditation requirements continue to be met and the detected deviations, if any, have been adequately addressed.

In 2010, LABCOMB included five tests in the requested scope. Currently, the number of accredited tests is 13: between 2010 and 2018. LABCOMB has not only maintained accreditation but has also increased the number of tests within its scope.

4. Conclusions

Obtaining the ISO/IEC 17025 accreditation by LABCOMB has allowed the laboratory to recognize its technical competence both nationally and internationally, which allows it to:

- Work regularly for various strata of Spanish public administration
- Greater visibility and better positioning among laboratories that offer the same services, which has increased the number of customers and has achieved their loyalty
- Work for the European Commission, Directorate General, Joint Research Centre, Directorate-D, Institute for Reference Materials and Measurements from the certification of the cold filter plugging point (CFPP) and the cloud point (CP) in gasoil and biodiesel

The implementation of the ISO 9001 and ISO/IEC 17025 Standards has improved the overall management of the laboratory in all its activities and has made it possible to demonstrate its technical competence; but also, since it is a university laboratory, the staff that works and is trained in it gets a curricular bonus that makes it valuable for different companies that look for personnel trained in high-quality standards.

In the near future, LABCOMB plans to extend its commitment to quality and consider Integrated Quality Management. There are many similarities between the concepts of quality management, environmental management, and management of occupational risk prevention, since the principles of good management are the same, as well as their implementations and regulatory points.

Integrated Quality Management is an increasingly recurrent option that is chosen by those organizations that maintain a strong commitment to excellence in their products, services, and processes.

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