

For the benefit of the company. For the

# benefit of the consumer.

A clear, distinguishing and transparent benefit.

Accreditation comes down to trust, reliability and new ways of doing business. It means ensuring the reliability and international recognition of calibration, testing, inspection and certification to give a company its competitive edge. It means being absolutely rigorous in performing these activities to bring peace of mind to the consumer.

Because, in short, accreditation comes down to benefits: benefits for the company and benefits for the consumer.

### Accreditation

In a business framework characterised by competitiveness and increasingly tough safety and quality standards, accreditation, rather than an option, is fast becoming an essential element to ensure the reliable assessment and certification of products and services.

In the regulated sector, public authorities apply laws requiring products and services to be assessed for reasons of safety, health, environmental protection, anti-fraud and fair competition. In the voluntary sector, a great many industries have put in place voluntary assessment systems, at local or global level, for products or services and for suppliers. The purpose of this is to achieve a minimum technical level which allows for comparability as well as ensuring fair play in terms of competition.

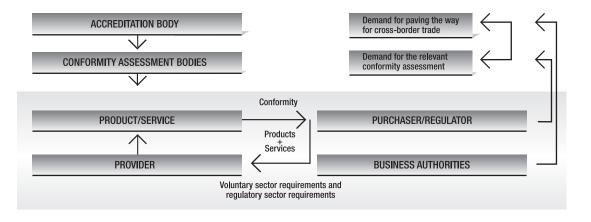
Conformity assessment bodies are organisations which oversee the objective determination of conformity. Activities such as the safety inspection of industrial facilities, analysis of foodstuffs, ISO 9001 certification, road vehicle inspection, industrial product testing, certifying a diverse range of products, environmental verification, just to name a few, are performed by conformity assessment bodies.

To be able to fully trust in the information received from a conformity assessment body, the purchaser, the authority concerned and the general public need to know that they are fit for the task they perform. This is why there is a growing demand for the impartial assessment of their **competence**. This assessment is carried out by **accreditation bodies**.

Accreditation bodies, therefore, are responsible for using independent and impartial assessment to check the conformity assessment bodies competence to give the purchaser and the authority peace of mind which, in turn, paves the way for national and international trade.

In order to do this, the accreditation bodies of different countries work to uniform international criteria, using the same transparent assessment methods, creating the trust required to enable mutual agreement on results.

So accreditation ensures that the conformity assessment bodies in different countries carry out their work in a similar way.





# Benefits of accreditation

Accreditation is the official recognition of a conformity assessor's technical competence. It is, therefore, an irrefutable way of identifying those assessors who provide unquestionable reliability in their services.

#### For government...

It is becoming increasingly common for local government - responsible for protecting people's health and safety and the environment - to put in place or oversee conformity assessment schemes in the undertaking of its regulatory competences or to support its policies on quality.

**ENAC** accreditation provides a unique, transparent and reproducible process:

- Avoiding the use of own resources.
- Cutting out the cost of reinventing.
- Reinforcing consistency.

It also provides a valuable resource: a team of conformity assessment bodies with proven technical competence according to internationally agreed criteria.

Further, it supports decision-making on health and safety issues, based on technically credible and homogenous information, which reduces risk and strengthens public trust in basic services (public health laboratories, food safety, etc).

Similarly, it helps reduce the need for multiple assessments, thereby leading to greater efficiency.

#### **For Conformity Assessment Bodies**

**ENAC** accreditation officially recognises the technical competence of conformity assessment bodies.

It allows them to work in sectors and activities in which accreditation is a compulsory requirement (mandatory inspections of facilities, official control of foodstuffs, environmental verification, etc.) as well as those in which accreditation is a voluntary yet increasingly required requirement by clients (testing, calibration, quality system certification, environmental management system certification, etc.).

Accreditation lessens the likelihood of having to go through multiple assessments by the various clients requesting their services and by the relevant authorities in their field of work.

This constitutes a differentiating trait in the marketplace, a guarantee of integrity and competence and a byword for an internationally recognised service, thereby boosting business opportunities.

Likewise, it is a means of raising awareness on the need for ongoing improvement.

#### For the company...

Choosing an accredited conformity assessment body means the company is dealing with a technically competent body employing qualified personnel, using proper equipment and performing its work with suitable working methods and, ultimately, managing its activity according to quality criteria.



#### Cutting time and costs

Tests (inspection or certification) which products have to pass come at a cost and take time to perform, even when they are carried out properly the first time round. Accreditation means companies can avoid the repetition of results, which wastes time and money. Accredited assessment services bring added value to products and services in terms of

reliability and international recognition, which has direct consequences for customer trust and reinforces the company image.

Accreditation also provides a unique, homogenous and reproducible Conformity Assessment Bodies selection process, meaning the company is less likely to need to use its own resources.

#### **Risk minimisation**

Using accredited Conformity Assessment Bodies helps reduce the levels of risk in manufacturing or delivering a faulty product, enabling decision-making with technically reliable information. Further, it reduces the risk that a product is refused by purchasers that do not accept non-accredited assessments.

In the event of litigation, it is evidently a way to prove that the company has taken all possible precautions when selecting and arranging a competent assessment service.

#### **Building client trust**

Trust in products increases if clients know they have been assessed by an accredited Conformity Assessment Bodies.

#### Greater acceptance of products in other markets

A system of international agreements enables results from accredited conformity assessors to be more easily agreed upon by foreign markets.

This acceptance helps to cut costs for manufacturers and exporters, reducing or eliminating the need to repeat tests in the importing country.

#### For the end consumer...

Accreditation inspires confidences as it guarantees that products have been assessed by a competent independent body.

It increases freedom of choice and encourages a free, yet reliable, marketplace.



# ENAC - Entidad Nacional de Acreditación

**ENAC** was designated by the Spanish Government (Royal Decree 1715/2010) as the **National Accreditation Body** to set up and run the national Accreditation System to international standards, at all times in line with European Union policies (Regulation (EC) N<sub>0</sub> 765/2008).

**ENAC** is an independent non-profit making organisation serving the public, which is overseen and backed by the Government. The organisation engages in its mission with a clear vocation towards public service, geared to Government and to the marketplace in general, bringing value to stakeholders in the distinct aspects of accreditation.

Its mission is to **assess the technical competence of conformity** assessment bodies, leading to greater trust in terms of its activities by Government, the marketplace and the wider community.

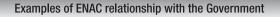
In this way, its services are recognised and accepted at national and international level, thereby leading to greater protection for people and the environment and an increase in the competitiveness of Spanish products and services.

ENAC accredits bodies engaged in conformity assessment tasks, whatever their activity.

- Laboratories
- Inspection Bodies
- Certifying Bodies
- Environmental Verifiers
- Proficiency Testing Providers
- Greenhouse gas emision trading verifiers
- Notified Bodies

Central and local government use ENAC accreditation in their respective fields of competence: sectors such as **industry**, **agrifood**, **the environment**, **defence**, **building**, **health**, **telecommunications**, **metrology**, **amongst others**.





#### Industry:

- Industrial safety regulations (lifts, electrical installations, pressure vessels, etc.)
- · Road vehicle inspection
- Technical centres for tachograph inspection
  Product safety directives (pressure vessels, lifts, etc.)
- Building product directive
- ·R+D+i
- Directive on measuring instruments and metrological control
- · GLP in chemical substances preparation & articles
- Directives on leisure craft and marine equipment
- Regular inspections on leisure craft
  Wind power

#### Health:

- · Official control of foodstuffs
- · Drinking water quality
- · Assessment of care centres
- · Public health laboratories
- Control of facilities at risk from legionnaire's disease
- · Biocide Register

#### **Telecommunications:**

- · Electromagnetic compatibility
- · Telecommunications equipment
- · Electronic signature

#### Agriculture:

- $\cdot$  Good laboratory practice (GLP) in pesticides.
- · Official control of foodstuffs.
- $\cdot$  Non-compulsory labelling of beef
- $\cdot$  Non-compulsory labelling of poultry
- $\cdot$  Quality of Iberian pork products
- Organic farm produce
- $\cdot$  Designations of Origin
- · Traditional Speciality Guaranteed

#### Environment:

- · Environmental Verifiers (EMAS)
- $\cdot$  Greenhouse gas emission verifiers
- Bodies working with the Government
  on water quality control
- $\cdot$  Environmental control bodies
- GLP in chemical substances preparation & articles



# Accreditation criteria

Accreditation requirements are based on international standards set down by standardisation bodies (ISO, ECS, etc.) and on other documents drawn up by the Government and international bodies.

CONFORMITY ASSESSORS	STANDARD
Testing Laboratories	UNE-EN ISO/IEC 17025
Calibration Laboratories	UNE-EN ISO/IEC 17025
Medical Laboratories	UNE-EN ISO 15189
Inspection Bodies	UNE-EN ISO/IEC 17020
Product Certification Bodies	UNE-EN ISO/IEC 17065
Management systems certifiers	UNE-EN ISO/IEC 17021-1
Personnel Certification Bodies	UNE-EN ISO/IEC 17024
Environmental Verifiers	Regulation CE 1221/2009
Proficiency Testing Providers	UNE-EN ISO/IEC 17043
Bodies conducting pesticide and chemical products studies	Royal Decree 1369/2000 on Good Laboratory Practice
Greenhouse Gas Emission Verifiers	EN ISO 14065
Reference Material Producers	UNE-ISO Guide 34 IN

This list is not exhaustive. New standards may be added to ENAC's framework.

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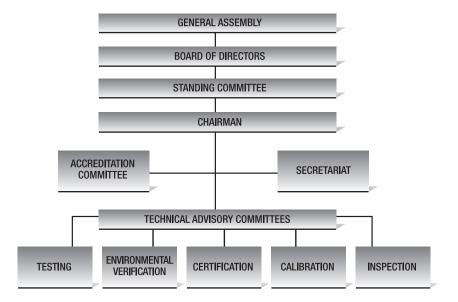
The framework and operating principles of the National Accreditation Body ensure that any undertakings are based on the principles of impartiality, independence and transparency.

#### Governing bodies and representation:

**General Assembly:** executive governing body of the association, whose members are stakeholders in the different aspects of accreditation: conformity assessors, central and local government representatives, companies and business associations which use conformity assessment services.

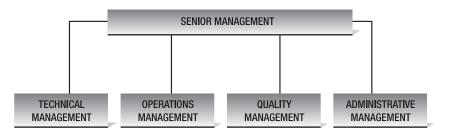
**Board of Directors:** this is chosen by the General Assembly from amongst its members to represent all accreditation process stakeholders equally. It represents and takes on the functions of the General Assembly between GA meetings.

**Standing Committee:** a permanent management body representing the Board of Directors, whose members are appointed by the Board of Directors. Its tasks include the drawing up of budgets, schedules, reports and accounts. It also oversees the performance of technical bodies.



**Technical bodies:** in order to fully undertake its activities and reach objectives efficiently, **ENAC** works around a functional structure made up of the following bodies:

- Secretariat: Comprising a team of highly-qualified professionals, the Secretariat is responsible for processing, managing and performing assessment activities for applicant bodies: drawing up technical documents; training and awarding qualifications to auditors and experts; representing ENAC in international technical forums; and overseeing the circulation of the body's activities.
- Accreditation Committee: a technical body for the study, processing and award of accreditation, ensuring, at all times, independent and objective conduct and impartial decision-making on accreditation.





The functional structure is supported by a large group of leading experts (over 700) from institutions, research centres, universities, companies and government bodies, that are a reference in the activity to be assessed, thereby providing the expertise required in each field. Hence added value is brought to the assessment process and a strong sense of trust is built in the marketplace as assessors with the highest proven technical skill are used.

#### Stakeholder participation

For an accreditation system to work properly, mechanisms enabling stakeholders to take part in the body's policy-making and technical development must be at their disposal.

At ENAC, stakeholder participation in policy-making is guaranteed thanks to the election system in place for Steering Board members as set down in the articles of association.

Participation in technical development and the body's access to the technical knowhow and expertise in each activity performed by ENAC is ensured through various means of participation such as Technical Advisory Committees, formed by reputable professionals in the distinct sectors of activity; Autonomous Community Forums, set up for any activities whereby there is direct supervisions by autonomous communities (self-governing regions); Agreements with Associations of Conformity Assessment Bodies, which further cooperation in technical development and the inclusion of their interests in ENAC activity; Agreements with professional organisations: scientific and technical institutions which support ENAC in the technical development of its activity; Participation in External Committees set up in certain sectors by one or more stakeholders, helping towards the information flow between ENAC and the different interests.



### Accreditation process

ENAC accreditation means that a Conformity Assessment Bodies has proved that it:

- Uses qualified and experienced personnel.
- Has suitable equipment which is calibrated and properly maintained and the infrastructure required to carry out the activity.
- Uses suitable valid assessment methods and procedures.
- Uses quality control techniques on results.
- Guarantees the traceability of measurements and calibrations to international standards.
- Fully briefs clients on the outcome of the activities by submitting clear and accurate reports or certificates.
- Has a quality management system in place to manage activity.

**ENAC**, therefore, employs a stringent assessment procedure which begins with an application for accreditation.

Applications are checked by ENAC professionals to confirm whether the activity is actually conformity assessment and whether it fits into one of the reference accreditation standards. The professional checks whether added value will be contributed to the marketplace by accrediting the activity.

After the application stage, the assessment process begins with the designation of an audit team of experts in the assessment activities in which the applicant is engaged.

The audit team checks that the applicant body meets accreditation criteria. The assessment process involves a technical documentation study, assessing and observing the activity being undertaken by those applying for accreditation.

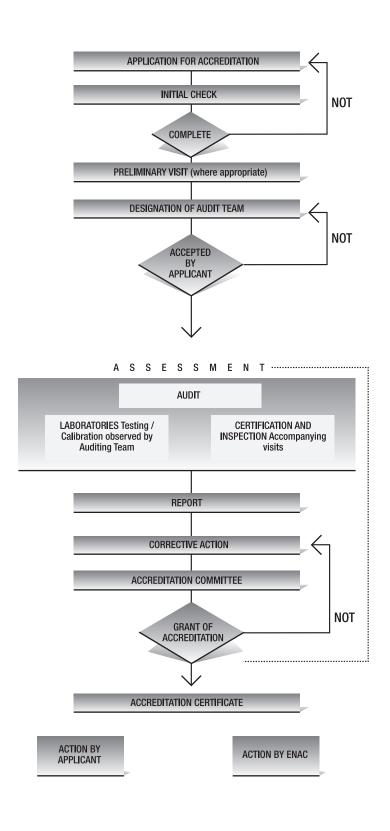
The outcome of this assessment is put into a report which is then sent to the applicant and describes any possible deviations observed in terms of accreditation requirements. The applicant must respond with the corrective actions thought appropriate.

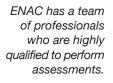
With the assessment report and in the light of any corrective actions, the Accreditation Committee comes to a decision which is then notified to the applicant. If it is positive, the Committee issues the corresponding accreditation certificate. If negative, the decision is withheld until resolution of any deviations has been verified.

Follow-up visits are regularly made to check that the body continues to meet the accreditation requirements and, every four or five years, depending on the scheme, the body's competence is reassessed by way of an audit similar to the original one.

Full information on accreditation processes and criteria is available on the website (www.enac.es)

Accreditation is not the result of a one-off procedure. To ensure its ongoing compliance, ENAC regularly reassesses accredited assessors, checking that technical competence is maintained.







### How to spot an accredited body

Documents without the ENAC mark or reference to accreditation may not be considered accredited documents. The **ENAC** mark, or reference to the accreditation status, in reports or certificates issued as a result of activities covered by accreditation, is the way accredited organisations publicly state that they meet accreditation requirements when engaged in these activities.

The **ENAC** mark will allow companies, users and consumers in general to easily spot documents issued as a result of accredited activities (test reports, certificates, etc.). Its presence on reports and certificates is the guarantee of the advantages of accreditation, including its international acceptance.

Documents without the **ENAC** mark or reference to accreditation may not be considered "accredited documents". These documents, therefore, do not possess the benefits which accreditation brings.

**ENAC** has drawn up and issued a document on the rules for using the **ENAC** mark or reference to accredited status.

**ENAC** marks enable accredited testing, calibration and certification to be clearly identified. The mark is endorsed by the Multilateral Recognition Agreements (MLAs) signed by over forty-five countries.

These agreements provide technical support to international trade by enabling certificates and reports issued by accredited organisations, and the products and services they refer to, to be easily accepted in international markets, contributing, in turn, to the breaking down of technical barriers and the reduction in assessment costs.



Using the mark means that clients and users receiving a certificate or report immediately see that the laboratory or certifying body which has issued it is accredited and internationally recognised.

To raise the international profile of accreditation, the ILAC and IAF - the accreditationbody associations - have designed their own marks to be used together with national marks. ENAC-accredited bodies may use this combination of marks, the meaning of which is identical to the ENAC mark.









## International Scope

**ENAC** is the Spanish Accreditation Body member of European Cooperation for Accreditation -EA, the body designed by the European Commission as responsible for the operation of the European Accreditation Infrastructure.

**ENAC** is a founding member of the international accreditation organisations:

The European Cooperation for Accreditation (EA) includes laboratory accreditation bodies and certification and inspection bodies, recognised nationally, at European Union level and by EFTA.

The International Laboratory Accreditation Cooperation (ILAC) includes laboratory accreditation bodies of sixty-four countries worldwide.

The International Accreditation Forum (IAF) includes the certifying body accreditation organisations of thirty-nine countries.

These organisations serve as a forum for debating and exchanging experiences between the various accreditation bodies. They are engaged in drawing up specific technical documents to ensure the bodies' performance is suitably uniform. **ENAC** plays a prominent role in these organisations.

In international circles, ENAC accreditation is fully recognised as **ENAC is a signatory** of all MLAs reached by the EA, ILAC and IAF.

Signing these agreements means that Spanish products and services entering foreign markets - with certificates issued by **ENAC**-accredited laboratories or bodies - are freely accepted, thereby significantly breaking down technical barriers (namely, additional controls or testing in the importing country) which may arise in such markets.

At present over 60 countries have signed these agreements, including virtually the whole of the EU and EFTA as well as the USA, Canada, Japan, China, Australia, etc. New countries are included into the multilateral agreements every year. This information is continuously revised on the **ENAC** website (www.enac.es).

These agreements are accessed once the organisations above have assessed, by way of international audits, whether the accreditation bodies wishing to be included in the agreement also meet the relevant requirements set down in international regulations.

These agreements are drawn up and managed by the aforementioned organisations and they are often recognised in the regulatory field by member states to accept accreditation awarded in other member states and by the European Commission as a basis for, for example, signing MLAs with third countries.



At present a great many industrial sectors are setting different requirements within the supply chain. Its compliance needs to be undertaken by accredited conformity assessment bodies **by signatories of the recognition agreements.** The same goes for international organisations which must make use of conformity assessors. Examples of this situation:

**Agrifood sector:** The widespread distribution through a number of organisations (BRC, IFS, EUREP, GFSI, etc.) sets requirements for suppliers, which should also hold accredited certification.

**WADA:** The World Anti-Doping Agency requires laboratories to carry out this kind of control in order to receive accreditation.

**Aerospace sector:** This requires, at a global level, that companies engaged in this sector put in place a quality system certified by a certifier that has been accredited by a multilateral agreement signatory (including ENAC).

**OPCW:** As a prerequisite to designating a laboratory, the Organisation for the Prohibition of Chemical Weapons requires accreditation by a signatory of the multilateral agreements in accordance with the Convention for the Prohibition of Chemical Weapons.

**ENAC's** international scope is a great opportunity for Spanish companies as they have official support in international markets to freely distribute their products and services.

The aim of international accreditation organisations is: Assessed once. Accepted anywhere.



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