

# CONFORMITY ASSESSMENT MECHANISMS IN ROMANIA: ARCHITECTURE OF THE NATIONAL ACCREDITATION AND CERTIFICATION SYSTEM

PhD. Assoc. prof. Daniela GHELASE  
PhD. Assoc. prof. Luiza DASCHIEVICI  
"Dunarea de Jos" University of Galati,  
Romania

## ABSTRACT

*This paper analyzes the architecture of the Romanian certification and accreditation system in the context of the European single market, highlighting the critical role of quality infrastructure for industrial competitiveness. The study explores the historical evolution of accreditation, from the first post-war technical standards to integrated digital systems, starting with 2025-2026. The Romanian accreditation system, although relatively young, has achieved remarkable digital and procedural integration, providing national companies with the "technical passport" necessary to operate on the most demanding European markets.*

**KEYWORDS:** Accreditation (RENAR), Certification (ISO 9001), CE Marking (Machinery Directive), Conformity Assessment, Safety Gate, Machining, Standardization (ASRO), Mutual Recognition (EA-MLA).

## 1. INTRODUCTION

In the economic architecture of the 21<sup>st</sup> century, quality is no longer just a competitive advantage, but a precondition for survival on the global market. In this context, the Certification and Accreditation System constitutes the "backbone" of trust between producers, authorities, and consumers. For Romania, integration into the European Union imposed rigorous alignment with a single conformity assessment model, aimed at eliminating technical barriers and guaranteeing product safety.

In the context of the European single market, guaranteeing the quality of products and services is essential for competitiveness.

ISO 9001 (Quality Management System) certification is the most popular international standard, adopted by over 1.1 million organizations globally to demonstrate their commitment to excellence and customer satisfaction.

Romania ranks 19<sup>th</sup> worldwide in terms of the number of active ISO 9001 certificates (over 12,000 certificates in 2024).

In Romania, the product conformity certification process is regulated by Law no. 608/2001 and is coordinated at national level by ASRO (Romanian Standardization Association).

For official recognition, Romanian certification bodies must be accredited by RENAR (Romanian Accreditation Association), the only national accreditation body.

In Europe, the standard is implemented uniformly, facilitating cross-border trade and participation in European public tenders. European countries are increasingly integrating ISO 9001 with other standards, such as ISO 27001 (information security), especially under the impact of new directives such as NIS2.

## 2. CERTIFICATION TIMELINE IN ROMANIA AND EUROPE

The history of certification in Romania

reflects the transition from a centralized system, based on state control, to a modern system, harmonized with European and international standards.

- 1948: The Standardization Commission is established, which later becomes the State Office for Standards (SOS).

- STAS (State Standard): Certification was mandatory for almost any product. The state was both the one who set the rules and the one who verified compliance through its own bodies.

- Quality Mark: Export products had to undergo rigorous controls (General State Inspectorate for Product Quality Control).

- 1992: A major change occurs through Government Ordinance no. 19/1992 regarding standardization activity. The distinction between mandatory and optional standards appears.

- Reorganization: IRS (Romanian Institute for Standardization) is established, the predecessor of ASRO.

- 1998: RENAR appears, marking the beginning of the separation of accreditation activity from certification and standardization, according to the European model.

- 2001: Adoption of Law No. 608/2001, the fundamental act that introduced the European concepts of "conformity assessment" and the CE Marking.

- 2006: Romania signs mutual recognition agreements with the European co-operation for Accreditation (EA), allowing Romanian laboratories to issue reports valid throughout Europe.

- 2009: Consolidation through Government Ordinance No. 23/2009, which designates RENAR as the sole national accreditation body.

- Digitalization: Introduction of IT systems such as Safety Gate and transition to international ISO standards fully adopted as Romanian standards (SR EN ISO).

The history of certification in Europe is the story of the transition from rigid national barriers to a fluid Single Market. The evolution was marked by the shift from state control to a system based on producer responsibility and mutual trust.

1. Each European country had its own standards (e.g.: DIN in Germany, AFNOR in France, BSI in the UK). A product certified in France could not be sold in Germany without being retested. This acted as a technical barrier to trade.

2. With the formation of the European Economic Community (EEC) between 1957 and 1980, detailed technical harmonization was attempted. The EU Court of Justice established the principle that a legal product manufactured

in one member state must be accepted in all others (the origin of Mutual Recognition).

3. The "New Approach" – The Great Revolution (1985) laid the foundation for the current certification system:

EU legislation (Directives) only sets out the Essential Safety Requirements (e.g.: "the machine must not cause electric shock"), leaving the technical details to the standardization bodies (CEN/CENELEC);

The CE symbol marking is born, certifying that the product complies with European directives, allowing free movement without additional border controls.

4. Between 1989 and 2008, the "Global Approach" and Accreditation were defined. To ensure trust in the CE marking, the EU defined standardized procedures called Conformity Assessment Modules (Modules A-H).

In 1991, the European co-operation for Accreditation (EA) is established, the organization that harmonizes the way testing laboratories are verified across Europe.

The New Legislative Framework (2008) is the system under which we operate today, defined by Regulation 765/2008.

- Golden Rule: Each member state must have a single national accreditation body (e.g.: RENAR in Romania, DAkkS in Germany).

- Strengthening the CE Marking: Strict rules are established for market surveillance and sanctioning abuses.

Table 1 shows the correlation between the European and Romanian history, as far as certification is concerned. It can be seen that the accession in 2007 forced the "burning of stages" in our national certification system. Romania went through transformations in just 15 years that in the West took half a century.

Table 1

Decade	Evolution Europe (CEE/EU)	Evolution Romania
1980-1990	Launch of the "New Approach" (1985).	Rigid STAS system, isolated from the west.
1990-2000	Strengthening Accreditation (EA).	<b>Jump:</b> Establishment of RENAR and ASRO.
2001-2007	Expansion to the East.	<b>Legislative Marathon:</b> Adoption of Law 608/2001.
2007-2010	Regulation 765/2008.	OG 23/2009 - RENAR becomes unique.

2024-2026	Green Deal and Digital Passport.	<b>Alignment:</b> ANPC implements GPSR (2024).
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The Romanian certification system is a success of forced synchronization. Although it started from a totalitarian control model, today RENAR and ASRO are equal pillars with their partners in Germany or France, offering Romanian companies the same rights on the global market.

The rapid transition to European standards represented a major investment shock for Romanian industry. In order to obtain the CE marking, factories not only had to change the label but also modernize the entire technological flow.

Many Romanian factories operated with machinery from the 1970-1980 period that did not comply with the Machinery Directive (2006/42/EC). The installation of protective systems (optical barriers, emergency stop buttons, protective housings) required investments of thousands of Euros per machine.

In many cases, adapting old machines was more expensive than purchasing new, already certified machines. This led to the closure of factories that did not have investment capital or access to European funds for digitalization and modernization.

Certification is not free, and for Romanian SMEs, the fees were significant. Testing a single machine tool prototype in a RENAR accredited laboratory can cost between 2,000 and 10,000 Euros, depending on the complexity.

Maintaining management system certification (e.g.: ISO 9001) involves recurring audit fees to certification bodies.

The forced transition worked as an economic sieve:

1. Many small companies were forced to turn to laboratories in Germany or Italy in the early years (2007-2010), because Romanian laboratories did not yet have all the necessary accreditations.

2. All these compliance costs were reflected in the final price of products, initially decreasing the profit margin of Romanian companies in the face of competition from China or Turkey (which often circumvented the rules).

To compensate for these costs, Romania launched support programs:

- *Competitiveness Growth Program*: Non-reimbursable funds specifically intended for implementing standards and obtaining product certifications.

- *Consulting*: The emergence of a specialized consulting market that helped

companies to prepare the "Technical File" without hiring permanent experts.

Although expensive, **this transition was the ticket to the "big league"**. Today, a Romanian machining company that invested in certification can deliver parts directly to Airbus or Renault, something impossible in the era of the old STAS standards.

### 3. THE CERTIFICATION AND ACCREDITATION SYSTEM IN ROMANIA

The Romanian certification and accreditation system is a pyramidal structure, designed to ensure the quality, safety, and competitiveness of products and services on the domestic and international market. It is composed of three main levels:

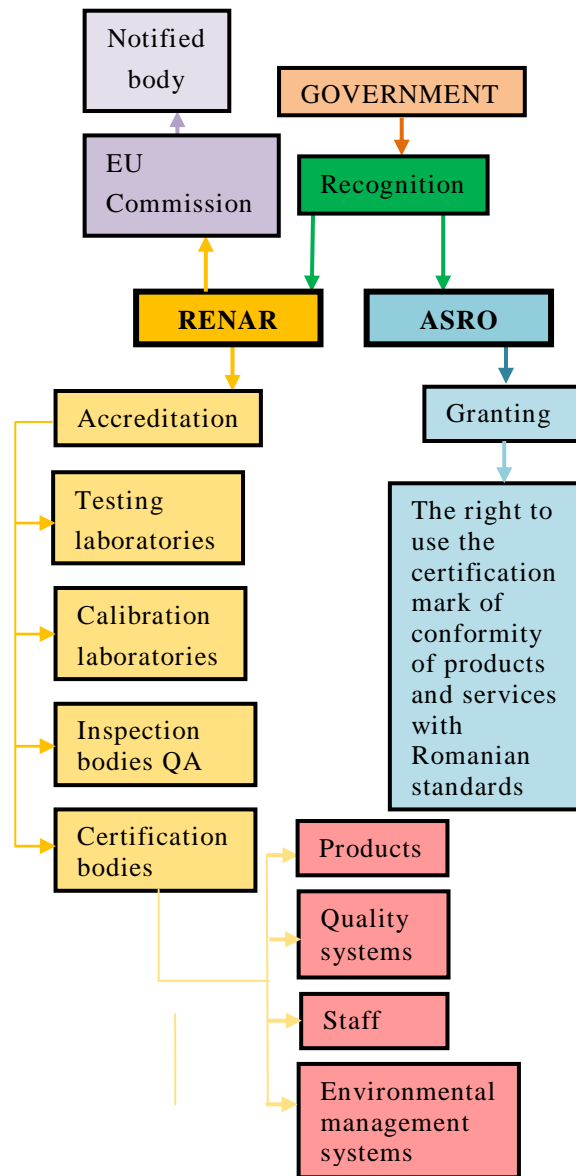


Fig. 1 The Romanian certification and accreditation system

1. Accreditation Level (Supreme Authority)  
 RENAR (Romanian Accreditation Association) is the only national accreditation body officially recognized by the Romanian state. RENAR officially verifies and certifies the technical competence and impartiality of certification bodies and laboratories.

The accreditation offered by RENAR provides international recognition to certificates issued in Romania, through mutual recognition agreements at European (EA) and worldwide (ILAC/IAF).

2. Certification Level (Assessment Bodies)  
 This level includes private or public entities that directly assess the conformity of products, services, or management systems.

Certification Bodies issue certificates (e.g.: ISO 9001, ISO 14001) after conducting audits. Testing and Calibration Laboratories perform the physical or chemical tests necessary to demonstrate that a product complies with standards. Inspection Bodies verify conformity at specific stages (e.g.: technical inspections).

3. Standardization Level (Technical Framework)  
 ASRO (Romanian Standardization Association) is the body that develops and manages Romanian Standards (RS).

ASRO represents Romania in international (ISO, IEC) and European (CEN, CENELEC) standardization organizations.

The standards published by ASRO serve as a technical reference for both voluntary and mandatory certification.

EU countries must apply Regulation (EC) No 765/2008, which requires the existence of a single national accreditation body (NAB) in each country. Although the rules are common, the institutional organization differs, as shown below and in Table 2:

**Germany - Technical Excellence Model**

In Germany, accreditation is centralized through DAkkS (Deutsche Akkreditierungsstelle). It is a joint entity (state and business), operating under the supervision of the Federal Ministry of Economics.

Germany places a great deal of emphasis on DIN (German Institute for Standardization). DIN standards are often adopted worldwide, giving Germany a huge competitive advantage in the mechanical engineering and electrical engineering industries.

**France - Centralized Model**

The French system is managed by COFRAC (Comité français d'accréditation).

France uses certification as a tool to promote traditional and high-tech products.

France is a leader in the standardization of services and risk management, using AFNOR to project normative influence at the ISO level.

**Italy - Flexible Model**

Italy uses ACCREDIA, a state-recognized non-profit association. Italy is very active in sustainability and design certification. They have very well-established systems for protecting origin marks (PDO, IGP) through strictly accredited certification bodies. The collaboration between UNI (National Standardization Organization) and ACCREDIA is a successful model in supporting SMEs for export.

Table 2

Country	Certification Body	Standardization Body	Dominant Characteristic
Romania	RENAR	ASRO	Rapid alignment with EU norms post-accession.
Germany	DAkkS	DIN	Leader in heavy industry standards.
France	COFRAC	AFNOR	Emphasis on service quality and regulation.
Italy	ACCREDIA	UNI.	Excellence in consumer product.

**4. CONCLUSIONS**

Currently, the certification system in Romania and Europe is in a phase of digital maturity, marked by three main pillars:

1. Full Implementation of GPSR (Regulation 2023/General Product Safety Directive): ANPC and European authorities have completed the integration of databases, so that any non-compliant product identified on a Marketplace (eMAG, Amazon) is automatically blocked throughout the EU in less than 24 hours through the Safety Gate interface.

2. Transition to the Machinery Regulation (EU) 2023/1230: Romanian certification bodies have completed their re-notification process, now assessing machinery not only for mechanical safety, but also for cyber resilience and integrated AI algorithms.

3. RENAR remains the sole guarantor of technical competence, with an updated list of laboratories that have adopted the new sustainability and digital ethics standards.

**REFERENCES**

[1] Ghelase, D., *Sisteme de Asigurarea Calitatii*, Braila, Editura Ceprohart, 2002.  
 [2] Wicke, L., *Quality Infrastructure: Metrology, Accreditation, and Standards*, Springer Nature, 2023.  
 [3] CEN-CENELEC – *Standards for the Digital Product Passport: A Roadmap for 2025-2030*, Bruxelles, 2024