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Technical standards and accredited conformity assessment for the development of Artificial Intelligence systems

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INTRODUCTION

The digital age has brought with it numerous technological advances, including Artificial Intelligence (AI), which is radically transforming the fabric of society. While it offers unprecedented possibilities for innovation and improving the quality of life, AI also raises significant questions related to safety, privacy, fairness, and ethics. As a result, the AI regulation has engendered considerable academic, political and social interest.

The Accredia Osservatorio, in "Technical standards and accredited conformity assessment for the development of Artificial Intelligence systems" explores the evolution of the AI regulation, focusing on EU Regulation 2024/1689 (also referred to here as "Regulation" or "AI Act") and develops – considering different implications based on the areas of use of AI systems – three Proofs of Concept, two in the biomedical context and the other simulating the application of a technical standard on Quality Management to a Public Administration. The analysis identifies a role for accreditation, a role that will become central in all those AI systems for which the Regulation provides for the involvement of a notified body before placing them on the market or putting them into service.

However, without adequate technical and scientific expertise, conformity verification processes would not be feasible. This expertise is essential to thoroughly assess the compliance of AI systems with regulations, ensuring safety, reliability and adherence to the harmonized technical standards that will be developed by the European Standardization Bodies (CEN, CENELEC, ETSI).

Compliance with the Regulation therefore requires a high level of scientific knowledge and the support of entities such as the National Interuniversity Consortium for Informatics (CINI), with its Artificial Intelligence and Intelligent Systems Laboratory, with which Accredia created the "Osservatorio", will be central to ensuring AI systems that meet the highest ethical and technical standards.

THE DEFINITION OF AN ARTIFICIAL INTELLIGENCE SYSTEM

AI systems are the subject of regulatory efforts, both in Europe and internationally, and their definition is a complex task. The difficulty arises from the intersection of various disciplinary fields, the continuous evolution of technologies and the different applications that span disparate sectors.

The vast range of techniques and approaches used in AI adds another layer of complexity. *Machine learning*, one of the most popular techniques, relies on analyzing large amounts of data to identify patterns and make predictions. Within it, we find sub-disciplines such as *supervised*, *unsupervised* and *reinforcement learning*, each with its own methods and applications. Deep learning, a subset of machine learning, uses deep neural networks to process complex data such as images and audio, but it is very demanding from an ICT point of view. *Fuzzy logic*, which allows for intermediate values between true and false, is useful in contexts of uncertainty but can be less precise than traditional logic. *Genetic algorithms*, inspired by natural selection, search for optimal solutions through well-established processes, but can be ICT intensive and do not always guarantee the best solution.

Every technique has its strengths and weaknesses, adapting better to specific problems and applications. This technological diversity makes it difficult to provide an over-arching definition that captures all the aspects of AI.

Precisely for this reason, in the Regulation the definition of an AI system has changed several times, moving from the definition in the first version of the draft Regulation – which listed specific technologies falling within the scope of the definition of AI systems – to a higher-level definition.

According to the European Regulation (art. 3), an AI system is: "a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments".

For the purposes of the research, we will therefore use the definition of AI systems developed within the AI Act.

THE ETHICS OF ARTIFICIAL INTELLIGENCE AND THE EVOLUTION OF ASSESSMENT METHODOLOGIES

The debate about AI ethics is not new, but its urgency and complexity have grown exponentially as technologies have advanced. Initially, ethical concerns focused on issues of bias and discrimination, for example in facial recognition or algorithmic decision-making systems. However, the focus has broadened to include the wider impact of AI on human autonomy, surveillance, the right to work, and privacy.

Ethical assessment methodologies have become increasingly sophisticated. Originally based on internal audits and compliance checklists, these methodologies have evolved into more integrated and holistic models. Modern approaches, such as ethics-by-design, seek to anticipate and mitigate ethical risks before AI products reach the market. These tools are vital to building trust among users and ensuring that AI innovations are responsible and transparent.

The need for a regulatory framework has led to the development of various initiatives at both national and international levels. One of the first significant attempts to regulate AI at a global level was the GDPR (General Data Protection Regulation - EU Regulation 2016/679) which, although not specifically focused on AI, has set important precedents in terms of data protection and algorithmic accountability.

In recent years, specific international frameworks have emerged to govern the use of AI. Organizations such as the OECD and UNESCO have developed guidelines that emphasize transparency, fairness, and respect for human rights in the use of AI. These guidelines serve as a reference for member countries and encourage the adoption of national regulations consistent with these international standards.

A defining moment in the regulation of AI was the introduction of the AI Act by the European Union.

WHY A EUROPEAN REGULATION ON ARTIFICIAL INTELLIGENCE?

The European AI Regulation aims to establish a harmonized and proportionate regulatory framework to regulate the use of AI within the European Union. The rationale is based on the idea that AI should be developed and used in a safe, ethical way, respectful of fundamental rights and European values. Accordingly, the Regulation aims to classify AI systems based on the degree of risk they pose to the safety and rights of individuals, as well as establishing a series of requirements and obligations for suppliers, distributors, importers and users of such systems. The AI Act represents a significant achievement in the regulatory evolution of the European Union, outlining a legal framework aimed at balancing the protection of fundamental rights and individual freedoms with the promotion of innovation in the AI sector.

The legislative process of the AI Act culminated with its publication in the OJEU (Official Journal of the European Union) on 12 July 2024. The timeframe for implementation of the Regulation is scaled over time with periods of 6, 12, 24 and 36 months. This reflects the complexity and scope of the rules outlined, allowing the interested actors to gradually adapt to the new obligations and requirements. As already happened with the GDPR, also for the AI Act it is expected that preventive and spontaneous implementation will play a fundamental role. The need to comply with the provisions of the Regulation will require a careful examination of corporate policies and practices, as well as constant monitoring of regulatory and technological developments in AI.

With the publication of the Regulation, the EU institutions have set themselves numerous objectives, including:

- creating a single market for AI by facilitating the free movement and recognition of AI systems that comply with EU rules, thus promoting integration and coherence in the European AI market;
- increasing trust in AI systems by ensuring that they are reliable, transparent and developed in an accountable manner, respecting the ethical principles and fundamental rights of people;
- preventing and mitigating the risks posed by AI by prohibiting or restricting the use of AI systems that pose an unacceptable risk to the safety, health, dignity or autonomy of people. In this sense, the Regulation aims to protect individuals and democratic values from possible threats arising from the unregulated use of AI;
- supporting innovation and excellence in AI by providing incentives, funding and guidance for the development and adoption of safe and ethical AI systems. The goal is to promote growth and technological progress in AI, fostering cooperation and coordination among Member States, institutions and stakeholders in order to maximize the benefits of AI for all European countries.

THE APPROACH TO RISK OF THE AI REGULATION

The Regulation revolves entirely around a *risk-based approach*, providing for a classification of those AI systems considered to be high-risk.

Article 3 of the Regulation defines risk as: "the combination of the probability of an occurrence of harm and the severity of that harm".

In assessing the risk, the Commission takes into account various criteria, including, for example, the intended purpose of the AI system, the extent to which it is used or will be used, the extent of any negative impact (damage) and the number of people who could be affected, or any provision by law for effective countermeasures also aimed at preventing or substantially reducing the risks.

In general, AI systems can be divided into four risk categories.

Unacceptable risk

AI systems that present an unacceptable risk are characterized by being in stark contrast with the fundamental values and principles of the EU, such as the democracy of institutions, respect for human dignity and the rule of law. Precisely because they conflict with the foundations of the Union, this type of system is prohibited or subject to severe restrictions, as in the case of real-time biometric surveillance for security reasons. Among the prohibited systems are, for example, AI systems that manipulate human behavior by coercing or influencing the will of users or that allow social scoring by public authorities[1].

High Risk

High-risk AI systems (Chapter III of the Regulation) are characterized by the possibility of having a systemic impact, i.e. a significant impact on the fundamental rights or safety of users and the surrounding environment. Such systems are subject to obligations and requirements (listed in Section 2 of Chapter III) before they can be placed on the market or used. Specifically, high-risk systems are those that meet both of the following conditions:

- they are among the systems covered by the EU harmonization legislation referred to in Annex I;
- they are subject to a conformity assessment before being placed on the market or put into service, in accordance with EU legislation.

Furthermore, Annex III contains a list of high-risk systems, dividing it into specific areas of occurrence, such as migration management and border control, employment, management of workers and access to self-employment, education and vocational training and access to essential public and private services. Due to the exponential growth of the technological level, this list is subject to continuous revision, in order to avoid a misalignment between the standardization and the technological reality of the moment. It should also be underlined that an AI system referred to in Annex III is not to be considered high-risk if it does not present a significant risk of harm to the health, safety or fundamental rights of natural persons.

[1] For a list of the prohibited systems see art. 5 of the Regulation.

Limited Risk

AI systems that present a limited risk, while having the ability to influence the rights or wishes of users, do so to a lesser extent than high-risk systems. Such systems are subject to transparency requirements, which aim to enable users to be aware that they are interacting with an AI system and to understand its characteristics and limitations. This will allow users to exercise their right to choose whether or not to rely on the system and to understand the possible consequences of their choices. Developers and users of such systems will also have to ensure that the information provided is clear, understandable and accessible. For example, this category includes AI systems used to generate or manipulate audiovisual content (such as *deepfakes*), or to provide personalized suggestions (such as *chatbots*). In essence, the user has the right to be aware that s/he is interacting with an AI system and not with a human being or, to return to the example of deepfakes, to be aware that the image was generated or manipulated by an AI system.

Minimal or Zero Risk

AI systems that present minimal or zero risk are characterized, instead, by the fact that they have no direct impact on the fundamental rights or safety of people, as well as by offering broad margins of choice and control to users. Where an AI system is categorized as representing a minimal or zero risk, it is to be considered free from any specific regulatory obligation, in order to strengthen and encourage innovation and experimentation. This does not mean that systems that present a minimal or zero risk must also comply with the laws and general regulations applicable to AI, such as those relating to the protection of personal data, competition, civil liability, or consumer rights. This category includes AI systems used for recreational purposes (such as video games) or for purely aesthetic purposes (such as photographic filters).

Notification Authorities and Notified Bodies and conformity assessment procedures

As in other European Regulations, the AI Act also calls into play the role of Notification Authorities and Notified Bodies in cases where the needs of protecting European citizens require particular attention. The notification procedure is set out in Section IV of Chapter III of the Regulation. The bodies responsible for assessing conformity must meet the requirements of independence, impartiality and competence in order to be designated as Notified Bodies by the competent authority of each Member State. Subsequently, it will be the task of the Notification Authority to communicate the list of Notified Bodies to the Commission.

Accreditation is a method whereby the above requirements can be demonstrated, therefore bodies are encouraged to submit an application for notification with an accompanying accreditation certificate[2].

[2] Article 29 of the Regulation provides that conformity assessment bodies are required to submit a request for notification to the Notification Authority of the Member State in which they are established. The request must:
- include a description of the conformity assessment activities;
- contain conformity assessment modules and the types of AI systems for which the body claims to be competent;
- be accompanied by an accreditation certificate, if available, issued by a National Accreditation Body attesting the conformity of the body with the requirements of Article 31 of the Regulation, which sets out requirements for notified bodies.

In the absence of this, the body must provide adequate documentation to demonstrate compliance with the provisions of the AI Act. Furthermore, Article 28 of the Regulation establishes that Member States may opt for assessment and monitoring to be performed by a national accreditation body in accordance with EC Regulation 765/2008 .

Notified bodies will therefore be involved, according to Article 43 of the Regulation, in the conformity assessment of certain AI systems considered to be high-risk. In particular, for high-risk AI systems covered by EU harmonization legislation listed in Annex I, Section A, the supplier is required to follow the relevant conformity assessment procedure provided for by those legal acts.

Furthermore, the use of notified bodies is foreseen for AI systems relating to biometrics in accordance with Annex III. Specifically, the supplier shall apply the conformity assessment procedure in accordance with Annex VII (which provides for the involvement of a notified body) in the following cases:

a) there are no harmonized standards and no common specifications are available;

b) the supplier has not applied the harmonized standard or has applied only part of it;

c) the common specifications referred to in the letter exist but the supplier has not applied them;

d) one or more harmonized standards have been published with a limitation only to the part of the standard which is subject to the limitation.

If the conformity assessment procedure, whether based on Annex VI (Conformity assessment procedure based on internal control) or VII (Conformity based on an assessment of the quality management system and an assessment of the technical documentation) has a positive outcome, the CE marking may be affixed, demonstrating compliance with the sector legislation and the AI Act. The marking must be affixed in a visible, legible and indelible manner. If this is impossible or difficult to achieve due to the nature of the AI system, the mark may be placed on the packaging or on the accompanying documents. The CE marking, where the use of a third party is foreseen in the context of the conformity assessment procedure, must be followed by the identification number of the notified body.

THE ROLE OF STANDARDS IN EU REGULATION IN RELATION TO THE ARTIFICIAL INTELLIGENCE REGULATION

In order to promote technical harmonization in the field of AI, making it reliable and uniform across the EU, it was deemed necessary to add European technical standards to the regulatory obligations, so as to cover the main technical areas involved in the AI Act.

By definition, a standard is a non-mandatory technical specification, adopted by a recognized standardization body (EU Regulation 1025/2012). Standardization, in general, may have technical specifications of a product or service as its object, i.e. the drafting of documents that prescribe

Italy has often used this option, delegating to Accredia - the National Accreditation Body - through specific agreements, the task of a preliminary evaluation of the conformity assessment bodies operating within the new legislative framework and the subsequent monitoring.

technical requirements that a given product, process, service or system must satisfy. Therefore, European standards constitute a set of technical specifications and/or criteria established by a European standardization body.

In general, European standardization is organized by and for stakeholders, represented nationally through the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC), and direct stakeholder participation through the European Telecommunications Standardization Institute (ETSI). The entire harmonization process revolves around the principles recognized by the World Trade Organization (WTO) in the field of standardization, namely coherence, transparency, openness, consensus, voluntary application, independence from special interests and efficiency.

The primary objective of AI technical standardization is to define technical and/or qualitative specifications to which AI-based products - already or not yet on the market - their production processes or the services provided, can conform (on a voluntary basis) with the aim of ensuring, in a harmonized way, the safety and reliability of AI systems, as well as their compatibility and interoperability with other products or systems.

In line with EU Regulation 1025/2012, the standards that will be developed in the field of AI will have a decisive role in supporting the implementation of the new compliance requirements. In order to analyse the role of accreditation in this area, it is important to carefully consider the definition of harmonized technical legislation. Pursuant to art. 2, par. 1, letter c of the Regulation, *harmonized standard* means: "a European technical standard, adopted on the basis of a request from the Commission for the purpose of applying Union legislation on harmonization".

RELATIONSHIP BETWEEN A STANDARDIZATION REQUEST AND THE AI ACT

The Accredia Osservatorio created an analysis of the Standardization Request (SR) drawn up by the European Commission according to the Regulation and published in May 2023. A new standardization request, updated to the final content of the AI Act, is expected by the end of 2024. Given this assumption, it is important to highlight how the SR moves within the well-defined regulatory landscape, as set out in the EU Standard Regulation 1025/2012, in the EU Directive 1535/2015, in the EC Regulation 765/2008 and in the EU Regulation 1020/2019.

Among the categories of parties involved in the standardization process are:

- the ESOs (European Standardization Organizations), currently CEN and CENELEC with a possible future involvement of ETSI;
- the NSBs (National Standardization Bodies), responsible for the production of technical standards in each of the Member States;
- the European stakeholder organizations (interest holders);
- the consultants for harmonized standards.

Start of the standardization process

In the initial phase, the European Commission, from which the request originates, having found the need for standardization, identifies the areas of intervention in which it considers it necessary to operate. Specifically, it develops a draft standardization request (SR for ESOs) including details on the scope, timing and legal requirements that the standard should specify.

In the case of the AI Act, the type of specification expected from the technical standards concerns some articles of the Regulation, generally the more technical ones (chapter 2, section III). For example, art. 15 contains general indications on the need to ensure the robustness, accuracy and cybersecurity of AI systems, but does not specify how this is to be done. The role of the technical standards, in relation to the Regulation, is therefore to specify the articles of the Regulation with technical procedures, providing "low-level" requirements, such as metrics to measure accuracy.

Preparation of the draft of standards

Once the SR has been approved and received, the European Standardization Committees in question start the procedures for drafting the standard. Following the consultation of stakeholders and the conduct of the necessary technical research, the "regulatory text" will be drawn up, aiming to produce standards compliant with the requests expressed by the Commission.

The European standards developed follow transparent and participatory procedures to ensure the representation of the interests of all the parties involved. In particular, the NSBs are called upon to provide a pool of experts to discuss matters in a technical committee.

As regards the SR relating to the AI Act, this will be a joint technical committee between CEN and CENELEC. The technical committee will then form a working group of experts consisting of the NSBs and observers in order to draft a document containing the structure outline of the standard relating to the AI Act.

Adoption of the standard

Once the drafting process is complete, the proposed European Standard is put to a vote among members of CEN, CENELEC or ETSI. Consultants assess whether the standards meet the requirements in the SR and are therefore suitable for publication. Consultants for harmonized standards may be involved throughout the process, but standards must finally pass the conformity check at the time of voting, as only minor changes can be made following the consultation.

In the specific case of the AI Act, consultants will not be involved, in accordance with some statements made by DG CNECT (Directorate General Communications Networks, Content and Technology) and of the European Commission, released informally during some public workshops. Once the document has been approved by the majority of members, where the rules are considered compliant, they will be published in the OJEU and will become harmonized standards.

As regards the harmonization of the rules relating to the AI Act, the NSBs will be responsible for the adoption of European rules at the national level and will have to, if necessary, eliminate any rule that conflicts with the EU legal requirements created on the basis of the principles established in the Regulation.

In conclusion, as regards the relationship between the AI Act and the SR, it is clear that the Regulation provides the reference framework within which the technical rules relating to this "family" of technologies will have to be developed.

PROOF OF CONCEPT

A central part of Accredia Osservatorio's analysis concerns PoCs (Proof of Concept). A bridge between normative theory and application practice, PoCs offer a platform to test, in a controlled environment, the effectiveness and compliance of AI systems with technical standards and make it possible to pinpoint a potential role for accreditation. PoCs assume significant relevance as essential tools for understanding the accreditation, inspection and certification processes of such technologies. These processes are essential to ensure that AI systems not only adhere to the quality and safety standards established by technical standards but are also implemented in a way that respects the rigorous requirements of the European AI Act.

The adoption of technical guidelines and standards, such as ISO/IEC TR 24027:2021 and ISO/IEC 42001:2023 in the context of PoCs, serves to explicitly illustrate how AI systems can be designed and evaluated to ensure that bias is minimized and quality management is maintained at optimal levels. PoCs facilitate the development of detailed inspection guidelines, as they can identify specific areas of risk and effectiveness that inspectors can then monitor and evaluate. Through PoCs, more targeted and effective verification procedures can be developed, resulting in more reliable and transparent certification processes.

Osservatorio's study describes a PoC in the biomedical context and one in Public Administration. In the first case, the PoCs developed regard an AI system for melanoma detection and one for the stratification of patients with multiple sclerosis, while, in the case of the Public Administration, the application of a technical regulation on Quality Management is simulated.

PoCs in the biomedical field have not only demonstrated the ability of AI to support clinical decisions, but have also served to demonstrate the importance of a procedure that includes data collection and preparation, model development and evaluation, and finally issuance of the system. In particular, a procedure for assessing the conformity of an AI system to ISO/IEC TR 24027:2021 was simulated.

A model for assessing conformity to the ISO guideline is presented, from which an operational checklist is created, on the one hand, to guide the verification activity of the notified body and, on the other, to help the manufacturer in the entire process of reviewing and improving the system. The ISO guideline aims to eliminate potential biases in AI systems, ensuring that the diagnoses and treatments proposed are not only accurate but also fair and impartial. Verification of conformity according to ISO/IEC TR 24027:2021 is a crucial step, which ensures that AI systems comply with the principles of reliability, thus supporting the implementation of the AI Act.

The AI Act requires that AI systems must be transparent, and ethical, and operate without discrimination, incorporating stringent regulatory requirements to prevent risks to fundamental rights and human safety. PoCs in the biomedical sector therefore represent not only an exercise in technical compliance but also an alignment with European values and standards on the ethical use of AI.

Similarly, in the Public Administration sector, the case study with INAIL (National Institute for Insurance against Accidents at Work) highlights the importance of the standard ISO/IEC 42001:2023 on Quality Management for AI systems. This standard focuses on the implementation of quality management systems, which are essential to ensure that decisions taken by AI systems are consistent, reproducible and reliable. In a complex environment such as that of Public Administration, where decisions can have large and significant impacts on the lives of citizens, compliance with these standards ensures that each automated decision-making process is subjected to rigorous checks before being implemented.

This approach is particularly relevant in light of the AI Act, which emphasizes the importance of adequate risk and quality management in AI. The standard ISO/IEC 42001:2023, therefore, not only responds to technical needs but also aligns with the objectives of the AI Act to promote responsible use of AI, based on high-quality standards. The need to adhere to rigorous and globally recognized technical standards is a prerequisite not only for regulatory compliance but also for strengthening the competitive position internationally in the AI sector.

THE ROLE OF ACCREDITATION

PoCs stress the importance of accredited conformity assessment to the requirements defined in the development cycle of an AI model, particularly in the biomedical field. Accredited conformity assessment for medical devices and in particular for devices containing AI systems requires impartiality, competence and operative consistency on the part of the organization undertaking these activities. Conformity assessment must be strategically placed before the release or implementation phase, to ensure that the model complies with regulatory requirements and quality expectations.

As highlighted in the Osservatorio, it is important to differentiate between a product intended to be placed on the market and one of a more strictly research nature (like a scientific product). While for the former an assessment is essential that includes aspects such as patient safety, regulatory compliance and clinical effectiveness, for scientific or research products, the assessment of regulatory compliance is not mandatory and the emphasis could be placed more on methodological validity, innovation and the potential to contribute to the medical knowledge base.

The importance of a conformity assessment process for AI-based systems in the medical sector is highlighted by considering the potential consequences of a premature release of such technologies without an adequate risk analysis. Once a model has entered the market or has been adopted in clinical contexts, taking action to correct defects or remove the system can be extremely difficult, expensive and harmful, also for users and patients.

In the case of medical devices and in vitro diagnostic medical devices, since these are products already covered by the provisions of EU Regulations 2017/745 and 2017 /746, prior to placing them on the market, a notified body, depending on the risk class of the medical device itself, must assess them. In this context, it should be reiterated that accreditation represents an important tool for ensuring the conformity of AI-based systems.

Accreditation contributes to ensuring the efficiency, transparency and quality of services offered to citizens. Compliance with the defined requirements is essential to ensure that AI systems are developed and applied in a safe, ethical and responsible manner. At the same time, accreditation, as an authoritative attestation of compliance with the relevant technical regulations, helps organizations achieve compliance with the Regulation. This is certainly a key step in protecting European citizens from a technology with potentially harmful and constantly evolving risk profiles.

Accredia, as the sole National Accreditation Body designated by the Government in the application of European Regulation 765/2008 and supervised by the Ministry of Business and Made in Italy, assesses the competence and impartiality of conformity assessment bodies, ensuring the correctness and conformity of verification and certification activities and processes. For this reason, Accredia can contribute - together with the institutions to which the functions of management and control of AI have been entrusted - to ensure that these technologies comply with the requirements established by the AI Act. This collaboration is already ongoing for other goods and services, easing the administrative burden of Public Administrations and, specifically in this case, it could increase the efficiency of the accreditation and monitoring of conformity assessment activities in the application of AI systems.

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