15

Companies developing compliance with requirements

Guide 15. Technical Documentation

European
Artificial Intelligence Act

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GOBIERNO DE ESPAÑA
MINISTERIO PARA LA TRANSFORMACIÓN DIGITAL Y DE LA FUNCIÓN PÚBLICA
SECRETARÍA DE ESTADO DE DIGITALIZACIÓN E INTELIGENCIA ARTIFICIAL

Plan de Recuperación, Transformación y Resiliencia

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This guide has been developed within the framework of the development of the Spanish pilot for the regulatory AI Sandbox, through collaboration among participants, technical assistance providers, potential competent national authorities, and the sandbox's expert advisory group.

The aim of the guide **is to serve as an introductory support to the European Regulation on Artificial Intelligence and its applicable obligations.** Although it is not legally binding and does not replace or develop the applicable legislation, it provides practical recommendations aligned with regulatory requirements, pending the approval of the harmonised implementing standards for all Member States.

This document **is subject to an ongoing process of evaluation and review, with periodic updates** in line with the development of standards and the various guidelines published by the European Commission, and it will be updated once the Digital Omnibus amending the Artificial Intelligence Act is approved.

Among the relevant technical references currently applicable are the following standards **ISO/IEC 42001 "Artificial Intelligence – Management System"**, **ISO/IEC 23894-2 "Information Technology – Artificial Intelligence – Risk Management"** and **ISO/IEC 24027 "Information Technology – Artificial Intelligence (AI) – Bias in AI systems and AI-aided decision-making"**, which will establish a management, risk assessment and bias mitigation framework applicable to artificial Intelligence systems, ensuring their reliability, transparency and fairness in the context of compliance with the European Artificial Intelligence Act.

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General Content

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1. Preamble

1.1 Purpose of the document

This guide within the framework of the AI sandbox provides indications of the content of the technical documentation of high-risk AI systems and the the criteria for its retention. The **purpose** of this guide is therefore **to explain** what **the European Regulation on Artificial Intelligence (AI Act) requires** of technical documentation, how to reflect it and how all required documentation should be retained.

This guide, therefore, presents in its content the understanding of the technical documentation requirements, the measures to be considered and also, as in other guides, how to structure the documentation, in detail.

1.2 How to read this guide?

The relationship of this guide with the others does not end with the aforementioned conformity assessment guide. This guide is directly related to the others. This guide indicates how the documentation detailed in each guide should be incorporated into the technical documentation. For example, in the guide we will see where the risk plan documentation fits within the technical documentation.

With this guide, the specific pieces of documentation of each guide are fitted within the requirements established by the European Regulation on Artificial Intelligence, which, as we have seen, gives technical documentation an important role within the regulatory framework it establishes, especially within the conformity assessment framework.

Thus, the provider must consider the section intended to address the requirements as well as the measures to be considered, section 3.2. Once this section has been read, sections 4 and 5 are aligned with what is described in the European Regulation on Artificial Intelligence in this regard, both in its article 11, technical documentation, Annex IV, and article 18, retention of documentation, **exclusively**. Under no circumstances should this be considered exhaustive regarding other obligations that the provider may have in compliance with other regulations (GDPR, sectoral regulations or others), and in ensuring the lawfulness of its activities.

The Self-Assessment section in this guide covers, on the one hand, the evaluation by the provider's evaluation of the measures, as usual, and on the other, verifying that the structure and content of the technical documentation fits with what is proposed; for this purpose, self-assessment issues have been added that allow the provider to evaluate the progress, status and ultimately quality of the **technical documentation**.

1.3 Who is it for?

This guide is exclusively addressed to the provider of the AI system, who is responsible, as indicated by the European Regulation on Artificial Intelligence, for the preparation of the technical documentation of the AI system.

Therefore, this guide does not include sections intended for the deployer, who, in any case, and on certain occasions (for example, instructions) must have access to the outcome of the technical documentation for its use, but under no circumstances for its preparation.

This is essentially a guide **intended for the** AI system provider, who is responsible for generating, updating, and retaining the documentation of the AI system. The guide should be regarded as a framework for developing the technical documentation of the AI system, which must be adapted to its specific nature while maintaining the requirements described in the European Regulation on Artificial Intelligence.

1.4 Use cases and examples throughout the guide

Throughout the guide, two **use cases** will be used as **examples** of how **to prepare** the technical documentation. The examples will focus exclusively on the provider, who is responsible for generating and retaining the documentation.

A detailed description of the use cases can be found in the Guide on Concepts and Cross-Cutting Information.

Note: Whenever an **example** is provided, it will be for **illustrative** purposes. **Provider and deployer** must consider the application of **all the measures** indicated in this guide.

The use cases have been selected based on two reasons:

- The ability to explain the information and procedures detailed in the guide. To facilitate the understanding of the documentation process, as they are quite complete in all the specific sections that this documentation guide in its continuity with the rest of the guides establishes.
- Apply continuity on top of other sandbox guides to develop the sample documentation shown in this guide.

The selected cases are:

- **Employee promotion system.**
- **Aid granting automatic system.**

2. Introduction

2.1 What is technical documentation for AI?

In the European Regulation on Artificial Intelligence, in recital (71) when it addresses the criteria taken into account to establish documentation, it sets out several important aspects about documentation.

AI Act

(71)

Having comprehensible information on how high-risk AI systems have been developed and how they perform throughout their lifetime is essential to enable traceability of those systems, verify compliance with the requirements under this Regulation, as well as monitoring of their operations and post market monitoring. This requires keeping records and the **availability of technical documentation**, containing information which is necessary to assess the compliance of the AI system with the relevant requirements and facilitate post market monitoring. Such information should include **the general characteristics, capabilities and limitations of the system, algorithms, data, training, testing and validation processes used** as well as documentation on the relevant **risk-management system** and drawn in a clear and comprehensive form. The technical documentation should be kept up to date, appropriately throughout the lifetime of the AI system. Furthermore, high-risk AI systems should technically allow for the automatic recording of events, by means of logs, **over the duration of the lifetime of the system**.

As we can see in the text presented, it focuses on three important points:

- Technical documentation is as important as the activity records of the AI system.
- A list is provided of the aspects that must be covered, which will be further developed, as we will see in the articles and throughout the guide.
- The management and preparation of the documentation do not end with the putting into service of the artificial intelligence system; it must be kept up to date.

In this regard, and for a definition of the life cycle referred to in the European Regulation on Artificial Intelligence, we recommend the reference to the draft regulation *ISO/IEC 5338 - Information technology – Artificial intelligence – AI system life cycle processes. 6. AI System life cycle processes,* where the concept of the life cycle and the phases composing it are extensively developed, although their scope and depth go beyond that of this guide.

In addition, and in relation to the conformity assessment procedure, the European Regulation on Artificial Intelligence establishes in its recital (173).

AI Act

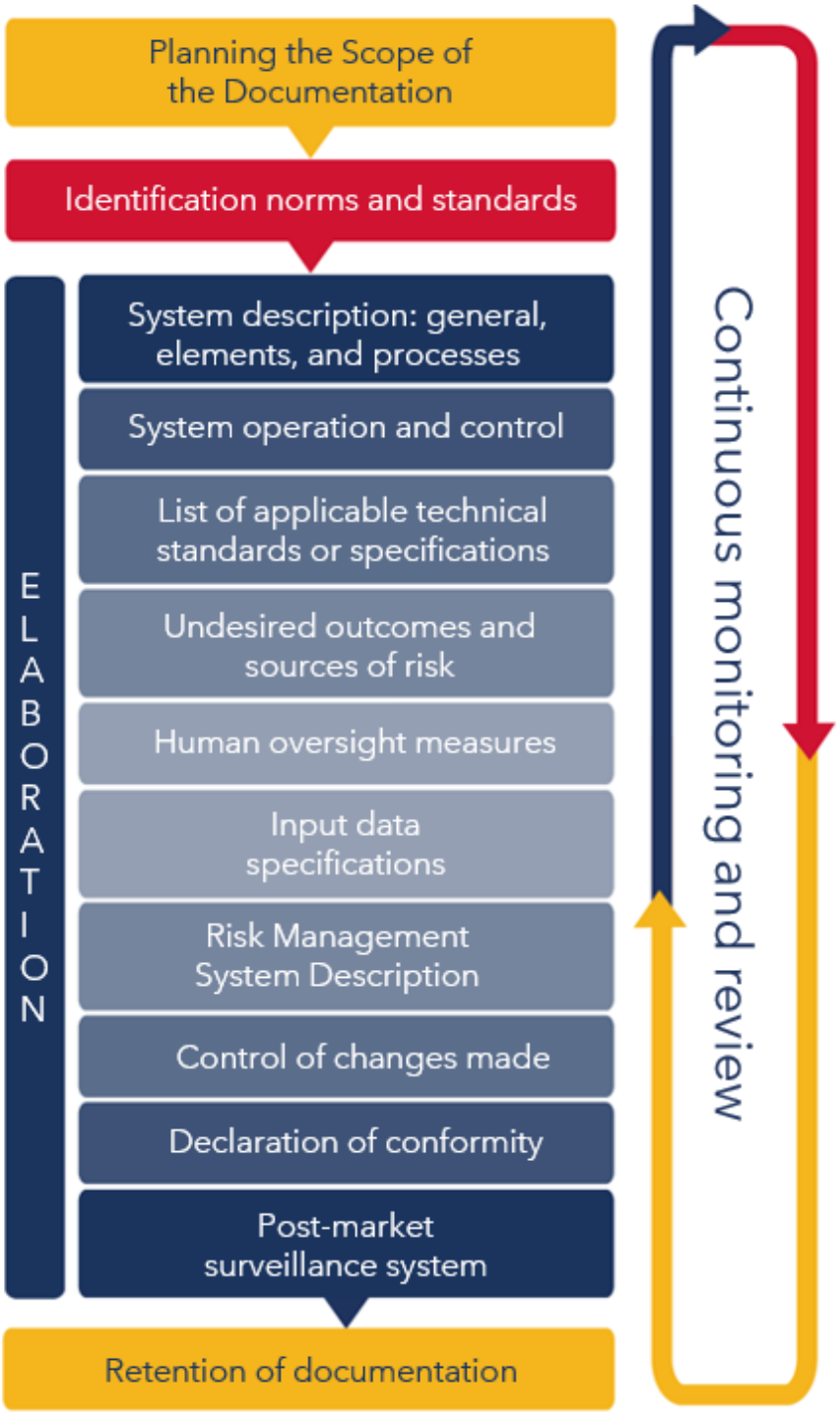
(173)

> […] conformity **assessment** procedures, the provisions establishing the high-risk AI systems to which the conformity assessment procedure based on assessment of the quality management system and **assessment of the technical documentation should apply** […].

The conformity assessment procedure, within the framework of the AI sandbox, has its own explaining how it should be faced, however, it is very important to bear in mind that the **technical documentation constitutes a significant part** of what the **conformity assessment process entails**.

The European Regulation on Artificial Intelligence considers, on the one hand, what technical documentation should contain, and, on the other hand, how this documentation should be kept. This guide has been structured in accordance with that criterion. Section 4 presents a proposed structure for the **technical documentation,** based on Article 11, technical documentation, and Annex IV of the European Regulation on Artificial Intelligence. Similarly, section 5 details the requirements and measures for the retention of documentation established in the articles.

A summarized and visual way to view the requirements of the Artificial Intelligence Act regarding the technical documentation imposed by:



3. European Regulation on Artificial Intelligence

The putting into service or use of high-risk AI systems shall be subject to compliance with certain mandatory requirements, including those relating to technical documentation and the retention of documentation. These requirements aim to ensure that high-risk AI systems made available in the Union, or whose outputs are used within the Union, do not pose unacceptable risks to important public interests recognised and protected by Union law.

This section includes the articles relating to the generation of records in Regulation 2024/1689 of the European Parliament and of the Council of 13 June 2024 (European Regulation on Artificial Intelligence) and specifies in which sections of this guide the different elements of those Articles are addressed.

3.1 Preliminary analysis and relationship of the articles

The obligations regarding the preparation of adequate technical documentation are mainly set out in the European Regulation on Artificial Intelligence, Article 11 "Technical documentation" together with the annex referenced in Article 11.1 "Annex IV Technical documentation referred to in paragraph 1 of Article 11" and is closely related to Article 18 "Retention of documentation".

Due to the nature and content of these articles, they will be addressed together in this guide. In this sense:

- **Article Technical Documentation** → defines and establishes the general characteristics that the technical documentation of the AI system must have. From the need to prepare the documentation before the market introduction and the need to keep it updated, to going into detail on how it must be written, and the requirements that it must meet not only in its form, but also in the objective of demonstrating that the requirements of chapter 3, section II, of the European Regulation on Artificial Intelligence.
- **Article Documentation keeping** → establishes the retention of all the **documentation** of the AI system. **In addition to** the **technical documentation** in the previous section, it specifies the **period** for which the documentation must be maintained, lists the documentation that must be available whenever the system is active and in operation, and indicates **which documentation** must be retained.
- **Annex IV** → This annex, referred to in Article 11.1, **defines the minimum content** that the technical documentation must have.

3.2 Content of the articles in the AI Act

AI Act

Art.11 – Technical documentation

1. The technical documentation of a high-risk AI system shall be drawn up before that system is placed on the market or put into service and shall be kept up-to date.

The technical documentation shall be drawn up in such a way as to demonstrate that the high-risk AI system complies with the requirements set out in this Section and to provide national competent authorities and notified bodies with the necessary information in a clear and comprehensive form to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV. SMEs, including start-ups, may provide the elements of the technical documentation specified in Annex IV in a simplified manner. To that end, the Commission shall establish a simplified technical documentation form targeted at the needs of small and microenterprises. Where an SME, including a start-up, opts to provide the information required in Annex IV in a simplified manner, it shall use the form referred to in this paragraph. Notified bodies shall accept the form for the purposes of the conformity assessment.

2. Where a high-risk AI system related to a product covered by the Union harmonisation legislation listed in Section A of Annex I is placed on the market or put into service, a single set of technical documentation shall be drawn up containing all the information set out in paragraph 1, as well as the information required under those legal acts.

3. The Commission is empowered to adopt delegated acts in accordance with Article 97 in order to amend Annex IV, where necessary, to ensure that, in light of technical progress, the technical documentation provides all the information necessary to assess the compliance of the system with the requirements set out in this Section.

AI Act

Art.18 – Documentation keeping

1. The provider shall, for a period ending 10 years after the high-risk AI system has been
placed on the market or put into service, keep at the disposal of the national competent
authorities:

(a) the technical documentation referred to in Article 11;

(b) the documentation concerning the quality management system referred to
in Article 17;

(c) the documentation concerning the changes approved by notified bodies, where applicable;

(d) the decisions and other documents issued by the notified bodies, where applicable;

(e) the EU declaration of conformity referred to in Article 47.

2. Each Member State shall determine conditions under which the documentation referred to in paragraph 1 remains at the disposal of the national competent authorities for the period indicated in that paragraph for the cases when a provider or its authorised representative established on its territory goes bankrupt or ceases its activity prior to the end of that period.

3. Providers that are financial institutions subject to requirements regarding their internal
governance, arrangements or processes under Union financial services law shall maintain
the technical documentation as part of the documentation kept under the relevant Union
financial services law.

AI Act

Annex IV – Technical documentation referred to in Article 11(1)

The technical documentation referred to in Article 11(1) shall contain at least the following information, as applicable to the relevant AI system:

1. A general description of the AI system including:

(a) its intended purpose, the name of the provider and the version of the system reflecting its relation to previous versions;

(b) how the AI system interacts with, or can be used to interact with, hardware or software, including with other AI systems, that are not part of the AI system itself, where applicable;

(c) the versions of relevant software or firmware, and any requirements related to version updates;

(d) the description of all the forms in which the AI system is placed on the market or put into service, such as software packages embedded into hardware, downloads, or APIs;

(e) the description of the hardware on which the AI system is intended to run;

(f) where the AI system is a component of products, photographs or illustrations showing external features, the marking and internal layout of those products;

(g) a basic description of the user-interface provided to the deployer;

(h) instructions for use for the deployer, and a basic description of the user-interface provided to the deployer, where applicable;

2. A detailed description of the elements of the AI system and of the process for its development, including:

(a) the methods and steps performed for the development of the AI system, including, where relevant, recourse to pre-trained systems or tools provided by third parties and how those were used, integrated or modified by the provider;

(b) the design specifications of the system, namely the general logic of the AI system and of the algorithms; the key design choices including the rationale and assumptions made, including with regard to persons or groups of persons in respect of who, the system is intended to be used; the main classification choices; what the system is designed to optimise for, and the relevance of the different parameters; the description of the expected output and output quality of the system; the decisions about any possible trade-off made regarding the technical solutions adopted to comply with the requirements set out in Chapter III, Section 2;

(c) the description of the system architecture explaining how software components build on or feed into each other and integrate into the overall processing; the computational resources used to develop, train, test and validate the AI system;

(d) where relevant, the data requirements in terms of datasheets describing the training methodologies and techniques and the training data sets used, including a general description of these data sets, information about their provenance, scope and main characteristics; how the data was obtained and selected; labelling procedures (e.g. for supervised learning), data cleaning methodologies (e.g. outliers detection);

(e) assessment of the human oversight measures needed in accordance with Article 14, including an assessment of the technical measures needed to facilitate the interpretation of the outputs of AI systems by the deployers, in accordance with Article 13(3), point (d);

(f) where applicable, a detailed description of pre-determined changes to the AI system and its performance, together with all the relevant information related to the technical solutions adopted to ensure continuous compliance of the AI system with the relevant requirements set out in Chapter III, Section 2;

(g) the validation and testing procedures used, including information about the validation and testing data used and their main characteristics; metrics used to measure accuracy, robustness and compliance with other relevant requirements set out in Chapter III, Section 2, as well as potentially discriminatory impacts; test logs and all test reports dated and signed by the responsible persons, including with regard to pre-determined changes as referred to under point (f);

(h) cybersecurity measures put in place;

3. Detailed information about the monitoring, functioning and control of the AI system, in particular with regard to: its capabilities and limitations in performance, including the degrees of accuracy for specific persons or groups of persons on which the system is intended to be used and the overall expected level of accuracy in relation to its intended purpose; the foreseeable unintended outcomes and sources of risks to health and safety, fundamental rights and discrimination in view of the intended purpose of the AI system; the human oversight measures needed in accordance with Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the deployers; specifications on input data, as appropriate;

4. A description of the appropriateness of the performance metrics for the specific AI system;

5. A detailed description of the risk management system in accordance with Article 9;

6. A description of relevant changes made by the provider to the system through its lifecycle;

7. A list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union; where no such harmonised standards have been applied, a detailed description of the solutions adopted to meet the requirements set out in Chapter III, Section 2, including a list of other relevant standards and technical specifications applied;

8. A copy of the EU declaration of conformity referred to in Article 47;

9. A detailed description of the system in place to evaluate the AI system performance in the post-market phase in accordance with Article 72, including the post-market monitoring plan referred to in Article 72(3).

3.3 Correspondence of the article with the sections of the guide

The following table details the sections of this guide that address the different elements of this article:

Article	AI Act Requirement	Section
11	Preparation of technical documentation.	Section 4.1
18	Retention of documentation	Section 4.2
Annex IV.1	Minimum information to collect in the overview of the AI system.	Section 5.1
Annex IV.2	A detailed description of the elements of the AI system and its development process.	Section 5.2
Annex IV.3	Monitoring of the operation and control of the AI system.	Section 5.3
Annex IV.3	The appearance of foreseeable undesired outcomes and sources of risk.	Section 5.4
Annex IV.3	The documentation of technical measures of human oversight.	Section 5.5
Annex IV.3	The specifications of the input data.	Section 5.6
Annex IV.4	A description of the suitability of the performance parameters for the AI system.	Section 5.7
Annex IV.5	A detailed description of the risks management system.	Section 5.8
Annex IV.6	A description of the relevant changes made by the provider to the system throughout its lifecycle.	Section 5.9
Annex IV.7	A list of harmonised standards or, in the absence thereof, a detailed description of the solutions adopted to meet the requirements set out in Section 2 of Chapter III.	Section 5.10
Annex IV.8	A copy of the EU declaration of conformity of conformity.	Section 5.11
Annex IV.9	A detailed description of the system established to assess the performance of the AI system in the post-market phase.	Section 5.12

4. How to approach the requirements?

4.1 Preparation of documentation

This section describes the **necessary measures** to enable participating providers to understand what technical documentation is expected and its relationship with other guides of the AI sandbox in which it is framed.

In this section, we address the measures that will make it possible to ensure understanding of the requirements as defined in the previous section.

The generation and retention of technical documentation are the responsibility of the system provider.

A high-risk artificial intelligence system must have **complete technical documentation before being placed on the market** and put into service, in order to ensure that the requirements of Chapter III, Section 2 have been met. To determine what technical documentation must be prepared, the provider must follow the sandbox guides, which provide clear indications and examples of how to address each concept. In addition, the provider must:

- **Plan** from the design stage and in an appropriate manner, the scope of the technical documentation of the AI system, including communication with the different departments/areas involved. In this way, the technical documentation will make it possible to demonstrate compliance with the active responsibility required under the AI Act in relation to its structure and content, as will be addressed throughout this guide.
- **Identify** the existence of approved **harmonised standards** available.
- **Identify** the existence of **available standards**.
- Consider the possibility of certification against existing standards or the obtaining of associated quality seals.

The harmonised standards and standards related to Artificial Intelligence are currently being drafted and developed. For this reason, within the framework of the sandbox, it is emphasised that providers should refer to the guides provided. The main organisations working on such standardisation are:

- At the European level CEN/CENELEC, see https://www.cencenelec.eu/
- At the international level ISO/IEC, ITU https://www.iso.org/organization/9657.html
- And at the national level, the UNE working committee, CTN71 SC 42

Example - Employee Promotion System

The provider of this AI system is a start-up in which, by its nature, flexibility and multiple employee roles are common.

For this AI system, the provider has chosen to integrate an **open-source** collaborative **Wiki/documentation** tool that allows version management of the information incorporated. Within the tool itself, **the people responsible** for each piece of documentation are indicated, together with a **guide** on how it should be incorporated, accompanied by this same document.

The provider has structured this platform in such a way that there is a main section serving as a nexus with the other sections related to the elements of this guide, and with links to facilitate the process and its management.

For access by the notified body, a controlled access has been established through its internal authorisation management system. Users of the system have an area of the wiki that is publicly accessible from the company's website, thereby ensuring that both the documentation and access to the tool itself are available to users within the same context.

SMEs or start-ups: : The technical documentation of the artificial intelligence system must cover all the aspects included in the guide. Since, in these companies, the same person often performs several roles, it is important to coordinate how the documentation process will be carried out. If harmonized standards and/or common specifications exist, it is important that these cover the required information to the greatest extent possible.

The technical documentation must be kept fully up to date on an ongoing basis once the AI system has been placed on the market and put into service, especially whenever updates are made to it, as will be detailed in this guide.

Example - Employee Promotion System

The system provider has included, within the life cycle processes of this AI system, a series of **milestones** aimed at **providing** the **necessary information** corresponding to each section of the **technical documentation**. Within their organization, each team has been assigned a **person responsible** for reviewing and keeping that documentation up to date. A **joint monitoring** mechanism has been defined among all responsible persons to coordinate efforts.

To manage the entire process, the provider has used a **centralized document management repository** in a commercial cloud environment already available to it, structured in folders according to the information described in this documentation guide, and containing a master document that references all information, its relationship with the AI Act, and its location in the various directories.

To enable access for notified bodies, a controlled level of access to all documentation has been established through the provider's authentication systems. In the public section of its corporate website, a download link has been made available for users (the General State Administration, Autonomous Communities, and local entities), consolidating all system information intended for them. This information is always kept up to date and synchronised with the repository.

Note: This guide does not refer to any specific commercial tool, as existing document management systems or repositories provided by technology suppliers are considered equivalent to one another. Likewise, the example of using a cloud environment is equivalent to an in-house system of the company that fulfils the same functions.

In this sense, the provider must implement the following measures, aimed at ensuring that documentation updates are agile, continuous over time, and reliable:

- Establish, within the management processes of the artificial intelligence system, a documented **procedure for monitoring changes**, ensuring that such changes are consistently reflected in the updated documentation.
- Define a clear **chain of responsibility** or designate a person responsible for managing system changes, who shall ensure that documentation is updated accurately and in a timely manner.
- Ensure that documentation of any modifications to the **AI system** maintains the same **level of completeness** and traceability as the rest of the technical documentation described in this guide.
- **Establish, define, and dimension** a document management system or an equivalent technical solution that guarantees proper retention, version control, and accessibility of documentation. The system must ensure that all documentation is retained for the required period and remains accessible to notified bodies for evaluation. Likewise, any technical documentation intended to serve as instructions for the deployer must be readily accessible to them.

The technical documentation must cover all elements related, at a minimum, to the requirements set out in **Chapter III, Section 2 of the European Regulation**, including the aspects described in the accompanying guides. It must provide a verifiable record of the actions, measures, metrics, and decisions taken throughout the AI system's lifecycle.

The documentation must encompass all relevant concepts addressed in this framework. The implementation of each measure proposed in the preceding guides must be accompanied by appropriate documentation, which shall be considered an integral part of the technical documentation, as specified in the corresponding sections.

Later in this guide, the specific contents of the technical documentation, as **defined in Annex IV** of the European Regulation on Artificial Intelligence, are detailed together with their relationship to the other accompanying guides. A proposed structure is provided to ensure parallelism with the Annex and facilitate compliance alignment.

The provider shall prepare the technical documentation in such a way that it contains all **information necessary to carry out the conformity assessment of the** AI system. This assessment shall be conducted either by a notified body or through a self-assessment

mechanism, as described in the **Conformity Assessment Guide** (see that guide for further details on the procedure).

Within the **sandbox framework**, a self-assessment of compliance with the requirements defined across all the guides will be performed. This includes a dedicated guide on the conformity assessment process that systems must complete before being placed on the market. In general terms (according to European Regulation on Artificial Intelligence in Annexes VI and VII) the conformity assessment process involves **the technical documentation** described in this guide, as well as the documentation of the quality control system (Article 17, quality management system, of the European Regulation on Artificial Intelligence). That is why the **preparation of the technical documentation** as developed in this guide has a **direct relationship** with the aforementioned **conformity assessment process**.

As indicated, **Annex IV** of the European Regulation on Artificial Intelligence defines the **minimum content** requirements of technical documentation that must be generated and maintained on a high-risk AI system. It establishes the necessary aspects for the minimum coverage of the technical documentation. An **inventory of all the necessary documentation must be made** and **kept centralized** and within **reach of those responsible for each area**. Relevant personnel must be notified of updates, and the organization and timelines for each section described in Annex IV must be clearly established.

SMEs and start-ups: Companies developing AI systems may vary significantly in size and may not always have sufficient resources or dedicated personnel to implement all processes described in full-scale governance frameworks. The European Regulation on Artificial Intelligence allows for the submission of **equivalent documentation**, provided that it demonstrably meets the same objectives and evidentiary requirements.

The guides included in this sandbox describe the measures to be followed in a detailed and explanatory manner. For smaller organizations, it is recommended to establish a **structured distribution of documentation tasks**, ensuring that each documentation activity is assigned to the person or team directly responsible for the specific topics addressed in the guides—or to the project or product manager, where applicable. **Covering** the sections of **Annex IV** of the European Regulation on Artificial Intelligence in this way, and meeting its minimum documentation requirements, constitutes an appropriate and proportionate approach for this category of companies.

The technical documentation for high-risk AI systems in Annex I, section A of the European Regulation on Artificial Intelligence must form part of the overall the documentation already required for the products regulated under the corresponding harmonised legislation. Providers of such systems should consider the following aspects:

- The necessary personnel resources, so current documentation processes used for conformity assessment encompass all aspects described in this guide. Where appropriate, it may be necessary to adequately train the responsible team or personnel, in order to achieve the documentation requirements indicated in Article 11 Technical documentation.
- The updating of existing documentation procedures so that they also account for the preparation of any additional documentation required under the AI Act.

As we have seen in the section said article, it ends in its third paragraph indicating that the **Commission will have the power to modify the content of Annex IV.** This implies that, since the documentation must be kept up to date, the provider must provide a procedure for monitoring changes in Annex IV that by virtue of Article 97, exercise of delegation, may be made to the legislation of the European Regulation on Artificial Intelligence and that may be applicable to it.

4.2 Retention of documentation

Article 18, retention of documentation, of the European Regulation on Artificial Intelligence establishes firstly, how long the documentation of the AI system must be kept, after putting into service, a period that will be 10 years.

AI Act

Art.18.1 – Documentation keeping

The provider shall, for a **period ending 10 years** after the high-risk AI system has been
placed on the market or put into service, **keep at the disposal** of the national competent
authorities.

This article includes other documentation that should be retained during this period.

AI Act

Art.18.1 – Documentation keeping

(a) the **technical documentation** referred to in **Article 11**;

(b) the **documentation concerning the quality management system** referred to in **Article 17;**

(c) the documentation concerning the changes **approved** by notified bodies, if applicable;

(d) the **decisions and other documents issued by the notified bodies**, if applicable;

(e) the **EU declaration of conformity** referred to in Article 47.

As previously indicated, the declaration of conformity will not be available during the execution period of the sandbox. However, information on its operation and procedural steps

will be provided within the sandbox through a dedicated guidance document describing how the conformity process will function.

The requirement to retain documentation for a period of 10 years obliges providers to select a storage format and medium that guarantees the integrity, accessibility, and durability of the documentation throughout that period. The **provider** must implement the necessary technical and organizational measures to ensure that documentation is properly preserved and safeguarded against loss, corruption, or unauthorized alteration.

Furthermore, as detailed in this same article, it must be kept available to the National Authorities in the format that they may have established.

Although not directly applicable to the sandbox, article 18, paragraph 2, retention of documentation, provides:

AI Act

Art.18.2 – Documentation keeping

Each Member State shall determine conditions under which the documentation referred to in paragraph 1 remains at the disposal of the national competent authorities for the period indicated in that paragraph for the cases when a provider or its authorised representative established on its territory goes bankrupt or ceases its activity prior to the end of that period.

Under no circumstances should the documentation retention requirements outlined in this section be interpreted as applying to other legal or regulatory obligations that the provider may have under different frameworks, such as the GDPR, sector-specific legislation, or any other applicable law governing the lawfulness of its activities. The purpose of this section and of this guide as a whole is strictly limited to the technical documentation obligations established under the European Regulation on Artificial Intelligence.

Following the completion of the sandbox phase, it is essential to maintain post-market monitoring consistent with future provisions that may be issued by the National Competent Authority, particularly regarding the manner and format in which technical documentation must remain accessible in order to ensure continued compliance with this requirement.

It must also be noted that a **provider**, or where applicable its authorized representative, is legally required to retain the technical documentation for a minimum **period of ten years**, even in cases of **bankruptcy, dissolution, or cessation of business activities.**

Example - Employee Promotion System

The provider, as mentioned, has chosen the collaborative Wiki platform for the management and organisation of the technical documentation. This system is hosted within the provider's own infrastructure.

To ensure compliance with the requirements of Article 18, retention of documentation, of the AI Act, as elaborated in this section, the provider has implemented the following measures:

- Migration to a high-availability infrastructure designed to guarantee continuous accessibility of the documentation within the organization, both for the personnel responsible for deployment and for the notified body.
- Provide the tool where the documentation resides with a backup mechanism that allows changes to be stored and retrieved. The last backup is stored in a cloud storage system, which ensures redundancy, to avoid losing data.
- Advised on the measure of retention of documentation, they decide to deposit before a notary, for a period of 10 years, the information of access to the persistent copy system, including access data.

In addition, it establishes a process of monitoring the regulations, to allow the provider to adapt to the request of the corresponding National Authority.

Providers that are financial institutions subject to requirements under Union legislation on financial services shall comply with the same criteria with respect to documentation for AI systems but shall retain the technical documentation as part already required under the legislation that applies to them. As indicated in the third paragraph of Article 18, Documentation keeping.

AI Act

Art.18.3 – Documentation keeping

Providers that are financial institutions subject to requirements regarding their internal governance, arrangements or processes under Union financial services law shall maintain the technical documentation as part of the documentation kept under the relevant Union financial services law.

5. Technical documentation

Article 11, technical documentation, establishes that **Annex IV defines the minimum content** that technical documentation must have. It begins by stating that:

AI Act

Annex IV – Technical documentation referred to in Article 11(1)

The technical documentation referred to in Article 11(1) shall contain at least the following information, as applicable to the relevant AI system:

In order to provide broad context for the reader of the guide, the full text of the Annex has been provided in section 3.2. *Technical Documentation referred to in Article 11, Section 1: Annex IV of the European AI Regulation*, within the annexes accompanying this guide, so that it can be consulted in its entirety and with all its parts in context.

This **section is presented as an example** of **the structure** that the technical documentation should have, for the AI system as a whole. In each section we will indicate which elements are covered in Annex IV and the necessary documentation to be applied to comply with these elements. In this way, this **section of** the **guide serves as an example** for the construction of documentation. Article 11, technical documentation, paragraph 1 and referring to SMEs, including start-ups indicates:

AI Act

Art.11.1 – Technical documentation

"[...] SMEs, including start-ups, may provide the elements of the technical documentation specified in Annex IV in a **simplified manner**. To that end, the Commission shall establish a **simplified technical documentation** form targeted at the needs of small and microenterprises. Where an SME, including a start-up, opts to provide the information required in Annex IV in a simplified manner, it shall use the form referred to in this paragraph. Notified bodies shall accept the form for the purposes of the conformity assessment.

The article establishes that an equivalent simplified documentation can be prepared, which meets the same objectives, making use of the simplified form that the Commission will establish.

Annex IV is extensive and detailed and is intended to specify what the technical documentation of the AI system must contain. In this section, in order to address the required level of granularity, the Annex has been divided into subsections. Within each subsection, the text of the Annex is broken down to assist in completing the required technical documentation, explaining each aspect.

Example - Aid granting automatic system

The provider has **structured** the **documentation** of the AI system *according* to the **eleven different sections** detailed in **this section** of the guide. In this way, a master document has been defined where initial information about the section and its location is structured, **associated with** a **structure** of folders and/or documents for each of the sections.

Likewise, based on these sections, **the** person responsible for **each of them has been established**. For example, section 5.2 has been assigned within the team of experts in AI and model development. Likewise, section 5.4 has been assigned to the risks management department.

Finally, as a guide for each of the **specific documents** per section (referenced in the master document), the **structure** for that section described in this guide **is used, aligned** with the content of **Annex IV.**

5.1 AI system overview

This section will have to contain the general description of the system, covering the information indicated in paragraph 1 of Annex IV of the European Regulation on Artificial Intelligence establishes that the contents that a general description of the AI system must have.

AI Act

Annex IV.1 – Technical documentation referred to in Article 11(1)

(a)its **intended purpose**, the **name of the provider** and the **version of the system** reflecting its relation to previous versions;

The **intended purpose** must indicate clearly and concisely:

- ✓ Description of the use for which the artificial intelligence system has been designed and developed.
- ✓ The context of use of said artificial intelligence system.
- ✓ The conditions of use of the system.

The **name of the provider,** the documentation will contain information about the qualification of the human resources used for the development of the system. It must indicate:

- ✓ The role or roles of the person in the context of the conception, implementation and life cycle of the AI system. Taking as a reference at least the following areas:
  - Data actors: profiles that act on the data that feeds the learning of the AI system (Data Analysts, Data Scientists, Computer Engineers, AI Experts, etc.);
  - Actors on the configuration and operation of the AI system (AI Experts, Computer Engineers, AI system administrators, System Analysts, ML Experts, etc.);
  - Developers of integration and/or interaction with the AI system (Including MLOps, if applicable) (Computer Engineers, Developers, etc.);
  - System administration actors that host and operate the AI system (AI system administrators, system analysts, etc.);
  - Actors on the conception, design, implementation and maintenance of the software that materializes the AI system itself (AI researchers, computer engineers, developers, analysts, AI experts, etc.);
  - Actors on the architecture, administration and maintenance of the AI system in its life cycle, both during development and once it is launched (AI researchers, Computer Engineers, AI Experts, AI system administrators, ML experts, etc.)
- ✓ The specific qualification or qualifications in AI and in the field of computer engineering in general, with special mention of technical knowledge on artificial intelligence, data and data computing technologies. Optionally, experience may be included in addition to the qualification, especially in the case of researchers.
- ✓ Experts in the application domain of the AI system, who have participated in the design and development.
- ✓ Profiles related to the provider's services to those responsible for the deployment of the AI system (implementation, operation, maintenance and support of the AI system by those responsible for the deployment of the AI system.)

System Version

- ✓ In the system development process, in order to support proper and reliable versioning of the system, the provider shall technically establish version control and detail it in this section.
- ✓ The versioning system must be correctly defined, including in the version information or metadata the corresponding date and its relationship to previous versions.
- ✓ Both the version and the date must be those corresponding to the most recent version of the AI system; that is, the documentation submitted must be that corresponding to the version referred to and not to another. Changes will be documented in the Detailed description of the risks management system.

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Annex IV.1 – Technical documentation referred to in Article 11(1)

(b) how the AI system interacts with, or can be used to interact with, **hardware or software**, including **other AI systems**, that are not part of the AI system itself, where applicable;

Interaction with hardware

- ✓ Technology of interoperability with the physical element (Driver, API, direct access to device elements, etc.) If it is an interaction based on actuators, relays, or mechanisms that allow the AI system to interact with the outside, for example, the AI system triggers an audible and visual emergency warning alarm within a range of set outputs. In this case, indicate, where appropriate, the additional technical parameters that allow such interaction to be specified.
- ✓ Description of the information exchanged with this system. At least on the exchange format (calls, custom format, embedded in programming, etc.) and the set of information and types of data exchanged (e.g., binary, alphanumeric, direct communication by GPIO, or any other hardware/software communication format.)
- ✓ Information on the type of connection between the systems;
- ✓ Description of the interconnection mechanism of the AI system with the hardware; for example, whether it is parallel direct wiring, USB direct wiring, Coaxial direct wiring, over the internet, Wifi wireless communication, 5G wireless communication, VPN, ...
- ✓ In the case of input systems, a unique identification of the system (sensor, dedicated machine, dedicated computer, etc.) must be provided that is associated as a source to the data that may be stored or recorded as part of the operation of the AI system.

Interaction with the software

- ✓ System integration format: The software in question receives the output of the AI system or provides the input of the AI system.
- ✓ Interoperability information: In particular about the interaction mechanism (API, direct within the execution environment, etc.) and the format of the information exchanged by the systems. At least on the exchange format (XML, custom format, etc.) and the set of information and types of data exchanged (binary, alphanumeric, etc.).
- ✓ Description of the communication channel of the AI system with the software. For example, on the same machine, on another machine on a physical local network, on another machine in wireless mode, on another machine via VPN, etc.
- ✓ Location of the software element in relation to the AI system (execution in the same computational context, external service, external microservice).
- ✓ An indication of whether it is a proprietary service managed by the provider, or by the AI system's runtime, or is an external service owned by a third party that is accessed by the AI system as *a Software as a service*.

- ✓ In the case of software that generates data that is input to the AI system, a unique identification of the software must be provided that is associated as a source to the data that is stored or recorded as part of the operation of the AI system.

AI Act

Annex IV.1 – Technical documentation referred to in Article 11(1)

(c) the versions of **relevant** software or firmware, and any requirements related to the version upgrades;

The technical documentation must contain a **list of both software and firmware,** which integrates the AI system. This includes information on the versions of **libraries**, **software components**, or **third-party elements**, whether in open-source format (in any of their licensing versions) or as commercial elements that may have been incorporated for the development of the AI system and are part of it. For each of these elements, the following must be included:

- ✓ Software identification: your identifying name, or trade name if applicable, type of software and level of data protection incorporated.
- ✓ Component element version.
- ✓ Date of incorporation and date of update.
- ✓ In the case of firmware components (microprograms) the hardware component to which they may be related.

During the life cycle of an AI system, updates can be made to its **software and/or firmware components, without** these affecting its **intended purpose**. The information described above must always be kept up to date according to these updates and keeping a history of versions of the AI system and their relationship with component versions in a clear way, for example, in a table.

The provider shall provide a schematic that includes all the software and hardware components related to the AI system, and shall indicate for each of them whether it is fully algorithmic in nature (non-AI) or whether it is AI in nature within the meaning of Article 3.1 of the European Regulation on Artificial Intelligence:

- ✓ Software components that make up the AI system.
- ✓ Software elements that interoperate with the AI system but are not part of the AI system.
- ✓ Hardware elements that interoperate with the AI system but are not part of the AI system.

AI Act

Annex IV.1 – Technical documentation referred to in Article 11(1)

(d) the description of all the forms in which the AI system is placed on the market or put into service, such as software packages embedded into hardware, downloads, or APIs;

For each **form of marketing** that the artificial intelligence system has, at least the following information must be provided:

- ✓ Indicate the marketing modality in terms of systems: Software installed on the deployer's own systems (*on-premise*); Software installed in Infrastructure as a Service (IaaS) mode, *Software* installed in the deployer's cloud, Software installed in the provider's or third-party cloud (distributors, etc.), other Software *as* a Service (SaaS) modalities, or in other formats such as *edge-computing*.
- ✓ Inform of the duration of the leave, if it exists and its format.
- ✓ If the AI system is integrated into hardware, indicate how this hardware is marketed.
- ✓ In the case of an Annex I A system, indicate the marketing formats of the product that the AI system may be or of which it may be a part.

Each of these categories requires adding additional information.

For SaaS marketing formats

- ✓ Indicate the interoperability technology of access to the SaaS system: API, direct interface, interconnection with the customer's systems.
- ✓ The different commercial levels of use of the AI system: their associated characteristics: Maximum daily requests, per second or any measurement format that has been selected to characterize and limit access.
- ✓ Indicate whether the AI system shares hardware for multiple deployers, or is instantiated individually for each deployer on specific, isolated hardware systems.

Installable merchandising formats

- ✓ Information on the format, periodicity and policy of updates, indicating whether they are included in the product or not.
- ✓ Access format to the system itself for installation on the deployer's systems: download, direct distribution, etc.
- ✓ If the AI system has support for the installation process by the provider.
- ✓ If the marketing includes a service in which the provider is responsible for managing and installing the system at the deployer's facilities in whole or in part.

Safety element of a product Annex I A of the European AI Act, or as an Annex II A product itself

- ✓ Information on the product acquisition format.

- ✓ Service information, if any, on product maintenance, in particular applicable to the AI system.
- ✓ As it is a product, indicate whether the AI system is directly integrated into it, or the product is remotely interoperated with the AI system.

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Annex IV.1 – Technical documentation referred to in Article 11(1)

(e) the **description of the hardware** on which the AI system is intended to run;

The **hardware description** must contain at least:

- ✓ The net resource requirements and recommendations for the operation of the AI system in terms of computing capacity (processors and/or machines and features) and storage (RAM, cache, secondary memory and its type). At least the minimums will be established, and those recommended for different configurations of use may be indicated. Where appropriate, with the indication of the role in the architecture of the AI system of the machine or machines that are going to be used for its execution, as well as its physical characteristics and operating systems.
- ✓ The machine or machines that are going to be used for its execution and the characteristics of these.
- ✓ Where appropriate, the characteristics of the network necessary for the operation of the system (bandwidth, availability, latency, etc.) will be indicated, both at the minimum and recommended level.
- ✓ The characteristics of secondary storage resources for the operation of the AI system will be specified: size, speed, availability, fault tolerance, etc. In the event that there is a requirement for file management or database management technology, the technology and, if applicable, the product and version will be indicated.
- ✓ The recommended hardware required for different configurations of use shall be described, in particular in relation to the expected volumes and intensities of data input into the system and the response times established in its design, and such times shall be indicated.
  If the artificial intelligence system is part of or embedded within a specific hardware in which it is distributed (i.e., included within equipment). The design elements and description of the components used must be provided. In these cases, this type of level of detail of description may already be covered by the conformity assessment requirements already applicable to the product, within the harmonised legislation that is applicable to it in accordance with Annex II A.

AI Act

Annex IV.1 – Technical documentation referred to in Article 11(1)

(f) where the AI system is a component of a product, photographs or illustrations showing external features, the marking and internal layout of those products;

The section is clearly prescriptive in what is required. In these photographs or images (product designs) it must be mentioned that:

- ✓ For external features, images must show the entire product.
- ✓ The location of the marking should be clearly highlighted.
- ✓ The internal layout will indicate those parts or components that correspond to the artificial intelligence system, to distinguish it from other elements accessory to the system.

AI Act

Annex IV.1 – Technical documentation referred to in Article 11(1)

(g) a basic description of the user-interface provided to the deployer;

(h) instructions for use for the deployer and a basic description of the user-interface provided to the deployer, where applicable.

General instructions for use are addressed to the person responsible for deploying the system. Each accompanying guide on requirements for compliance with Chapter III, Section 2, indicates in detail and in detail how to generate instructions. It is important that, although in this section it may seem that it is redundant with others in the technical documentation itself, here we are referring **to the instructions of the AI system for the deployer** it is important to remember at this point that the European Regulation on Artificial Intelligence is the deployer it is considered the company or institution that uses it and not the end user or operator, so the instructions of the system have to take into account this high-level aspect and address it vertically, so that from the person responsible for the deployment (according to the European Regulation on Artificial Intelligence) to the *end* user or operator, have the necessary scope in the instructions.

Whereas the instructions in each guide should be indicated for its scope, these instructions should contain at least:

- ✓ The clear indication that it is an artificial intelligence system.
- ✓ Information on how to interpret the results, accompanied by examples of uses and results.

- ✓ A description of the level of human supervision of the system, and how it is expected to be performed, as described in the supervision guide. The instructions will include all aspects related to this aspect of application to the deployer in the use of the AI system.
- ✓ Depending on the level of human supervision available to the system, explanation of the mechanism for overriding the system's decision or its intervention.
- ✓ Appropriate information for the deployer, according to the metrics described in the accuracy guide.
- ✓ Regarding the transparency of the AI system, it must contain information on the use cases according to the intended purpose, and those potential use cases that are not recommended indicating reasonably foreseeable misuses. As for its operation, it should include: performance and accuracy of the system, biases, the possibility of attacks on the AI system and a description of the data used.
- ✓ Regarding transparency of the AI system, it should contain information about the configuration of the system's training data where any, as well as validation data. If the system is knowledge-based, provide information on the hypotheses of applicability.
- ✓ Learn how to interpret AI system event and recording files.
- ✓ Application information to the deployer on the risks analysis regarding potential harms and benefits, especially applicable to certain demographic groups, if they fall within the application domain.
- ✓ Information about potential biases in the system and their risks.
- ✓ In any scenario, the documentation must be versioned and updated with respect to the version of the AI system to which it refers.

If your system has a **user interface** it should be added to the general instructions:

- ✓ The description of how the system is interacted, with a description of the elements of the interface and their functionalities. If applicable, a description of how to manage user roles/levels and how they act on the system.
- ✓ Relationship between the elements of the interface and the intended purpose of the system, with a clear interpretation of the information.
- ✓ Indicate how many languages the interface is available in and the number of languages with which the system can operate.
- ✓ Indicate, if implemented, the level of accessibility of the system in such a way that the interface, if required, is inclusive of minorities with functional diversity.
- ✓ Detailed description of how to obtain from the user interface itself the necessary information to be able to interact correctly and satisfactorily with the system.

Instructions for use for **products covered by Annex II section A.** Since these products already have their specific harmonised legislation (indicated in Annex I A), the instructions for use already established should be extended to add and include the general aspects described.

Installation instructions; Applicable to artificial intelligence systems depending on their form of commercialization, installable and/or configurable by the deployer in their systems (or*n-premise, in-house, in-cloud* or *edge-computing*, for example)

- ✓ The indications of the hardware system required for the execution of the system in relation to its volumes, as described in section (e) of this same section.
- ✓ The indications of the software components required for the execution of the system.
- ✓ In the case of having production, development and/or testing environments of the AI system, the configuration specification of these environments.
- ✓ Step-by-step instructions on installation processes and mechanisms.

- ✓ Those cybersecurity measures related to AI applicable to the system, as described in the cybersecurity guide, to be considered in the installation process, applicable to the person responsible for the deployer.
- ✓ Information about the implementation and configuration mechanism of system records as indicated in the records guide, required in the installation process.
- ✓ Applicable information to the deployer, for the management of records storage in relation to the indications in the records guide).

Example - Aid granting automatic system

The provider has allocated a specific area of the AI system Wiki in such a way that the instructions for the end user are integrated into it. In order for these instructions to have more effect, it has decided to involve the UX *user experience department*, to facilitate the understanding and handling of them. As a result of this collaboration, they decide to add a step-by-step guided process to facilitate installation. For the instructions on the interface side, a series of explanatory videos have been added.

5.2 Detailed description of the elements and processes of the AI system

Paragraph 2 of Annex IV provides a list of aspects that should be covered in detail.

This section of the technical documentation requires more extensive detail than the previous section. In this section the relationship with the content already described in other guides is more direct, and it will be in this section where the documentation that each guide has defined must be included.

AI Act

Annex IV.2 – Technical documentation referred to in Article 11(1)

(a) the methods and steps performed for the development of the AI system, including, where relevant, recourse to pre-trained systems or tools provided by third parties and how those were used, integrated or modified by the provider;

Methodology in the development process.

There is extensive literature for existing methodologies in the field of artificial intelligence system development (e.g., *Machine Learning*, logical representation and knowledge, statistical models, etc. included in Article 3.1 of the European Regulation on Artificial Intelligence). The documentation must include the adequacy of the selected methodology to the intended purpose of the AI system and its nature.

The technical documentation must contain, at least:

- ✓ A description of the process of selecting the AI approach or model selection, and if applicable the learning format used, e.g. supervised or unsupervised.
- ✓ The detailed description of the architecture used in the model selected for the AI system, with all the necessary elements for its description and detail, which depends on the different types of possible model.
- ✓ A detailed description of the steps taken during the development of the software that implements the AI system, starting with the decision of the technological model (development on existing platforms, MLOps, own development...) indicating the design stages, the selection processes and the general development methodology used. For example, traditional or agile development methodologies and their specific type.
- ✓ A detailed description of how the model is to be trained to achieve the established robustness and accuracy metrics; in the case of ML-based AI systems, describe the training conditions of the system and how the established metrics are guaranteed.
- ✓ Detail of the model refinement process, and its relationship with the experiments carried out.
- ✓ An enumeration of the experiments carried out, and the validation criteria of these experiments and their impact on the choice of the model. In this section, the list of tests and methodology will be detailed, as the details of the tests will be carried out in section (d) later in this section.
- ✓ A description of how the versioning criteria of the models are established, for their control and monitoring.
- ✓ Regarding the data, add in the technical documentation, a summary description of the configuration of the original data and the data already processed and prepared for analysis, the description of the data processing mechanisms within the development process. Thus, a data versioning mechanism should be established and reflected in the technical documentation.
- ✓ Likewise, regarding the data, a description of the typology and form of construction of the training data, and the design considerations that are related to the data used for the training of the system.

Systems pre-trained by third parties. To reflect how they have been used and integrated by the provider, the technical documentation must contain:

- ✓ If the AI system uses pre-trained model(s); the motivation for the selection of such models, the advantages they bring to the development process, and the measures taken to mitigate their drawbacks or risks. This will apply regardless of the pre-training level of such models.
- ✓ If the AI system uses a model without pre-training, but whose base technology is developed by a third party, the same criteria as the previous point will be applied.

- ✓ In both cases, the version of the pre-trained system must be indicated, a reference to its documentation and the indication of whether the provider of said system has developed it following the guides of a high-risk AI system, or with the possibility of being used to implement a high-risk AI system.
- ✓ Any modifications or adaptations shall be detailed, indicating their motivation in relation to the intended purpose of the AI system.

AI Act

Annex IV.2 – Technical documentation referred to in Article 11(1)

(b.1) the design specifications of the system, namely the general logic of the AI system and of the algorithms; the key design choices including the rationale and assumptions made, including with regard to persons or groups of persons in respect of who, the system is intended to be used;

System design specifications. The technical documentation in this section must relate the intended purpose of the AI system, described above, with the design specifications, in such a way that **the purpose** serves as a **motivation** for the establishment of the specifications. It must be detailed at least:

- ✓ Relate the specifications of the system to the intended purpose.
- ✓ Indicate the selection of metrics, as set out in the accuracy and robustness guides used to establish the system specifications, indicating their motivation and associated ranges.
- ✓ The expected processing time in the system design, and whether the system processes in real time, in a time interval defined as response time, or if the system performs post-processing of the data.

Foundations and assumptions in relation to people or groups of people. This section must reflect at least:

- ✓ Assumptions about the domain of input data and the relationship of these hypotheses to system design decisions. For example, in the case of using an employee promotion system, in the non-quantitative input data, the hypothesis of a *bag of words* analysis is established that includes a list of positive words (*good, correct, efficient, etc.)*, with their statistical frequencies, to assign them values that will be used later in the process.
- ✓ If the data that the AI system is going to use as input data is from natural persons, detail the assumptions related to these groups, and explain their relationship to the intended purpose.
- ✓ In relation to human supervision. Those assumptions considered in the design of the operation of the system, its human supervision interface and the AI/Human system interaction will be detailed.

AI Act

Annex IV.2 – Technical documentation referred to in Article 11(1)

(b.2) [...] main **classification choices**;

- ✓ For systems that classify into discrete categories, a detailed description of the different classification categories and their relationship to the intended purpose.
- ✓ In the event that the system itself does not establish a classification, but performs an interpolation, estimation or any other operation on a continuous variable, the range of the input and output values of the system, and their relationship with the intended purpose.
- ✓ If the system is not in either of the above two cases, indicate this in this section of the technical documentation. Detailing the domain and expected context of its response. For example, in a conversational system intended to guide the curricular adaptation of a secondary school student's education, indicate that he or she has been trained for the subjects of mathematics and science, but not for those corresponding to language and history, so it is expected that the answers in these areas will either not be accurate or cannot be provided.

AI Act

Annex IV – Technical documentation referred to in Article 11(1)

(b.3) [...] what the system is designed to optimize and the relevance of the different parameters;

In those cases, in which the system **performs an optimisation**, in this section the intended purpose already described will be related to the objective of the optimisation. It must be considered to establish the relationship, therefore, between:

- ✓ The type of model used (ML, statistical, etc.), with a low-level detail of the associated architecture of the model used in the AI system.
- ✓ The variant of the model used (for example, in supervised vs. unsupervised ML, or other possibilities such as reinforcement learning, deep learning...), developing a diagram that indicates how it interacts with all the inputs and outputs and other elements of the AI system itself as a whole.
- ✓ All the parameters of the system, in relation to the model used. For each parameter, its importance and its relationship with the optimization objective must be described.

For example, in an AI system that controls an insulin pump to establish the optimal value to provide to the patient, indicate that a supervised model, based on an RNN, has been used to

predict temporal trends, and that the parameters of blood pressure, pulse and blood sugar have been selected as the most significant with respect to the patient's immediate needs, ruling out blood oxygen saturation due to its difficulty of measurement and inaccuracy.

AI Act

Annex IV – Technical documentation referred to in Article 11(1)

(b.4) [...] the description of the expected output and output quality of the system; the decisions about any possible trade-off made regarding the technical solutions adopted to comply with the requirements set out in Chapter III, Section 2;

The European Regulation on Artificial Intelligence establishes in chapter III section 2 a series of requirements that require the application of specific technical measures, described and explained throughout all the guides of this sandbox.

Sometimes, the implementation of a technical solution may involve establishing a ***trade-off*** between possible approaches, due to the impossibility of absolutely satisfying all the possibilities. In the event that during the design of the system a compensation decision has been made between any of the aspects described in Chapter III, **such compensation shall be documented** by indicating:

- ✓ Aspects involved in compensation, related to the items involved, and these guides.
- ✓ Reason for the need to make compensation.
- ✓ Functional description of compensation.
- ✓ Technical description of the compensation.
- ✓ Consequences of applying the compensation and its relationship with the intended purpose.

Example - Aid granting automatic system

For example, in this AI system, the provider has indicated in the system's risks analysis the risk of excluding a family unit from the aid due to a false negative (in short, by mistake), and the consequences that it would have for the family. To mitigate this risk, in the design phase of the AI system, and during the definition of the accuracy metrics, it is decided that the system will slightly increase its false positive rate, to exclude the aforementioned risk. The provider documents this adjustment (or trade-off), according to the points indicated above and reflects it in the technical documentation.

Annex IV.2 – Technical documentation referred to in Article 11(1)

(c) the description of the system architecture explaining how software components build on or feed into each other and integrate into the overall processing; the computational resources used to develop, train, test and validate the AI system;

For the description of the **system architecture at the component level**, the design of the application and therefore its software component architecture, must be documented using:

- ✓ In the system of modeling components by layers of complexity, for example, the use of the **C4 system** is proposed, where the components are described from high to low level progressively, identifying artifacts, systems and actors.
- ✓ Use **UML design and modeling for the last level of component architecture** , in which software components and their interaction sequences are described at a low level.

For the architecture of the system at the level of **computer resources** , the following must be detailed:

- ✓ The server/computer architecture involved, the databases and the network interconnection between them. If there is a container architecture deployed on top of the aforementioned hardware architecture, detail and explain how container architecture relates to the physical architecture.
- ✓ Description using that architecture of the development, integration, and production environments. It will indicate whether these systems are isolated from each other, and the architecture mechanisms related to MLOPS.
- ✓ At any of the levels at which the hardware architecture is described, they must be related to what is reflected in section (e) of section 5.1.
- ✓ If it is an embedded AI system or one that is itself a product or is a safety component of a product covered by Annex II A, the **emulation** computing resources of the final environment of the system should be described.

The provider shall provide a schematic that includes all the software and hardware components related to the AI system, and shall indicate for each of them whether it is fully algorithmic in nature (non-AI) or whether it is in the nature of AI within the meaning of Annex 1 of the European Regulation on Artificial Intelligence:

- ✓ Software components that make up the AI system.
- ✓ Software elements that interoperate with the AI system but are not part of the AI system.
- ✓ Hardware elements that interoperate with the AI system but are not part of the AI system.

A standard reference for the description of the system architecture where aspects of the system are conceptually developed and which must be consulted for its application, *ISO/IEC 5392*

Information Technology – Artificial Intelligence – Reference Architecture of Knowledge Engineering. 6.3.1 Functional architecture of KE.

AI Act

Annex IV.2 – Technical documentation referred to in Article 11(1)

(d.1) where relevant, the data **requirements in terms of datasheets** describing the training methodologies **and** techniques **and the** training data sets used, **including** a general description of **these data sets**, information about their **provenance**, **scope** and **main characteristics**;

The information requested in the section is quite self-descriptive. The data used for training, testing and validation must be clearly described, following the guides of the data and data governance guide, which covers article 10, data and data governance, of the European Regulation on Artificial Intelligence.

The datasets shall be distinguished from each other by referring to different domains of application according to the intended purpose. Each dataset must have a descriptive sheet detailing:

- The proposed methodology used for the formation of the data.
  - General description of them. Clarifying the internal labels representing the data and associating them with their real meaning (for example, columns **labeled AGE could respond to the age of a patient, or** the age at which a disease is contracted.
  - Identify whether extension techniques or noise addition techniques have been used, if so, which ones. Indicate how the internal representation of the missing data is, in order to be able to correctly identify and interpret the missing data.
  - The data domain should be adequately described, identifying membership intervals and ranges for the data. Those discrete data or belonging to categories, establish and describe the categories of these.
  - The origin of the data must be recorded, indicating whether they have been obtained from public sources, from agreements with third parties, or collected by the company's own systems.

AI Act

Annex IV.2 – Technical documentation referred to in Article 11(1)

(d.2) [...] how the data was **obtained and selected**; **labelling** procedures (e.g. for supervised learning), **data cleaning** methodologies (e.g. outliers detection);

To complete the detailed information about the data, the following must be added in the documentation file:

- ✓ The origin of the data must be recorded, indicating whether they have been obtained from public sources, from agreements with third parties, or collected by the company's own systems. If these data followed a selection process with respect to the original source, it must be indicated how it has been carried out and whether it affects categories or the domain that the data may have.
- ✓ For supervised learning, the technique used for labelling and categorisation should be described, identifying the process that has been followed to label the data and relating it to the categories previously described in the technical documentation.
- ✓ In cases where the data are pre-processed to increase distribution and make the training of the model more robust, the procedure for increasing the data and its relationship with the intended purpose and design specifications of the AI system should be detailed in the file.
- ✓ Specify and describe in detail all the hypotheses that have been made in order to be able to pre-treat and clean the data before analysis and compare the characteristics of the original data with those of the pre-processed data.
- ✓ With regard to the pre-processing of the data, it is necessary to cover at least, in cases where the following is carried out:
  - Processing of missing data.
  - Impact of processing missing data on the distribution of input data
  - Identification, diagnosis and treatment of outliers.
  - Transformation of variables and derived variables.
- ✓ In cases where the data may contain outliers, the procedure for each of the deletion datasets used should be detailed and explained, indicating the reason for its deletion from the dataset and providing a sample copy of the deleted data.

The data governance guide, relating to Article 10, Data and Data Governance, refers to additional ways of documenting data and its categorization, the information in this section should be completed with what is described in said guide.

AI Act

Annex IV.2 – Technical documentation referred to in Article 11(1)

(e) **assessment of the human oversight measures** needed in accordance with Article 14, including an assessment of the **technical measures** needed to **facilitate the interpretation of the outputs of AI systems** by the deployers, in accordance with Article 13(3), point (d);

In the **human oversight guide** (article 14, human oversight) and the **transparency guide** (article 13, transparency and communication of information to those responsible for deployment) of this sandbox, a series of technical measures have been taken to achieve the requirements requested by the European Regulation on Artificial Intelligence. The

documentation of the technical measures generated in compliance with these guides must be included in this section.

The documentation submitted must indicate, at least:

- ✓ Description of the technical measures in a functional way.
- ✓ A detail of the user experience, indicating how it reports the results.
- ✓ The visual, sound, warning or any other mechanisms that may help to interpret the results provided by said interface and its operating ranges.
- ✓ The technical measures set out in the interface of the system, and in its operation, aimed at complying with the transparency requirements.

The aspects described here relating to the **documentation** of human oversight are exclusively **technical** (given the scope of this guide) and do not represent the total of applicable measures that will be described in the corresponding human monitoring guide and must be applied to the extent described, to cover the requirements of the European Regulation on Artificial Intelligence.

AI Act

Annex IV.2 – Technical documentation referred to in Article 11(1)

(f) where applicable, a **detailed description of pre-determined changes to the AI system and its performance**, together with all the relevant information related to the **technical solutions adopted** to ensure continuous compliance of the AI system with the relevant requirements set out in Chapter III, Section 2;

Throughout the lifecycle, the AI system **will have scheduled updates** aimed at **providing improvements**, **updating resources,** or **troubleshooting issues** that may have occurred. In any case, these improvements must be reflected in the documentation. It is important to bear in mind that each of the improvements must replicate, in those sections of the technical documentation that are applicable, what is explained in this guide for the entire AI system.

The information must contain, at least:

- ✓ A date of the change and entry into operation of the system.
- ✓ The identification of the system version.
- ✓ A description of the motivation for the change or changes implemented, as a recording of evolutionary changes.
- ✓ Records of changes to the AI system made in the update
- ✓ The update documentation must be self-contained in relation to all the documentation of the system, referencing in the areas in which it is applicable, the sections described here in this guide.
- ✓ Description of the results of the validation tests and their pre-post change/upgrade comparison, not only in terms of model accuracy, but also in terms of compute costs or data volumes.

Example – Employee Promotion System

During the use of the system, two large companies (insurance and banking), users of the AI system, have indicated that it is necessary to improve the time it takes for the AI system to analyse the data, given that both have a large volume of employees and several promotion periods throughout the year, so response times are essential.

To this end, new response time specifications are drawn up, which are sent to the AI system's design and implementation team.

The action involves an improvement in the response times of the system that has required various actions in different parts of the system; An *update sheet is prepared* covering the points described in this section (f). The card contains the following information:

- The date the change was made, when it goes into effect, as well as the version of the AI system that includes it.
- The information provided by the users of the system on the need for improvement is collected, with their comments and the need for this time to be shorter to speed up their evaluation processes.
- A record is collected of all the changes made to achieve the objectives described in the previous point. In this case, the following changes are included.
    - Updating of specific libraries to versions that allow parallel computing.
    - Adjustments to the component architecture to support parallel computation appropriately.
    - Modifications to the interface where the processing time of an individual employee is indicated.
- The technical documentation has also been adapted to reflect these changes, so in this *update sheet* it indicates the **sections** of the documentation **modified** and a **summary** of the reason for their modification:
    - In the overview (see 5.1) section (c) has been modified to indicate the new libraries used.
    - In the general specifications (see 5.1) in section (g), the instructions for use have been modified to reflect the information of the change in the interface.
    - The detailed description (see 5.2) section (c) updates the component interaction diagram to reflect the adaptation to parallel processing.
    - In the detailed description (see 5.2) section (g) the validation and testing processes have been adjusted to include the verification of the processing time, as well as using the processing time as an additional parameter of robustness.

It is important to bear in mind that these types of changes **require** a **relationship between** the **version** of the **AI system** and the documentation itself, as indicated in section 5.1.

AI Act

Annex IV.2 – Technical documentation referred to in Article 11(1)

(g.1) the **validation and testing procedures** used, including information about the **validation and testing data** used and their **main characteristics**;

The validation procedures used during the design of the system must be described, in order to consider that it achieves the intended purpose in the process. Testing should not be confused only with the evaluation of the model in relation to other parameters (e.g. robustness, accuracy or cybersecurity).

The documentation must record the **testing methodology** considering the AI system as a software artifact:

- ✓ Description of the scope of unit tests, both of the model itself and of the elements related to it and that are an integral part of the AI system and may affect its intended purpose, accuracy and robustness; regardless of whether you are AI/ML parts, for example: whether there is a process of pre-processing the data before the unit tests of the system are introduced into the system, indicating the percentage of code coverage.
- ✓ The integration tests carried out between the different components that make up the AI system, including the model and its interaction with the parts.
- ✓ Methodology used for testing the system interface intended for monitoring and/or configuration interfaces that the system may have.

Regarding the **validation and testing data** used to evaluate the model, the documentation must reflect:

- ✓ The nature of the data and its implicated variables. For example, if it is tabulated data, the different variables considered; if it is data in the form of images or audios, a description of its characteristics or duration.
- ✓ Indication of the dimensions of the total data set and the test, validation and assay distribution.
- ✓ Records changes to the dataset since its creation and throughout the life of the AI system, when these are modified. For example, a Git-like version control tool can be used for textual data.
- ✓ The relationships between the tests and the changes in the model that this could cause, and the value obtained in each test of the accuracy metrics.

In some standards that are currently under development, these aspects are addressed from a formal and regulatory point of view, such as *ISO/IEC 17847 Information technology – Artificial intelligence – Verification and validation analysis of AI systems*. There are also other already consolidated standards, which could serve as a guide in the testing phase of an AI-based system, such as ISO/IEC TR 29119-11:2020 Software and systems engineering – Software testing – Part 11: Guides on the testing of AI-based systems

(https://www.iso.org/standard/79016.html)

AI Act

Annex IV.2 – Technical documentation referred to in Article 11(1)

(g.2) [...] metrics used to measure accuracy, robustness and compliance with other relevant requirements set out in Chapter III, Section 2 […]

(h) the cybersecurity measures adopted

The guides corresponding to Article 15, relating to precision and robustness, define a series of metrics that allow defining the working ranges of the system and its behaviour, within the intended purpose. The selected metrics, their established ranges and their motivation must be reflected in this section of the documentation, accompanied by the generated documentation indicated in those guides.

The cybersecurity guide, also related to Article 15, accuracy, robustness and cybersecurity, establishes a series of controls to mitigate the risks of an AI system. In relation to this aspect, the documentation must reflect:

- ✓ The cybersecurity plan for AI established.
- ✓ The assets and actors identified.
- ✓ The vulnerabilities identified and the controls applied to the data for poisoning attacks.
- ✓ The vulnerabilities identified and the controls applied to protect against adversarial attacks.
- ✓ Vulnerabilities and controls for protection from attacks that use the model's defects.

The rest of the guides that accompany the sandbox also establish a series of requirements and define metrics to ensure compliance. These metrics should be reflected in this section. In relation to the rest of the guides, **whenever there is a technical measure** that has a metric for its monitoring, it must be reflected in this section.

AI Act

Annex IV.2 – Technical documentation referred to in Article 11(1)

(g.3) [...] as well as potentially **discriminatory impacts** […]

The data governance guide has established that an examination must be carried out in data processing "taking into account possible biases that may affect the health and safety of people or that lead to discrimination prohibited by Union law". In this regard, the technical documentation must have the result of the analysis carried out, indicating in particular the

discriminatory repercussions that may appear, related to the intended purpose, indicating the selected metric. According to the Data guide, these metrics may be:

- ✓ Parity differences.
- ✓ Unequal impact.
- ✓ Disparity in results.
- ✓ Difference in indicator features in predicted values.
- ✓ Difference in equal opportunities.
- ✓ Average odds difference.

Accompanied by a previous analysis of the training data from which the model is built, in order to put the indicated points into context. For this discrimination analysis, it is necessary to assess what types of data to collect and whether such collection is feasible within the framework of the intended purpose.

Likewise, the accuracy guide indicates that it is necessary to carry out tests to detect possible types of biases that the system may suffer affecting the accuracy for categories of data that may be discriminated, and how the same metrics provided at a global level of models to measure accuracy do not present unequal or disparate impact (*disparate impact*) for different groups belonging to sensitive variables. This analysis from the point of view of model accuracy, in relation to potentially discriminatory impacts, should be documented in this section.

Regarding the analysis of possible biases and cleanliness of the algorithm, the following regulatory standards are recommended:

- ISO/IEC TR 24027:2021, Information technology – Artificial intelligence (AI) – Bias in AI systems and AI aided decision making (https://www.iso.org/standard/77607.html)
- And currently under development the one related to the treatment of unwanted biases ISO/IEC AWI TS 12791 - Information technology – Artificial intelligence – Treatment of unwanted bias in classification and regression machine learning tasks

AI Act

Annex IV.2 – Technical documentation referred to in Article 11(1)

(g.4) [...] relevant requirements set out in Chapter III, Section 2, as well as potentially discriminatory impacts; test logs and all test reports dated and signed by the responsible persons, including with regard to pre-determined changes as referred to under point (f);

Throughout this section (g) of Annex IV, the **tests that have been carried out for the validation of the model** have been discussed, the documentation must have **records** of the information on the performance of the tests. Such information shall contain at least:

- ✓ The date of the trial.
- ✓ The version of the data that is related.
- ✓ The version of the AI system.

- ✓ The results of the trial.
- ✓ The signature of the persons responsible.

In the event that predetermined changes or updates have been made, the tests carried out must be incorporated and contain the same information.

5.3 Monitoring the operation and control of the AI system

Annex IV in its paragraph 3, indicates to the provider that the technical documentation must contain information on the monitoring and control of the system.

AI Act

Annex IV.3 – Technical documentation referred to in Article 11(1)

Detailed information about the monitoring, functioning and control of the AI system, in particular with regard to its capabilities and limitations in performance, including the degrees of accuracy for specific persons or groups of persons on which the system is intended to be used and the overall expected level of accuracy in relation to its intended **purpose**;

As stated in the AI system robustness guide, the documentation should include the possible **ranges** of **configurable model parameters**, input **and** output data **ranges**, as well as estimated latency and efficiency measurements to obtain the established robustness. The documentation should indicate the procedure used to properly monitor these defined ranges. The documentation must reflect the technical measures taken to record (see records guide) the information collected from monitoring.

The documentation must also contain:

- ✓ The minimum acceptable values for applicable robustness and accuracy metrics that should reflect and be a sign of the quality of the system.
- ✓ In the event that these cannot be guaranteed, the documentation will reflect the notification mechanisms of a possible interruption/shutdown of the system.
- ✓ You should explain how the system works in terms of the most common engagement challenges taken. For example, by indicating minimum guarantees that the system provides for known compromises: between global group impartiality and individual privacy (demonstrated).
- ✓ The documentation must establish the minimum expected guarantees, as well as those *commitments* that have proven not to be able to be guaranteed and that affect the result of the intended purpose, both in the input domain and in the expected values.

5.4 Undesired results and sources of risk

The focus of this section is on the appearance of foreseeable undesired outcomes and sources of risk. They are presented together in **paragraph 3** of Annex IV, but their conceptualization is different.

AI Act

> Annex IV.3 – Technical documentation referred to in Article 11(1)
>
> [...] the **foreseeable unintended outcomes** and **sources of risks** to health and safety, fundamental rights and discrimination in view of the intended purpose of the AI system;

Unwanted, foreseeable outcomes: This is an aspect that, throughout the European Regulation on Artificial Intelligence, is specifically mentioned in this section of documentation.

This type of result refers to responses of the system that, given their intended purpose, are unwanted, but that, given their design and characteristics, can be predictable, that is, a result that should not occur in any case, but that when the system makes the inference it can appear. For example, in a system of granting aid, denying them to a family group (being beneficiaries), because its parameters are incomplete or outside the training domain and the system is not prepared to analyse them; it is a predictable result, within the example, but not desired.

The **risks management system** guide, which covers Article 9, risks management system, of the European Regulation on Artificial Intelligence, details how to inventory, manage and document the risks associated with the concepts of health, fundamental rights and discrimination. The technical documentation must include a summary that covers all the risks identified in said process for the aspects indicated.

5.5 Human oversight measures

Paragraph 3 of Annex IV also indicates that technical measures of human oversight must be documented.

AI Act

> Annex IV.3 – Technical documentation referred to in Article 11(1)
>
> [...] the **human oversight measures** needed in **accordance with Article 14**, including the **technical measures** put in place to **facilitate the interpretation** of the outputs of AI systems by the deployers;

In the human monitoring guide, it is established that for the deployer to be able to interpret the output information, the following must be documented:

- ✓ The description of its accuracy, its typical failures, its causes and the confidence interval of the results.
- ✓ What **elements** are taken into account for decision-making.
- ✓ Simplified **guides for human supervision in the** form of a **leaflet** that include: what the system allows to be done, what are its appropriate uses, what cannot be done and what are the foreseeable inappropriate uses.
- ✓ The **documentation** should **contain examples** where the system can make disparate decisions and samples of cases where it fails or succeeds more.
- ✓ Insights into automation bias and how to avoid it.
- ✓ The aforementioned guide also proposes the development of an explanatory video for the human supervision process that can cover, in addition to the aforementioned elements, a detail of the operation of the human-machine interface (if any) of human supervision. The documentation must include a link or reference to that video.

5.6 Specification on input data

Paragraph 3 concludes by stating that the specifications of the input data should be provided.

AI Act

Annex IV.3 – Technical documentation referred to in Article 11(1)

[...] the **specifications on the input data**, as appropriate.

Technical description of the specifications expected in the input data, to have information on what the system is expected to receive as *input*. This technical description must contain:

- The expected format of the input data, indicating whether it is text, images, sounds, time series, tabulated data or any other type.
- The frequency of reception of these for which the system is designed, maintaining the specifications of robustness and response time.
- The validations carried out on such data that lead to it being discarded and not being entered into the system either for security reasons (investment or extraction attacks) or out-of-domain values.
- The manner in which such input data is recorded in the system, whether accepted or not, and in relation to the records-keeping system.

5.7 Description of the suitability of performance parameters

As indicated in paragraph 4 of Annex IV, the technical documentation should include:

AI Act

Annex IV.4 – Technical documentation referred to in Article 11(1)

A description of the **appropriateness of the performance metrics** for the specific AI system;

In accordance with the details provided in the accuracy and robustness guides, it is necessary to identify which of the parameters described there are most relevant to the specific AI system and to include a description of their suitability in the technical documentation.

5.8 Detailed description of the risks management system

As indicated in paragraph 5 of Annex IV, the technical documentation should include:

AI Act

Annex IV.5 – Technical documentation referred to in Article 11(1)

A **detailed description of the risk management system** in accordance with Article 9;

In accordance with the details of the risks management guide, the report resulting from its application and the associated documentation of controls and measures applied must be included in the technical documentation, as an integral part of the technical documentation.

5.9 Tracking of Changes Made

AI Act

Annex IV.6 – Technical documentation referred to in Article 11(1)

A **description** of **relevant changes** made by the provider to the system **through its lifecycle**;

This paragraph 6 sets out aspects equivalent to the corresponding section relating to the updates described in section 2(f) of Annex IV and previously described in section 5.2, and the same information indicated in that section must be replicated.

The documentation of each change made to the AI system must indicate the sections of the technical documentation that have been adapted to reflect the update made to the system and continue to maintain the requirement of completeness and updating in those cases in which the change affects any of the sections. In other words, in addition to the changes undergone by the AI system, their documentation must refer to the adapted sections of the documentation to adapt to these changes. Therefore, the technical documentation must relate the date of the AI system version and the version of the documentation, as indicated in section 5.1.

The aspects described in section 5.2 are applicable for relevant changes to reflect your documentation.

5.10 Harmonised standards or equivalent documentation

Paragraph 7 of Annex IV sets out the need for technical documentation to contain a list of harmonised standards used.

AI Act

> Annex IV.7 – Technical documentation referred to in Article 11(1)
>
> A list of the **harmonised standards applied in full or in part** the references of which have been published in the *Official Journal of the European Union*;

All harmonised standards used in planning, organisation, governance, design, implementation and commissioning shall be inventoried indicating the scope of application. Their references will necessarily be published in the Official Journal of the European Union. When available, they will be issued by the CEN-CENELEC https://www.cencenelec.eu/ https://www.cencenelec.eu/

Annex IV.7 – Technical documentation referred to in Article 11(1)

[...] where no such harmonised standards have been applied, a detailed description of the solutions adopted to meet the requirements set out in Chapter III, Section 2, including a list of other relevant standards and technical specifications applied.

Within the scope of the AI sandbox in which these guides are framed, **these harmonised standards** are not published, and other ISO or NIST reference standards are in the process of being developed. If it were the case that for the coverage of any of the sections described in the AI sandbox guides, one of these standards (ISO or NIST) had been published, it could be indicated to which section it corresponds and its application.

The Annex that accompanies this guide refers to those standards that have been consulted (as well as their relationship with the sections) for the **preparation of the documentation**. On the other hand, each of the companion guides of this documentation, and related to the aspects covered in them, make a compilation of the standards (in progress or applicable) that are also applicable to them.

If during the duration of the sandbox these harmonised standards, or other technical specifications, are not published, the actions and measures that each of the guides provided indicate for the aspects covered by Chapter III section 2 of the European Regulation on Artificial Intelligence must be included in the documentation.

5.11 Declaration of conformity

Paragraph 8 of Annex IV states that a copy of the EU declaration of conformity must be incorporated in the technical documentation.

During the period of the sandbox, this conformity procedure will not be established, as the notified bodies have not been defined, among other conditions. However, the sandbox is accompanied by a guide dedicated to conformity assessment, which establishes what needs to be done to obtain such conformity.

The technical documentation shall include this EU declaration of conformity, at the time it is available.

Below, we indicate the content that the declaration of conformity must contain, when the conformity assessment process is available, in accordance with the European Regulation on Artificial Intelligence.

The European Regulation on Artificial Intelligence establishes in Article 47 of the *EU Declaration of Conformity*, in paragraph 1.

AI Act

Art.47.1 – EU Declaration of Conformity

The provider shall draw up a **written machine readable, physical or electronically signed EU declaration of conformity** for each high-risk **AI system**, and keep it at the disposal of the national competent authorities for **10 years after the high-risk AI system has been placed on the market or put into service**. The EU declaration of conformity shall identify the high-risk AI system for which it has been drawn up

The content of this declaration of conformity is indicated that it must refer to Annex V of the European Regulation on Artificial Intelligence, as indicated in paragraph 2 of the aforementioned article.

AI Act

Art.47.2 – EU Declaration of Conformity

The EU declaration of conformity shall state that the high-risk AI system concerned **meets the requirements set out in Section 2**. The EU declaration of conformity **shall contain the information** set out in **Annex V.**

In addition, paragraph 3 of Article 47, which applies to AI systems in Annex II, as such AI systems are subjects to other harmonisation legislation of the European Union, a single declaration shall be established and this shall contain all the information necessary to identify the harmonisation legislation applicable to the declaration of conformity.

In accordance with Annex V of the European AI Regulation, the declaration of conformity must contain:

1. Name and type of the AI system, and any information that allows the AI system to be identified and unambiguously traced.
2. Name and address of the provider. If the provider has an authorised representative, this information must be added as well.
3. The provider must indicate a paragraph stating that this conformity assessment is issued under its sole responsibility.
4. It must also affirm that the AI system is in compliance with the European AI Regulation. To this end, the conformity assessment process has had to be passed, the details of this process are established in the **conformity assessment guide** that has been provided in this sandbox.
5. Reference to the harmonised standards and/or common specifications for which conformity has been declared. This section within the declaration of conformity is equivalent to the indications described in this same guide in section 5.10.

6. As can be found in the conformity assessment guide in detail, the conformity assessment process may include the involvement of a notified body, in which case, the name and identification of that body should be appropriately identified. It is important to take into account that during the implementation of the AI sandbox, this notified body will not be established.
7. Place, date of issuance of the declaration with the name and position of the signatory.

5.12 Post-market monitoring system

As a final part of the technical documentation of the AI system, Annex IV in paragraph 9 establishes that the post-market monitoring system must be provided, in the following terms.

AI Act

Annex IV.9 – Technical documentation referred to in Article 11(1)

A **detailed description** of the system in place to **evaluate the AI system performance in the post-market phase** in accordance with Article 72, including the post-market monitoring plan referred to in Article 72(3).

The accuracy and robustness guides establish the technical measures for the evaluation of the system's performance. The documentation should reflect how those technical measures and associated metrics are evaluated throughout the life of the system, once it is put into production.

The post-market monitoring plan also establishes the necessary mechanisms and measures to be taken into account once it has been implemented, as established in **Article 72, post-market monitoring, of the European Regulation on Artificial Intelligence.** Such a post-market monitoring system shall be designed to cover the risks identified in the system. The measures taken must adequately document how they carry out the function of monitoring the risks detected.

The documentation of the post-market performance monitoring system should include the solutions adopted for the retention of records (Articles 12, records, and 19, archive of automatically generated records, of the European Regulation on artificial intelligence), as indicated in the relevant guide, **relating** such information **stored** with the **performance evaluation system**.

A post-market monitoring plan has been provided in the sandbox, as a guide for the completion of this section, together with the technical details already indicated above.

However, companies participating in the sandbox should note that according to **Article 72 Post-Market monitoring, paragraph 3** it is stated:

AI Act

Art. 72.3 – Post-market monitoring by providers and post-market monitoring plan for high-risk AI systems

[...] The Commission shall adopt an implementing act laying down detailed provisions establishing a template for the post-market monitoring plan and the list of elements to be included in the plan by … [18 months after the entry into force of this Regulation]. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 98(2).

Therefore, it is necessary to have special **vigilance of these provisions**, which may affect the technical documentation and the post-marketing monitoring plan.

6. Self-assessment questionnaire

To carry out a self-assessment of compliance with the requirements of the Artificial Intelligence Act referred to in this guide, a global self-assessment questionnaire has been generated with a series of questions with the key points to be taken into account with respect to the obligations dictated by the articles of the AI Act mentioned in this guide.

It will be necessary to refer to this document in order to carry out the section of the self-assessment questionnaire corresponding to this guide.

7. References, Standards & Norms

7.1 List of ISOs Consulted

This section presents a list of the ISOs consulted to help reference and structure the technical documentation. It is important to note that these standards have been consulted and referenced and are aligned with what is indicated in the European Regulation on Artificial Intelligence, regarding technical documentation covered in this guide, but they are not a generic prescription for compliance with the Regulation.

The ISO standards consulted were:

- **ISO/IEC 42001 Artificial Intelligence Management System**. This ISO contains important information on how to document properly, but not as a main focus, since its objective is the management system for AI development. The referenced aspects related to documentation have been contrasted with Annex IV of the European Regulation on Artificial Intelligence.
- **ISO/IEC 23894-2 Information Technology – Artificial Intelligence – Risk Management**. It has been consulted about its parallel relationship with a process that requires a high level of documentation but has less relationship with technical documentation. The risks management system itself, as detailed in its specific guide, already establishes an important documentation mechanism that extends to the technical documentation process with the guide to include the risks plan document, as indicated.
- **ISO/IEC 24027 Information technology - Artificial Intelligence (AI) - Bias in AI systems and AI-aided decision making.** It occurs in a similar way to the previous standard, its use is transparent through the documentation generated from the data guide. However, two sections of this have been used to support the analysis of the technical documentation necessary in the areas of bias and data.

The following table shows the relationship between ISO Standards and their sections versus Annex IV in relation to this document.

Iso	Relationship with Annex IV / Guide
ISO/IEC 42001 Artificial Intelligence Management System **B.4.2 Resource documentation**	It details how to comment on resources and a small detail on how to do it. Regulations: Annex IV paragraph 1 in full, paragraph 2(a), 2(b) and 2(c). Guide: Section 5.1 and sections (a), (b), and (c) of Section 5.2.
ISO/IEC 42001 Artificial Intelligence Management System **B.4.3. Data resources**	Establish a short list of documentation to be added to the data. Regulations: Annex IV paragraph 2(d) Guide: Section (d) in section 5.2.
ISO/IEC 42001 Artificial Intelligence Management System B.4.4 Tooling resources.	It provides information on how to document the use of the tools, particularly: models, algorithms, optimization methods, etc. European Regulation on Artificial Intelligence Annex IV: 2(a) Guide: Section (a) in section 5.2.
ISO/IEC 42001 Artificial Intelligence Management System **B.4.5 System and computing resources**	Information to document about the system and computing resources. European Regulation on Artificial Intelligence Annex IV: 1(b) and 1(e) Guide: Sections (b) and (e) in section 5.1.
ISO/IEC 42001 Artificial Intelligence Management System **B.4.6 Human resources**	Relating to the documentation of the human resources to be considered. European Regulation on Artificial Intelligence Annex IV: 1(a) Guide: Section (a) in section 5.1.
ISO/IEC 42001 Artificial Intelligence Management System **B.5.3 Documentation of AI system impact assessments**	Describes how to document the foreseeable impacts of the system. It also provides references to how to describe the purpose of the AI system. Regulations Annex IV: Paragraph 3 mainly, with details applicable to 1(a). Guide: section 5.4 and section (a) in section 5.1.

Iso	Relationship with Annex IV / Guide
ISO/IEC 42001 Artificial Intelligence Management System **B.6.2.2 Documentation of AI system design and development**	Specific section on recommended content for the technical documentation of the AI system. European Regulation on Artificial Intelligence Annex IV: Paragraph 2(a) and 2(b) Guide: sections section 5.2.
ISO/IEC 42001 Artificial Intelligence Management System **B.6.2.3 AI system verification and validation**	Brief indication of the documentation to be generated for verifications and validations. European Regulation on Artificial Intelligence Annex IV: Paragraph 2(g) Guide: Section (g) in Section 5.2.
ISO/IEC 42001 Artificial Intelligence Management System **B.6.2.5 AI system operation and monitoring**	The focus on the operation of this section provides details on how to document the usage portion of the AI system's lifecycle. European Regulation on Artificial Intelligence Annex IV: Partially paragraph 3 on monitoring and especially paragraph 8 on post-market monitoring. Guide: section 5.3 and section 5.11.
ISO/IEC 42001 Artificial Intelligence Management System **B.6.2.6 AI system technical documentation**	It establishes in a summarized way the needs for technical documentation. European Regulation on Artificial Intelligence: Annex IV paragraphs 1 and 2 in full, but in a distributed way throughout them because it establishes in a very summarized way the needs. Guide: sections 5.1 and section 5.2.
ISO/IEC 42001 Artificial Intelligence Management System **B.8.2 System documentation and information for users**	Regarding the information for those responsible for the deployment, a list of what the documentation must contain. European Regulation on Artificial Intelligence: Paragraph 1(g) Guide: Section (g) in section 5.1.

Iso	Relationship with Annex IV / Guide
ISO/IEC 23894-2 Information Technology – Artificial Intelligence – Risk Management	The relationship with the technical documentation is *made transparent* through the indication of the AI Regulation to incorporate the information on risks. European Regulation on Artificial Intelligence: Paragraph 4 Guide: section 5.8.
ISO/IEC 24027 Information technology - Artificial Intelligence (AI) – Bias in AI systems and AI-aided decision making **9.2.6 Selection and documentation of data sources**	Basic indications of how to provide technical documentation of the aspects related to the data. European Regulation on Artificial Intelligence: related to the data aspects described in paragraph 3. Guide: section 5.6.
ISO/IEC 24027 Information technology - Artificial Intelligence (AI) – Bias in AI systems and AI-aided decision making **9.3.3 Transparency tools**	Basic indications of how to document the aspects of the transparency tools. European Regulation on Artificial Intelligence: Annex IV, paragraph 1(g) and 2(e) on points related to transparency. Guide: corresponding sections in section 5.1 and section 5.2

In addition, the following references to standards are added, in order to better contextualize the guide in the ISO/IEC international regulatory framework:

- ISO/IEC 22989 - Information technology – Artificial intelligence – Artificial intelligence concepts and terminology
- ISO/IEC 5339 - Information technology – Artificial intelligence – Guidance for AI applications
- ISO/IEC 5338 - Information technology – Artificial intelligence – AI system life cycle processes
- ISO/IEC 24368 - Information technology – Artificial intelligence –
- Overview of ethical and societal concerns

In the same way, as they are indirectly related to the European Regulation on Artificial Intelligence and the relevance to the compliance process, two regulatory references related to conformity are included, which are being worked on by CEN/CENELEC in the new regulatory framework.

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