SLOVENSKI STANDARD
SIST EN 18286:2026

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Umetna inteligenca - Sistem vodenja kakovosti za namene regulativnih zahtev Akta EU o UI

Artificial intelligence - Quality management system for EU AI Act regulatory purposes

Künstliche Intelligenz - Qualitätsmanagementsystem für EU-AI-Act-Regulierungszwecke

Intelligence artificielle - Système de management de la qualité pour le règlement européen sur l'IA

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Artificial intelligence - Quality management system for EU AI Act regulatory purposes

Intelligence artificielle - Système de management de la qualité pour le règlement européen sur l'IA

Künstliche Intelligenz - Qualitätsmanagementsystem für EU-AI-Act-Regulierungszwecke

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European foreword

This document (EN 18286:2026) has been prepared by the Joint Technical Committee CEN/CLC/JTC 21 “Artificial Intelligence”, the secretariat of which is held by DS.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2027 and conflicting national standards shall be withdrawn at the latest by January 2027.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN-CENELEC shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a standardization request addressed to CEN-CENELEC by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies can be found on the CEN-CENELEC website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

0 Introduction

0.1 General

The EU's Artificial Intelligence Act (EU AI Act) [1] regulates *AI systems* through the product safety system established under the New Legislative Framework. An *AI system* that is classified as high-risk and must comply with the relevant EU AI Act obligations can be a product or a component of a product.

NOTE 1 Classification rules for high-risk *AI systems* can be found in the EU AI Act, Article 6.

AI systems must be in compliance with applicable *regulatory requirements* at the moment that the *AI system* is placed on the market or put into service. An *AI system* is placed on the market when it is supplied for first distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge. An *AI system* is put into service when it is supplied for the first use directly to the *deployer* or for own use in the Union for its *intended purpose*.

EXAMPLE 1 An in-house developed *AI system* is put into service when it is used internally.

EXAMPLE 2 An *AI system* is placed on the market when it is offered for sale on a website.

The *quality* management system defined in this document can be used by a *provider* for one or more *AI systems* that are intended to be placed on the market or put into service. *Quality*, in this context can be understood as compliance with all of the *regulatory requirements* of the EU AI Act.

Depending on the intended purpose of the *AI system*, sector-specific regulations including obligations for a *quality* management system, can apply. The *provider can* extend a *quality* management system following a sector-specific regulation in such a way that it fulfils the *requirements* of the EU AI Act regulation instead of using a separate *quality* management system.

EXAMPLE 3 Medical devices are commonly compliant to EN ISO 13485 [2] *quality* management system requirements. Incorporating the *requirements* of this document within the existing *processes* is desirable when achieving *compliance* with this document.

This document is intended for use by *providers* that provide *AI systems* irrespective of size, nature or location. The *requirements* and guidance in this document are, however, specifically tailored to support *providers* that operate inside of the European Union, and those located outside of the Union who are active in the European Union market or who intend to enter that market.

The *requirements* in this document are the practical implementation from specific *requirements* from the EU AI Act (see Annex ZA) by relying on state of the art practices from other widely used standards where possible (see informative references throughout this document).

The *quality* management system in this document is described in a way that the implementation can take into account the size of the *provider*, while providing the degree of rigour and level of protection required by applicable *regulatory requirements*.

Clause 1 defines the scope of applicability of this document, while Clause 2 identifies normative references essential for its application, although there are none in this document.

Clause 3 establishes the terms and definitions used throughout this document, including terminology related to management systems, the EU AI Act, *AI systems*, and *risk management*, to ensure consistent interpretation. References to how most of these concepts are based on other standards are also provided in Clause 3.

Clause 4 specifies the *requirements* for establishing, implementing and maintaining the *quality* management system, including the identification of *regulatory requirements*, determination of scope, strategy for regulatory *compliance*, and control of *documented information*. After reading the Introduction and Clause 1, this is a good place to start for readers new to management system standards.

Clause 5 addresses management responsibility, defining leadership commitment, *quality* policy, and the assignment of roles, *responsibilities*, and *authorities*.

Clause 6 focuses on planning, including actions to address *risks* to the *quality* management system and the setting and achievement of *quality objectives*.

Clause 7 describes the support *processes* required for the effective operation of the management system, covering resources, *competence*, communication and awareness.

Clause 8 addresses *AI system* realization, detailing *requirements* across the *AI system lifecycle*, not least the "design and development" and "verification and validation" phases as well as requirements regarding data management, retirement, identification of the *AI system* and product documentation. Clause 8 also contains a subclause on continuous learning *AI systems* and their predetermined changes.

Clause 9 covers operations and control, during deployment, including *monitoring*, supply chain management, change control, post-market *monitoring*, incident reporting, and handling of *non-compliance*.

Finally, Clause 10 specifies *requirements* for *performance* evaluation of the management system, including reviews and planning of changes to ensure ongoing *effectiveness* and *compliance*.

Annex A describes *procedures* for *consultation* with *interested parties* about risks to health, safety and *fundamental rights*, Annex B contains the correspondence between the clauses of this document and EN ISO 9001:2015 [3], and Annex C contains the correspondence with EN ISO/IEC 42001:2026 [4].

NOTE 2 Italicised terms are defined in Clause 3.

0.2 Verbal forms

In this document, the following verbal forms are used:

— "shall" indicates a *requirement*;

— "should" indicates a recommendation;

— "may" indicates a permission;

— "can" indicates a possibility or a capability.

0.3 Fundamental rights

The EU AI Act aims to ensure the protection of health, safety and *fundamental rights* in relation to *AI systems* and this document sets out technical *requirements* to achieve this regulatory objective through a *quality* management system.

Fundamental rights are universal legal guarantees without which individuals and groups cannot secure their fundamental freedoms and human dignity and which apply equally to every human being regardless of nationality, place of residence, sex, national or ethnic origin, colour, religion, language or any other status as per the legal system of a country without any conditions.

The EU Charter of Fundamental Rights [5] sets out and codifies the European approach to these *fundamental rights* in law which is applicable throughout the EU.

NOTE Further information about their scope and strength can be found in the Charter. Additional EU and country-specific *regulatory requirements* can apply.

1 Scope

This document specifies the requirements and provides guidance for the definition, implementation and maintenance of a quality management system for organizations that provide AI systems.

This document is intended to support the organization in meeting applicable regulatory requirements. It is primarily intended for organizations placing on the market or putting into service high-risk AI systems and is not specific to any particular sector.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp/

— IEC Electropedia: available at https://www.electropedia.org/

3.1 Terms relating to management systems

3.1.1
audit
systematic (3.1.30) and independent *process* (3.1.22) for obtaining evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled

Note 1 to entry: An audit can be an internal audit (first party) or an external audit (second party or third party), and it can be a combined audit (combining two or more disciplines).

Note 2 to entry: An internal audit is conducted by the *organization* (3.1.18) itself, or by an external party on its behalf.

Note 3 to entry: "Audit criteria" is defined in EN ISO 19011.

[SOURCE: ISO/IEC Directives Part 1, Consolidated ISO Supplement, Annex SL Appendix 2 (rev 4 2024), 3.1.18, modified — Removed "audit evidence and" from Note 3.]

3.1.2
authority
authorities
ability of an individual, group or *organization* (3.1.18) to do something without intervention by another function on the details of that action

3.1.3
competence
ability to apply knowledge and skills to achieve intended results

[SOURCE: ISO/IEC Directives Part 1, Consolidated ISO Supplement, Annex SL Appendix 2 (rev 4 2024), 3.9]

3.1.4
compliance
fulfilment of all applicable *regulatory requirements* (3.1.26)

3.1.5
control
measure that is modifying *risk* (3.4.5)

Note 1 to entry: Controls include any *process* (3.1.22), policy, device, practice, or other actions which modify *risk* (3.4.5).

Note 2 to entry: It is possible that controls not always exert the intended or assumed modifying effect.

[SOURCE:ISO Guide 73:2009, 3.8.1.1, modified — Note 2 to entry has been changed.]

3.1.6
corrective action
action to eliminate the cause(s) of a *non-compliance* (3.1.15) and to prevent recurrence

[SOURCE: ISO/IEC Directives Part 1, Consolidated ISO Supplement, Annex SL Appendix 2 (rev 4 2024), 3.17, modified — Changed “nonconformity” to “non-compliance”.]

3.1.7
documented information
information controlled and maintained by an *organization* (3.1.18) and the medium on which it is contained

Note 1 to entry: Documented information can be in any format and media and from any source.

Note 2 to entry: Documented information can refer to:

a) the management system, including related *processes* (3.1.22);

b) information created in order for the *organization* (3.1.18) to operate (*documented information*);

c) evidence of *compliance* (3.1.4) and results achieved.

[SOURCE: ISO/IEC Directives Part 1, Consolidated ISO Supplement, Annex SL Appendix 2 (rev 4 2024), 3.10, modified — Removed “required to be” from the definition, in Note 2 b) referenced documented information instead of documentation, in Note 2 c) added “compliance and” and removed reference to records.]

3.1.8
effectiveness
extent to which planned activities are realized and planned results are achieved

[SOURCE: ISO/IEC Directives Part 1, Consolidated ISO Supplement, Annex SL Appendix 2 (rev 4 2024), 3.13]

3.1.9
essential requirement
definition of the results to be attained, or the *hazards* (3.4.4) to be dealt with, without specifying the technical solutions for doing so

Note 1 to entry: Essential requirements in relation to the EU AI Act [1] are specified in Chapter III, Section 2 of that Regulation.

Note 2 to entry: Essential requirements are a subset of *regulatory requirements* (3.1.26).

[SOURCE: The Blue Guide on implementation of EU product rules 2022/C247/01, modified — Changed “but do not specify” to “without specifying”.]

3.1.10
harmonized standard
European Standard adopted on the basis of a request made by the Commission for the application of Union harmonization legislation

Note 1 to entry: A European standardization *organization* can develop a new standard, adopt an existing international standard or adapt an existing international standard.

[SOURCE: Regulation (EU) 1025/2012, Article 2(1)(c), modified — Removed “a”, added Note 1 to entry.]

3.1.11
interested party
stakeholder
individual, group or *organization* (3.1.18) that can affect, be affected by or perceive itself to be affected by a decision or activity

Note 1 to entry: *Affected persons* (3.4.1) are a subset of interested parties.

Note 2 to entry: Interested parties include relevant regulatory bodies, national public bodies, bodies that enforce the protection of *fundamental rights* (3.4.2) and market surveillance authorities.

[SOURCE: ISO/IEC Directives Part 1, Consolidated ISO Supplement, Annex SL Appendix 2 (rev 4 2024), 3.2, modified — In the definition, replaced “person” with “individual” and added “group”; added Notes 1 and 2.]

3.1.12
life cycle
evolution of a system, product, service, project or other human-made entity, from inception through retirement

[SOURCE: ISO/IEC/IEEE 15288:2023, 3.21, modified — Changed “conception” to “inception”.]

3.1.13
measurement
process (3.1.22) to determine a value

[SOURCE: ISO/IEC Directives Part 1, Consolidated ISO Supplement, Annex SL Appendix 2 (rev 4 2024), 3.19]

3.1.14
monitoring
repeatedly determining the status of a system, a *process* (3.1.22) or an activity using inputs including *measurements* (3.1.13)

Note 1 to entry: To determine the status, there can be a need to check, supervise or critically observe.

[SOURCE: ISO/IEC Directives Part 1, Consolidated ISO Supplement, Annex SL Appendix 2 (rev 4 2024), 3.20, modified — Added “repeatedly” and “using inputs including measurements” to definition.]

3.1.15
non-compliance
non-fulfilment of applicable *regulatory requirements* (3.1.26)

[SOURCE: ISO/IEC Directives Part 1, Consolidated ISO Supplement, Annex SL Appendix 2 (rev 4 2024), 3.16, modified — Replaced “a requirement” with “applicable regulatory requirements”.]

3.1.16
object
object of conformity assessment
entity to which specified *requirements* (3.1.27) apply

EXAMPLE Product, *process*, service, system, installation, project, data, design, material, claim, person, body or *organization* (3.1.15), or any combination thereof.

[SOURCE: EN ISO/IEC 17000:2020, modified — Switched preferred and admitted terms, removed Note 1.]

3.1.17
objective evidence
data supporting the existence or verity of something

Note 1 to entry: Objective evidence can be obtained through observation, *measurement* (3.1.13), test, or by other means.

Note 2 to entry: Objective evidence for the purpose of *audit* (3.1.1) generally consists of records, statements of fact or other information which are relevant to the audit criteria and verifiable.

[SOURCE: EN ISO 9000:2015, 3.8.3]

3.1.18
organization
entity consisting of a person or group of people that has its own functions with *responsibilities* (3.1.33), *authorities* (3.1.2) and relationships to achieve its objectives

Note 1 to entry: The concept of *organization* includes, but is not limited to, sole-trader, company, corporation, firm, enterprise, authority, partnership, charity or institution, or part or combination thereof, whether incorporated or not, public or private.

Note 2 to entry: If the *organization* is part of a larger entity, the term “organization” refers only to the part of the larger entity that is within the *scope* of the *quality* (3.1.23) management system.

[SOURCE: EN ISO 9000:2015, 3.2.1, modified — Added “Entity consisting of a”.]

3.1.19
performance
<quality management system> measurable result

Note 1 to entry: Performance can relate either to quantitative or qualitative findings.

Note 2 to entry: Performance can relate to the management of activities, *processes* (3.1.22), products, services, systems or *organizations* (3.1.18).

[SOURCE: EN ISO 9000:2015, 3.7.8, modified — Removed Note 3.]

3.1.20
policy
intentions and direction of an *organization* (3.1.18) as formally expressed by its *top management* (3.1.28)

[SOURCE: ISO/IEC Directives Part 1, Consolidated ISO Supplement, Annex SL Appendix 2 (rev 4 2024), 3.5]

3.1.21
procedure
specified way to carry out an activity or a *process* (3.1.22)

Note 1 to entry: Procedures can be documented.

[SOURCE: EN ISO 9000:2015, 3.4.5, modified — Removed "or not" from Note 1.]

3.1.22
process
set of interrelated or interacting activities that uses or transforms inputs to deliver an intended result

Note 1 to entry: Whether the result of a process is called an output, a product or a service depends on the context of the reference.

Note 2 to entry: Process can achieve an immediate result but can also consist of information-sharing or other activities.

[SOURCE: ISO/IEC Directives Part 1, Consolidated ISO Supplement, Annex SL Appendix 2 (rev 4 2024), 3.8, modified — Added Note 2; replaced "may" with "can" based on the use of verbal forms in standards.]

3.1.23
quality
set of characteristics of an *object* (3.1.16) that fulfils *regulatory requirements* (3.1.26)

Note 1 to entry: *Quality* includes the protection required by applicable *regulatory requirements* (3.1.26) aimed at ensuring and maintaining the protection of health, safety and *fundamental rights* (3.4.2).

Note 2 to entry: In the context of this document, *quality* pertains to regulatory *compliance* to at least the EU AI Act, including ensuring and maintaining the protection of health, safety and *fundamental rights* (3.4.2). It differs from the concept of quality in EN ISO 9001 which includes expectations of customers and other *interested parties* (3.1.11).

[SOURCE: EN ISO 9000:2015, 3.6.2, modified — In the definition, removed "degree of" and "inherent", and added "regulatory" to "requirements"; removed original Notes 1 and 2; and added new Notes 1 and 2.]

3.1.24
quality objective
measurable goal established to ensure that *regulatory requirements* (3.1.26) are consistently met throughout the *life cycle* (3.1.12)

Note 1 to entry: In the context of *quality* (3.1.19) management systems, *quality* objectives are set by the *provider* (3.2.5), consistent with the *quality policy* (3.1.20), to achieve specific results.

Note 2 to entry: An objective in EN ISO/IEC 42001:2026, 3.6 and EN ISO 9000:2015, 3.7.1 is a general result to be achieved. In this document, the term "quality objective" is linked specifically to the *regulatory requirements* (3.1.26).

3.1.25
quality policy
policy (3.1.20) related to *quality* (3.1.23)

[SOURCE: EN ISO 9000:2015, 3.5.9, modified — Removed notes.]

3.1.26
regulatory requirement
requirement (3.1.27) defined by applicable regulation and that is necessary to be met for the purposes of complying with the regulation

Note 1 to entry: Applicable regulation includes at least the EU AI Act [1]

Note 2 to entry: Applicable regulation also includes law and regulation aimed at ensuring and maintaining the protection of health, safety and *fundamental rights* (3.4.2).

3.1.27
requirement
need or expectation that is stated or obligatory

Note 1 to entry: A specified requirement is one that is stated, e.g. in *documented information* (3.1.7).

[SOURCE: ISO/IEC Directives Part 1, Consolidated ISO Supplement, Annex SL Appendix 2 (rev 4 2024), 3.14, modified — Removed “generally implied” from the definition, replaced Note 1.]

3.1.28
top management
person or group of people who directs and controls an *organization* (3.2.5) at the highest level

Note 1 to entry: Top management has the power to delegate *authority* (3.1.2) and provide resources within the *organization* (3.1.18).

Note 2 to entry: If the *scope of the quality management system* (3.1.29) covers only part of an *organization* of the *provider*, then top management refers to those who direct and control that part of the *organization* of the *provider*.

Note 3 to entry: In different *organizational* contexts, top management can be referred to with different terms.

Note 4 to entry: Where the *organization* is a person, top management is that person.

Note 5 to entry: In this document, top management refers to personnel of the *provider*.

[SOURCE: ISO/IEC Directives Part 1, Consolidated ISO Supplement, Annex SL Appendix 2 (rev 4 2024), 3.3, modified — Added “of the provider” to Note 2, added Notes 3, 4 and 5.]

3.1.29
scope of the quality management system
set of *AI system(s)* (3.2.1) that are covered under a *quality* (3.1.23) management system and the boundaries that define where the *quality* management system applies

EXAMPLE Boundaries can include physical (geographic), *organizational* (3.1.18), functional, *process*, system, service and interface boundaries.

3.1.30
systematic
pursuing defined objective(s) in a planned, step-by-step manner

[SOURCE: ISO/TR 18307:2001, 3.140]

3.1.31
validation
confirmation, through the provision of *objective evidence* (3.1.17), that the *requirements* (3.1.27) for a specific *intended purpose* (3.2.3) or application have been fulfilled

Note 1 to entry: The *objective evidence* needed for a validation is the result of a test or other form of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The word "validated" is used to designate the corresponding status.

Note 3 to entry: The use conditions for validation can be real or simulated.

Note 4 to entry: The concept of validation as a *procedure* (3.1.21) is not directly related to validation datasets used in machine learning.

[SOURCE: EN ISO 9000:2015, 3.8.13, modified — Changed "intended use" to "intended purpose" and added Note 4.]

3.1.32
verification
confirmation, through the provision of *objective evidence* (3.1.17), that specified *requirements* (3.1.27) have been fulfilled

Note 1 to entry: The *objective evidence* needed for a verification can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The activities carried out for verification are sometimes called a qualification *process*.

Note 3 to entry: The word "verified" is used to designate the corresponding status.

Note 4 to entry: Verification can rely on testing activities and results to provide *objective evidence*.

[SOURCE: EN 18228:—, 3.30]

3.1.33
responsible
responsibility
responsibilities
state of being accountable or answerable for an obligation

[SOURCE: EN ISO 17427-1:2018, 3.21, modified — Removed reference to other types of responsibilities.]

3.2 Terms relating to the EU AI Act

3.2.1
AI system
machine-based system that is designed to operate with varying levels of autonomy and that can exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments

Note 1 to entry: The verb "can" represents a possibility, not all AI systems that fit the above definition have this ability to adapt after deployment.

[SOURCE: EU AI Act (Article 3(1)), modified — Removed "a", replaced "may" with "can" based on the use of verbal forms in standards, added Note 1.]