

prEN 18286 - Primer

Artificial Intelligence - Quality Management System for EU AI Act Regulatory Purposes

What it is

prEN 18286 is a draft European standard being developed by CEN-CENELEC Joint Technical Committee 21 (JTC 21). It translates Article 17 of the EU AI Act - which requires providers of high-risk AI systems to establish, document, implement and maintain a quality management system (QMS) - into concrete governance, documentation, lifecycle, and evidentiary requirements.

"pr" means it is still a draft (proposé/proposed). It is not yet a formal harmonized standard and does not itself confer a presumption of conformity until it is adopted and its reference is published in the Official Journal of the EU.

Status & timeline

- 30 Oct 2025 - Draft released for the CEN/CENELEC enquiry stage (first AI Act harmonized standard to reach this stage), circulated to national standards bodies for technical comment.
- Enquiry phase ran through ~Jan 2026, gathering comments and assessing member-state support.
- Next steps: comment resolution, formal vote, and eventual publication - with a version sometimes referenced as prEN 18286:2025/2026 reflecting the ongoing revision.
- Most EU AI Act high-risk obligations apply from 2 August 2026, ahead of formal standard publication - so organizations are expected to build toward it now rather than wait.

Scope & structure

- Applies to AI system providers of any size, nature, or location placing systems on the EU market or into service in the Union.
- Targets deterministic AI systems with defined lifecycles and manageable risk profiles - not explicitly built for probabilistic/continuously learning systems such as LLMs, though guidance on applicability is still evolving.
- Contains 10 normative clauses and 5 informative annexes, covering governance, risk management, documentation, and lifecycle controls under Article 17.
- Designed to interoperate with existing frameworks: correspondence annexes map it to ISO 9001:2015 (quality management) and ISO/IEC 42001:2023 (AI management systems).

Why it matters for us

- Gives the clearest available blueprint for Article 17 QMS compliance ahead of formal publication - useful for shaping our compliance evidence now.
- Because it's still a draft, we should treat alignment as building readiness and evidence, not as a claim of legal presumption of conformity.
- Worth tracking the enquiry-comment outcomes and final vote, since clause numbering and requirements may still shift before publication.

Sources

CEN/CENELEC JTC 21 draft (30 Oct 2025); standards.iteh.ai catalog entry; CMS Law-Now briefing (Dec 2025); Lumenova AI breakdown (Nov 2025).

