

Shippable document and market access for high-risk AI systems

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Shippable documents are lifecycle work products, referred to as “*information items*” in ISO/IEC/IEEE 15289:2019 and as “*work products*” in ISO 26262:2018, that are prepared to be accurate, complete, traceable, and ready for scrutiny by assessors and certification bodies. In safety-regulated domains, shippable documents typically comprise (1) the safety case or certification report and its supporting references, (2) procurement information for products and systems, and (3) certification documentation. Inspired by the agile concept of “*shippable code*,” shippable documents operationalize regulatory compliance by providing review-ready, traceable evidence that can be continuously assessed against the requirements of the EU AI Act and applicable AI, safety, and cybersecurity standards.

Shippable documents enhance regulatory compliance, reduce documentation-related errors, and streamline certification processes. Examples include safety plans, hazard logs, and work products mandated by standards such as ISO 26262, ISO/PAS 8800, ISO 21448 (SOTIF), and IEC 61508, as well as standardized reporting forms such as IEC Test Report Forms, Compliance Report Forms, and documentation structures defined in IEC 61508-1. Their inherent structured traceability ensures transparency among stakeholders by maintaining verifiable links between requirements, analyses, test evidence, and validation results. Continuous readiness for incremental review supports proactive compliance and reduces risks associated with late-stage documentation gaps. By applying agile practices such as Definition of Ready and Definition of Done, organizations can iteratively improve clarity, completeness, and validation throughout the lifecycle. This paper examines the implementation and benefits of shippable documents as dynamic compliance tools for AI systems, highlighting their integration with existing safety and cybersecurity practices and their role in sustaining innovation without compromising safety.

Keywords: Market access, Safety case references, AI, Documents, Work Products, Compliance

1. Introduction

High-risk AI systems are subject to increasingly stringent regulatory requirements under the EU AI Act (2024/1689) and a growing set of AI, functional safety, and cybersecurity standards. Achieving compliance depends not only on sound engineering practices but also on lifecycle documentation that is complete, consistent, and traceable. In regulated domains such as automotive, rail, maritime, and offshore, documentation is typically fragmented across safety cases, certification reports, procurement material, and other work products (WPs), leading to excessive volume, inconsistent formats, and late-stage integration of compliance evidence.

To address these challenges, shippable documents have emerged as an adaptation of agile’s “*shippable code*” concept. Introduced by Myklebust et al. (2022), shippable

documents are WPs and information items that are accurate, traceable, and continuously ready for scrutiny. By enforcing structured traceability between requirements, analyses, tests, and validation results, they improve transparency and auditability while reducing redundant and low-value documentation.

When embedded in agile and incremental development, shippable documents align documentation evolution with engineering progress and support proactive compliance. Practices such as “*Definition of Ready*”, “*Definition of Done*”, and structured work-product reviews strengthen documentation quality, reduce rework, and improve certification readiness. However, challenges remain in aligning evidence across multiple standard families, maintaining traceability in agile environments, and ensuring consistent communication among stakeholders.

The contribution of this paper is threefold. First, it conceptualizes shippable documents as lifecycle WPs that bridge agile development practices with formal regulatory and certification requirements for high-risk AI systems. Second, it analyzes how shippable documents relate to the documentation expectations of major safety, cybersecurity, and AI standards, identifying practical alignment challenges relevant for conformity assessment. Third, it reflects assessor perspectives on documentation readiness and assessability, providing practice-oriented guidance on how documentation can function as authoritative compliance evidence across development, certification, and post-market phases. The topic is timely because high-risk AI systems are entering regulated markets faster than many organizations are able to produce documentation that is both agile in development and robust enough for external scrutiny. This paper therefore investigates the role of agile-aligned shippable documents in regulatory compliance and stakeholder collaboration, addressing the following research questions:

RQ1: How can agile-aligned shippable documents improve compliance and certification readiness for high-risk AI systems across safety, cybersecurity, and AI standards?

RQ2: How do shippable documents enhance communication, traceability, and shared understanding among key stakeholders such as developers, safety assessors, and certification bodies?

2. Background

This chapter establishes a common conceptual foundation for the discussion that follows. It clarifies how terminology defined in safety, AI, and cybersecurity standards should be understood and applied when integrating agile development practices with regulatory and certification expectations. Clear definitions are essential to avoid ambiguity, ensure traceability, and support effective conformity assessment across stakeholders.

Methodologically, the paper is based on a structured analysis of international safety, cybersecurity, and AI standards, combined with evidence and observations from multiple industrial

assessor and certification projects in regulated domains. The analysis focuses on documentation-related requirements, WPs, and assessability criteria rather than on system performance or algorithmic properties. While the findings are qualitative in nature, they reflect recurring patterns observed across domains and standards and are intended to support both research discussion and practical application.

2.1. Terminology

Clear and consistent terminology is essential for aligning agile practices with regulatory expectations in safety-critical and AI-based systems. Standards use precise terms such as WP, information item, and assurance evidence, which are more specific than the generic agile term artifact. Using the vocabulary of the standards improves communication with assessors, auditors, and certification bodies, and reduces ambiguity during conformity assessment.

WP according to ISO 26262 refers to documentation produced to satisfy specific standard requirements, either as a single document or a set of related documents. Typical examples include the safety plan, hazard log, system description, Operational Design Domain (ODD), and the safety case.

Information item according to ISO/IEC/IEEE 15289 is a cross-domain term for structured lifecycle documentation such as plans, reports, specifications, or records. It supports consistent content and traceability across engineering processes.

Safety case according to ISO 26262 is a structured argument that functional safety is achieved, supported by evidence drawn from WPs. It consolidates requirements, analyses, test results, assumptions, and references to related safety cases, forming the primary basis for regulatory confidence. Evidence using a Safety case can be extended to cover safety issues beyond the scope of AI and safety standards.

Assurance evidence is the body of material that supports the safety case arguments. Conformity evidence, used in certification report formats e.g., TRF and CRF (IEC TRF and Myklebust 2025), documents compliance with a specific standard or regulation.

In agile development, artifacts such as backlogs or increments are operational tools for planning and transparency. For regulated

domains, these artifacts must map to formal WPs to maintain traceability and audit readiness.

Shippable documents extend agile’s “*shippable code*” concept. They are complete, accurate, and traceable WPs or information items that are ready for internal or external review. Their purpose is to support assessments, certification, procurement, or integration, ensuring that documentation evolves in step with engineering progress. Examples include safety plans, safety manuals, test documentation, TRF, CRF, and referenced documents in the safety case and cybersecurity case.

Using this standardized terminology strengthens communication across stakeholders such as developers, safety assessors, notified bodies, and market surveillance authorities, while supporting consistent interpretation of evidence across safety, cybersecurity, and AI standards.

2.2.Safety and AI standards

Below we have commented some of the key international standards that define expectations for documentation, WPs, and lifecycle information across systems, software, functional safety, and AI-based systems. It highlights ISO/IEC/IEEE 15289:2019 “*Requirements engineering*” as the foundational documentation standard, defining information item types such as plans, procedures, specifications, and reports, and specifying their required content rather than fixed formats. This approach supports consistency, traceability, and adaptability across different organizations and projects, allowing documentation to be tailored while still meeting lifecycle and governance need.

IEC 61508:2010 is the generic functional safety standard, introducing a lifecycle-based approach and strong documentation requirements to support hazard analysis, safety requirements, design, verification, validation, operation, modification, and decommissioning. Documentation is treated as essential evidence that functional safety has been achieved and maintained, with Annexes providing example documentation structures across system and software lifecycles.

ISO 26262 “*Automotive*” builds on principles for the automotive domain, defining numerous mandatory WPs across its parts and emphasizing “*shippable documents*” such as hazard analyses, safety manuals, tool

qualification reports, and lifecycle compliance reports. These documents enable regulatory review, integration by OEMs, and certification readiness, including adaptations for machine learning components.

Newer AI-focused standards are: The generic ISO/IEC TR 5469:2024 “*AI and FuSa*” and ISO/PAS 8800:2024 “*AI and FuSa for automotive*” extend functional safety concepts to AI systems, stressing that safety arguments rely heavily on documented evidence from data management, training, testing, validation, and operational monitoring. ISO 21448:2022 (SOTIF) further emphasizes documentation of assumptions, operational design domains, scenarios, and residual risk justification where systems function as intended but remain imperfect.

Overall, the document underscores documentation as a unifying backbone across standards, enabling traceability, assurance, and confidence in safety and engineering outcomes across complex, evolving systems.

A review of the relevant standards shows a substantial number of required WPs. When aggregated across the applicable standards, the total amounts to 224 WPs, illustrating the breadth of documentation, analyses, and evidence typically expected to demonstrate safety, reliability, and compliance.

Table 1. Number of WPs in different standards. The sum is 224 WPs

Standard	Number of WPs
ISO 26262-1:2018	0
ISO 26262-2:2018	11
ISO 26262-3:2018	5
ISO 26262-4:2018	11
ISO 26262-5:2018	14
ISO 26262-6:2018	19
ISO 26262-7:2018	13
ISO 26262-8:2018	26
ISO 26262-9:2018	7
ISO 26262-10:2018	0
ISO 26262-11:2018	8
ISO 26262-12:2018	4
ISO 21448:2022 SOTIF	13
ISO/PAS 8800:2024 FuSa and AI	13
ISO/SAE 21434:2012 Cybersecurity	46

Standard	Number of WPs
ISO/PAS 8926:2024 Pre-existing SW	9
ISO 24089:2023 SW update	25

2.3. Stakeholders

High-risk AI systems involve a broad set of stakeholders whose responsibilities span the entire system lifecycle, from development and integration to operation, certification, and post-market monitoring. Core stakeholders include developers, system integrators, operators, and maintainers, as well as independent safety assessors, certification bodies, notified bodies, and regulatory authorities.

Independent safety assessors play an increasingly central role for AI-based systems, as they must scrutinize a larger and more diverse set of WPs than in traditional safety engineering. This is particularly evident in standards such as ISO 21448 (SOTIF) and ISO/PAS 8800, where assessors are required to evaluate assumptions, ODD, scenario coverage, data-related evidence, and residual risk arguments in addition to conventional functional safety artifacts.

Certification bodies are responsible for assessing conformity of components or systems, for example sensors, detectors, or AI-enabled subsystems, against applicable functional safety and AI-related standards. Notified Bodies (NoBos), in contrast, provide conformity assessment services as defined in EU legislation. Their primary role is to assess a manufacturer's conformity with the essential requirements set out in relevant directives or regulations, using assessment routes such as inspection, quality assurance, type examination, design examination, or combinations thereof. A key benefit of NoBo involvement is that conformity assessment results are, in principle, recognized across the EU/EEA (European Union and European Economical Area).

However, classification of an AI system as high-risk under the EU AI Act does not, by itself, automatically mandate the involvement of a Notified Body. The need for NoBo participation depends on the selected conformity assessment procedure, the availability and use of harmonised standards, and the interaction with existing product safety legislation. As harmonised

standards under the AI Act are developed and adopted, these conditions may evolve.

With the adoption of AI engineering practices and DevOps-based development and deployment models, additional stakeholders become safety-relevant. These include data providers, tool and platform vendors, MLOps (Machine Learning Operations) and operations teams, and organizations responsible for monitoring and updating AI models in operation. Their activities directly affect the validity of assumptions, the integrity of evidence, and the continued compliance of the system after market entry.

Clear identification of stakeholders and explicit allocation of responsibilities are therefore essential. This is necessary to ensure effective communication, human oversight, traceability of evidence, and continuous compliance throughout development, conformity assessment, certification, operation, and post-market monitoring. In the context of this paper, these stakeholder relationships also define who produces, reviews, approves, and relies upon shippable documents as authoritative compliance and assurance evidence.

2.4. Challenges of documentation volume and complexity

Documentation is fundamental for compliance, safety, and operational efficiency in safety regulated industries. However, excessive volume and growing complexity can reduce clarity, obscure safety critical information, and introduce operational and safety risks. Studies from the petroleum and subsea domains illustrate how documentation has expanded beyond what is practically usable, despite repeated efforts to streamline content through standardization and improved processes.

In safety-critical and AI-based systems, excessive documentation complexity should be treated as a risk factor rather than a protective measure, as increased volume and procedural layering can raise cognitive load and introduce new opportunities for error. The Norwegian petroleum industry documentation project (Ptil 2016) initiated by Petroleumstilsynet identified overlapping requirements, extensive customization, and weak standardization as key drivers of unnecessary documentation growth. These factors increase cost and effort while

making it harder for engineers and operators to identify information essential for safe operation. Similar challenges are addressed in DNVGL-RP-O101:2016 “*Recommended Practice for Technical Documentation for Subsea Projects*”, which emphasizes standardized documentation structures to reduce duplication and improve consistency across engineering, procurement, construction, and operational phases.

Recent research (Thomas 2025) further indicates that documentation effort can be reduced by up to 40 percent through automated verification, model based methods, and digital twins. Techniques such as Model Based Safety Engineering, standardized safety templates, and AI supported optimization reduce manual effort while improving traceability and accuracy. These findings highlight the need to balance regulatory rigor with operational usability by controlling documentation volume and complexity.

3. Shippable documents

This chapter introduces the concept of shippable documents as a practical and unifying approach to managing documentation in safety- cyber- and AI-regulated domains. Building on the background presented in Chapter 2, the chapter moves from terminology and standards context to an operational perspective, focusing on how documentation can be produced, structured, and governed to support continuous compliance, assessment readiness, and market access. The chapter examines both the challenges and benefits associated with treating key WPs as review-ready artifacts throughout the lifecycle, rather than as late-stage deliverables. It further distinguishes between documents explicitly named in safety standards and additional WPs that are widely used in practice but only implicitly required. Finally, the chapter addresses assessor perspectives on scrutiny, including the use of modern documentation platforms, and clarifies the conditions under which documentation can be relied upon as authoritative compliance and assurance evidence.

3.1.Challenges and benefits

Building on the documentation challenges outlined in Section 2, this section examines shippable documents as an operational mechanism for addressing assessability, traceability, and lifecycle governance in safety-

and AI-regulated domains. As review-ready WPs, shippable documents must consistently reflect the current system state, underlying assumptions, and supporting evidence, which imposes stringent requirements on how documentation is planned, produced, maintained, and governed throughout the system lifecycle. Depending on context, shippable documents operate across multiple temporal and organizational boundaries. They are produced incrementally during development, primarily by the alongside engineering team as discussed in Chapter 2.6 “*Alongside engineering*” of Myklebust and Stålhane (2021), reused (i.e., carried forward as approved evidence under configuration control) during procurement and integration, and scrutinized during certification and market surveillance. Consequently, these documents must remain sufficiently stable to support assurance activities while accommodating iterative change, evolving requirements, and post-deployment updates. This dual role creates inherent tension between flexibility and formality, particularly when agile practices are applied in traditionally document-driven safety environments.

Shippable documents also rarely stand alone. They are embedded in networks of references, safety arguments, TRF, CRFs, and lifecycle evidence spanning multiple standards and regulatory regimes. Maintaining coherence across these interconnected elements requires disciplined traceability and consistent interpretation of terminology, assumptions, and scope. Misalignment can rapidly propagate across dependent documents, affecting both internal decisions and external assessments. Finally, shippable documents serve as a primary communication mechanism among diverse stakeholders, including developers, safety managers, assessors, certification bodies, purchasers, and regulators. As these groups have differing expectations, technical depth, and assurance objectives, ensuring that a single document set supports all perspectives without fragmentation remains a significant challenge.

In safety- and AI-regulated domains, the systematic use of shippable documents provides measurable benefits for compliance assurance, stakeholder communication, and certification readiness. These documents are structured to be immediately reviewable by regulatory bodies and other stakeholders, ensuring high standards of

accuracy and completeness across safety, security, and traceability requirements. Key benefits include:

1: Regulatory compliance: Shippable documents are aligned with safety and security standards, providing clear and structured information that directly supports regulatory reviews. This reduces rework and facilitates smoother certification processes.

2: Traceability: They enable clear traceability between requirements and implementation, ensuring that regulatory, safety, and hazard requirements are systematically addressed. This improves auditability and reduces compliance risk.

3: Stakeholder readiness: Due to their completeness, shippable documents serve as a primary communication mechanism with stakeholders, including certification bodies. This readiness helps maintain project timelines by reducing iterative clarification cycles.

4: Error reduction: By requiring completeness and thoroughness, shippable documents help minimize errors. Clear quality criteria and early review reduce the likelihood of costly late-stage modifications.

5: Improved estimations: By being complete, traceable, and review-ready at defined lifecycle points, shippable documents provide an early and realistic view of compliance status and remaining work. This enables more reliable estimation of effort, cost, and schedule for certification, integration, and regulatory approval activities.

6: Decision support: By consolidating verified requirements, risks, and evidence in a structured and traceable form, shippable documents support informed decision-making at key lifecycle milestones, such as readiness for integration, certification submission, or market release.

3.2.Relevant work products, documents

This section examines the WPs and documents that constitute shippable documentation in safety- and AI-regulated domains. It distinguishes between documents explicitly named in safety standards and additional WPs that are widely used in practice but only implicitly required. Together, these documents form the evidence base referenced from the safety case and enable effective assessment, traceability, and regulatory scrutiny.

3.2.1.Work products and other documents

In the IEC 61508-4 draft 2025, ISO 26262-1:2018, EN 50129:2018 and EN 50129:draft 2026 safety standards, only a limited set of documents is explicitly named and defined in the definitions clauses. These WPs are the safety case, safety plan, safety manual for compliant items, and the hazard log. Other documents are required or referenced elsewhere in the standards, but they are not defined as standalone document types in the formal definitions' sections, highlighting the special normative status of this small core set of safety documents.

In addition to the core safety documents, safety standards explicitly mention a range of supporting WPs that are referenced from the safety case and form part of the overall compliance evidence. These documents are typically tied to specific lifecycle phases and technical activities and are essential for demonstrating that required processes, analyses, and verification activities have been performed correctly.

Examples include system and item definitions, requirements specifications, architecture and interface descriptions, verification and validation plans, and verification, validation, and assessment reports. In standards such as EN 50126, EN 50128, EN 50129, IEC 61508, and ISO 26262, these documents are often listed as mandatory or expected outputs of lifecycle phases, even if their structure is not always strictly prescribed. They provide the technical substance behind the safety arguments and enable assessors to trace requirements through design, implementation, testing, and validation.

Other commonly referenced documents include independent safety assessment plans and reports, integration and test reports, change requests and impact analysis reports, release notes or delivery sheets, and operation, maintenance, and decommissioning documentation. In automotive and railway standards, additional lifecycle-specific reports, such as production readiness, commissioning, and field observation records, are also explicitly mentioned.

Treating referenced documents as shippable documents encourages disciplined review and reuse and discourages the accumulation of marginal procedures and reports that add formality without improving safety outcomes.

Although these documents may differ in naming and structure across domains, they share common characteristics: they are configuration-controlled, versioned, reviewed, and used as authoritative evidence during assessment and certification. Treating these referenced documents as shippable documents ensures they are complete, traceable, and ready for scrutiny, thereby strengthening the credibility and assessability (Buyse et al 2025) of the overall safety case without increasing unnecessary documentation overhead. Table 1 below summarizes selected IEC standards and the analysis and WPs (safety reports) they explicitly define, illustrating how these documents function as shippable evidence in regulated domains.

Table 1. Standards and related work products

Standards	Work products
IEC 61160: 2005 Design review	Defines a structured process for planning, conducting, and following up design reviews.
IEC 62502: 2010 Event Tree Analysis (ETA)	Defines principles and procedures for ETA and includes explicit requirements for documentation. Clause 9 requires documentation of objectives, scope, system description etc
IEC 60812:2018 FMEA	Defines principles and procedures for FMEA and includes explicit documentation requirements.
IEC 61025: 2006. FTA	Defines principles, methods, and applications for FTA and includes explicit requirements for documentation.
HazOp IEC 61882:2016	Defines principles and procedures for conducting HazOp Studies.
Markov IEC 61165:2016	Provides guidance on using Markov models to analyse reliability, availability, maintainability, and safety.
IEC 62551:2012 Petri net techniques	Provides guidance for dependability modelling and analysis using Petri nets.
IEC 61078:2016 (ed.3.0) RBD	Provides guidance on using Reliability block diagrams (RBDs) for dependability analysis.
IEC 62740:2015.	Defines principles, processes, and techniques for conducting RCA across industries.

Standards	Work products
Root Cause Analysis	

3.2.2. Work products not named in standards

Beyond the small set of documents explicitly defined in safety standards, such as the safety case, safety plan, safety manual, and hazard log, a number of important WPs are widely used in safety and AI projects without being concretely named in the standards. Based on assessment practice, ten such documents are identified in this work. These ten include 1: techniques and measures, 2: verification and validation plans for development technologies and toolchains, 3: tool qualification documentation, 4: TRFs, 5: CRFs, extended test and analysis reports, 6: architecture and interface descriptions, 7: change and impact analysis reports, 8: evidence linkage matrices, 9: assurance argument and rationale documents, and 10: project-specific documentation plans. While not explicitly defined in standards such as IEC 61508, ISO 26262, or ISO/IEC TR 5469, these documents are implicitly required to demonstrate compliance, traceability, and justification of applied methods. In practice, these WPs provide the necessary structure to connect requirements, analyses, tools, and evidence into a coherent safety argument. From an assessor perspective, they are often critical for assessability (Buyse et al 2025). Treating them as shippable documents improves transparency and reduces certification risk, even though they are not formally defined in the standards.

3.2.3 Improvements of standards

AI and safety standards could be improved by explicitly recognizing shippable documents as lifecycle WPs and by clarifying expectations for review and audit readiness, configuration control, and traceability. Stronger alignment with agile practices, such as incremental evidence development and continuous assessment, would reduce late-stage compliance risks. In addition, clearer guidance on documenting AI-specific aspects, including data management, model evolution, and operational monitoring, would improve consistency, assessability, and cross-domain harmonization without increasing unnecessary documentation burden.

3.3. Platform-hosted documentation and assessability of shippable evidence

In several of our assessor projects, documentation subject to scrutiny has been published using collaborative documentation platforms. As both IEC 61508 and the EU AI Act are tool-agnostic, the use of such platforms is not itself a compliance concern. Instead, documentation can only be treated as shippable evidence when it is under configuration control, formally reviewed, approved, and traceable. From an assessor perspective, scrutiny is therefore limited to released document versions (e.g. version 1.0 or later) that have been approved by the manufacturer in accordance with documented procedures. Draft material may be consulted for context but cannot be relied upon as compliance or assurance evidence. Consistent with IEC 61508-1, manufacturers are expected to have procedures for modification approval (Clause 6.2.8) and configuration management throughout the lifecycle (Clause 6.2.10); without these, platform-hosted documentation cannot be considered authoritative, regardless of the tooling used.

4. Conclusion

This paper has examined shippable documents as a practical mechanism for improving compliance, certification readiness, and stakeholder coordination for high-risk AI systems operating under the EU AI Act and related safety, cybersecurity, and AI standards. The analysis shows that treating key WPs as review and audit ready throughout the lifecycle addresses recurring problems related to documentation volume, late-stage evidence gaps, and fragmented assurance. The findings also indicate that safety is better supported by reducing unnecessary procedural complexity than by adding layers of documentation that increase cognitive burden without strengthening assurance.

RQ1 asked how agile-aligned shippable documents can improve compliance and certification readiness. The results indicate that by applying agile principles such as Definition of Ready and Definition of Done to formally required WPs, organizations can ensure that documentation is accurate, complete, traceable, and configuration-controlled at all times. This enables incremental scrutiny, earlier assessor involvement, and continuous alignment with standards such as IEC

61508, ISO 26262, ISO/PAS 8800, ISO 21448, and the AI Act. As a result, compliance becomes a continuous activity rather than a late-stage consolidation effort, reducing rework and shortening time to market.

RQ2 addressed how shippable documents enhance communication and shared understanding. The study shows that shippable documents function as a common, authoritative reference point across developers, safety assessors, certification bodies, and regulators. Their structured traceability and standardized status reduce ambiguity, support consistent interpretation of evidence, and improve decision-making at key lifecycle milestones.

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