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ISO 9001-2026 VERSUS ISO 9001-2015

QUALITY MANAGEMENT SYSTEMS - REQUIREMENTS

<i>Report Description</i>	ISO 9001-2026 VERSUS ISO 9001-2015
<i>Industry Type</i>	Healthcare Industry
<i>Document Type</i>	Pre-audit record
<i>Summary of changes</i>	2026 introduces important enhancements focused on quality culture, ethical behavior, climate change considerations, opportunity management, organizational knowledge, stakeholder expectations, and continual improvement. While the overall structure of the standard remains largely aligned with the 2015 edition, the 2026 revision places greater emphasis on organizational resilience, proactive management, and integration of quality into strategic decision-making

Disclaimer:

This document has been prepared as an independent gap assessment and impact analysis based on a review of applicable standard requirements and generally accepted industry practices at the time of preparation. Referenced ISO standards remain copyrighted property of ISO.

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1.0. Comparison Table:

Below Table describes the alignment clause-by-clause between the two versions of the ISO standard, which can be fully aligned (**Full**) or partially aligned (**Part**) or not aligned (**Not**).

2026 Clause	Requirement	2015 Clause	Requirement	Align ment	Remar ks
4 CONTEXT OF THE ORGANIZATION 4.1 Understanding the organization and its context	The 2026 clause is a reminder that organizations must stay aware of both their internal realities and the external environment, treating this awareness as a continuous process rather than a one-time check. The standout change is the explicit mention of climate change, signaling its importance as a mainstream business issue. Overall, the commentary emphasizes that context analysis isn't just about spotting risks—it's about recognizing opportunities too, and keeping the quality system resilient by regularly monitoring and reviewing evolving conditions.	4 CONTEXT OF THE ORGANIZATION 4.1 Understanding the organization and its context	The 2015 clause is essentially about building awareness of context as a foundation for a quality management system. It encourages organizations to keep an eye on both external influences—like laws, technology, markets, and culture—and internal factors such as values, knowledge, and performance. The tone is more about establishing the habit of scanning the environment and reflecting on internal dynamics, so the system stays aligned with strategic direction. In commentary terms, it's laying the groundwork for continuous situational awareness, without yet spotlighting specific global issues like climate change.	Full	2026 (4.1) rephrases the requirement to determine external and internal issues by adding a specific mention of climate change, while 2015 required the same determination without this specification.
4.2 Understanding the needs and expectations of interested parties	The 2026 clause highlights stakeholder engagement as central to quality management. It stresses that organizations must identify who their key interested parties are, understand their requirements, and decide which ones the system will address. The commentary angle here is that quality isn't just about internal processes—it's about	4.2 Understanding the needs and expectations of interested parties	The 2015 clause places stakeholder awareness firmly in the context of compliance and customer satisfaction. It highlights that organizations need to identify relevant interested parties and understand their requirements because these directly affect the ability to deliver consistent, regulation-compliant products and services. In commentary style, it's about tying stakeholder expectations to operational	Part	2026 (4.2) removes the emphasis on customer and statutory requirements while adding a note on climate change-related requirements, whereas 2015 required the organization to determine requirements that affect its ability to provide products and services meeting customer and regulatory needs

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	staying aligned with evolving stakeholder expectations. The explicit mention of climate change shows how global concerns are now part of those expectations, underscoring that resilience and relevance depend on continuously monitoring and responding to what matters most to stakeholders.		reliability—monitoring them isn't optional, it's a safeguard to ensure the quality system stays aligned with customer and statutory demands.		
4.3 Determining the scope of the quality management system	The 2026 clause on scope makes the process of defining boundaries for a quality management system more rigorous and transparent. In commentary style, it emphasizes that organizations must clearly state what products and services are covered, justify any exclusions, and ensure those exclusions don't compromise conformity or customer satisfaction. The requirement for documented information signals accountability—scope isn't just a statement, it's a formal commitment. Overall, this version strengthens clarity and credibility by tying scope directly to external/internal issues, stakeholder requirements, and product/service realities.	4.3 Determining the scope of the quality management system	The 2015 clause on scope is about making sure the quality management system has clear boundaries and applicability. In commentary style, it stresses that organizations must define what products and services are covered, document the scope, and justify any exclusions. The key point is that exclusions cannot weaken the organization's responsibility to deliver conforming products or to enhance customer satisfaction. Overall, it frames scope-setting as a structured, documented exercise that ensures transparency and credibility in how the quality system is applied.	Part	2026 (4.3) updates 2015 (4.3): clarifies requirements in 4.2 must be considered (removes 'of relevant interested parties'), requires scope to justify any non-applicable requirement (not just provide), changes conformity claim from 'may only be claimed' to 'can only be claimed', and separates scope requirements for product/service types and justification (2015 combined).
4.4 Quality management system 4.4.1	The 2026 clause portrays the QMS as a dynamic framework built on interconnected processes. In commentary style, it stresses that organizations must define how processes work together, clarify inputs and outputs, and ensure resources and responsibilities are in place. It also highlights the importance of monitoring performance with indicators, addressing risks and opportunities, and continuously evaluating outcomes. The overall message is that the QMS	4.4 Quality management system and its processes 4.4.1	The 2015 clause frames the QMS as a disciplined system built on defined processes and their interactions. In commentary style, it highlights the need to map inputs and outputs, clarify responsibilities, and ensure resources are in place. It also stresses monitoring with performance indicators and addressing risks and opportunities. The overall message is that the QMS must be continuously evaluated and improved, making it a structured but evolving framework designed to achieve consistent results and maintain effectiveness.	Full	2026 (4.4.1) restates 2015 with no change to intent or parameter values