Quality Management System Design to ISO 9001:2026

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What to have ready

Each item below ties to ISO 9001:2026 (Edition 6, September 2026), ISO's transition guidance, DNV's NIAHO page or 42 CFR 482.21, as linked.

- Your organization's purchased copy of ISO 9001:2026, or your accreditor's QMS requirements, as the governing text (ISO 9001:2026 [https://www.iso.org/standard/9001]).
- A first decision on the scope of the QMS: which sites, services and processes it will cover, since the standard is built around setting up, running and improving the system over time (ISO 9001:2026 [https://www.iso.org/standard/9001], page opened October 3, 2026).
- Your current quality policy, quality objectives and any quality manual.
- Your current certificate and certification body's correspondence, if you hold ISO 9001:2015 certification, for the transition conversation ISO's 2026 page points to (ISO 9001:2026 [https://www.iso.org/standard/9001], page opened October 3, 2026).
- Whether you intend to certify, since ISO's page says certification is optional (ISO 9001:2026 [https://www.iso.org/standard/9001], page opened October 3, 2026).
- Your DNV survey reports and your copy of the NIAHO requirements, if you are a DNV-accredited hospital (DNV NIAHO [https://www.dnv.us/services/niaho-accreditation-for-hospitals2/], page opened October 3, 2026).
- For hospitals, your list of quality indicators, including adverse patient events, that you measure, analyze and track (42 CFR 482.21(a)(2) [https://www.ecfr.gov/api/renderer/v1/content/enhanced/current/title-42?part=482&section=482.21]).
- Existing procedures for document control, internal audit, corrective action, complaints and supplier control.
- Recent internal audit reports, corrective action records and management review minutes.
- A list of process owners for each major process.