

REGULATION/ STANDARD	SCOPE	IMPACT FOR SOFTWARE AND SYSTEMS TEAMS
ISO 14971	Requirements for an application of a risk management system for medical devices	Requires engineering teams to provide evidence of traceability between risk analysis and product design documentation
ISO 13485	Quality management for medical devices	Demands a defined and integrated process for product development from concept through end-of-life
IEC 62304 (acc. to FDA)	Software lifecycle process for medical devices	Demands a defined and integrated process for software development
FDA 21CFR Part 820	Quality management for medical devices sold and distributed in the US	US regulatory requirement that specifies the quality management requirements, placing a demand on a defined and integrated process for product development
FDA 21CFR Part 11	Regulatory requirements for electronic records	US regulatory requirement that requires engineering teams to provide evidence that electronic records are authentic and reliable, ensuring that electronic signatures are fully equivalent to hand-written signatures in all areas where signed records are required
CMMi	Capability Maturity Model, Integrated	A multi-level model for improving the process maturity and capability of software teams. This specifies practices and competencies required in software development as well as a framework for measuring and improving your process. This places a demand on defined and integrated processes, management of development assets, metrics gathering and reporting, and traceability across assets
ISO 26262	Road vehicles – functional safety standards	Specifies processes for integrating risk and hazard analysis into automotive product, system, and software development, requiring domain-integrated traceability
IEC 61508	Functional safety of electrical/electronic/programmable electronic safety-related systems	Specifies processes for integrating risk and hazards analysis into electrical product design, system, and software development, requiring domain-integrated traceability
ISO / IEC 15504	Automotive Software Process Improvement Capability Determination (SPICE)	Specifies a reference model and assessment approach for developing software in select industries; widely used by automotive industry
DO—178B/C	Software considerations in airborne systems and equipment certification	Specifies software lifecycle artifacts required in developing software used in airborne systems, requiring specific practices and competencies that are enhanced through traceability and a defined lifecycle process