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ISO 62083:2026 VERSUS ISO 62083;2010

Medical device software - Requirements for the safety of radiotherapy treatment planning systems

STANCE KONE LLP
REVISION;01

Report Description	ISO 62083:2026 VERSUS ISO 62083;2010
Industry Type	Medical device
Document Type	Pre-audit record
Summary of changes	Based on the clause-by-clause comparison between ISO 62083:2026 and ISO 62083:2010, the 2026 edition introduces major new requirements and expanded compliance expectations for radiotherapy treatment planning systems. The changes emphasize cybersecurity, usability, transparency, and structured risk management, moving beyond the 2010 baseline.

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.

This assessment is intended solely for internal quality planning, risk evaluation, and audit readiness purposes. It does not constitute certification, audit, regulatory approval, or a declaration of compliance with any ISO or other industrial standard.

Responsibility for implementation of recommended actions and for achieving and maintaining compliance with applicable standards and regulatory requirements remains with the organization.

No representation or warranty is made that implementation of the recommendations herein will guarantee certification, regulatory approval, or audit outcome.

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**).

Clause ISO 62083-2026	Requirement ISO 62083-2026	Clause ISO 62083-2010	Requirement ISO 62083-2026	Alignment	Remarks
4 General **4.1 Quality, security, and risk management**	The 2026 update underscores how security is now woven into the medical device life cycle through established quality and risk management systems. It points manufacturers toward ISO 13485 for quality, IEC 62304 for software processes, and IEC 81001-5-1 for cybersecurity, signaling that security is treated as a structured discipline rather than an add-on. For radiotherapy planning systems, usability standards like IEC 62366-1 (and its amendment) are explicitly tied in, showing the broader expectation that safety, security, and usability all converge in modern compliance.			NOT	NEW REQUIREMENT

4.2 Test grades	The 2026 framework introduces three test grades that scale from design-level analysis (Grade A), to practical inspection and functional checks under normal and fault conditions (Grade B), and finally to more intrusive testing that bypasses safety features or edits data under manufacturer supervision (Grade C). The structure highlights a progression from theoretical assurance to hands-on validation, with the highest grade reserved for controlled, supervised scenarios where safeguards must be overridden.	[redacted]	NOT	NEW REQUIREMENT
4.3 Compliance	The 2026 approach makes compliance demonstration highly explicit, requiring direct reference to each requirement and a formal statement in the technical description. Verification under Grade A testing is documentation-driven, focusing on detailed protocols and reproducible outcomes, with conformity clearly declared. This reflects a shift toward transparency and traceability in how compliance is evidenced.		NOT	NEW REQUIREMENT