

ISO 62083:2026 Versus ISO 62083:2010

Consolidated Conclusion Summary:

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. The major gaps requiring action are summarized below, with the applicable parameters highlighted for implementation.

1. Quality, Security, and Risk Management

- 2026 integrates ISO 13485, IEC 62304, IEC 81001-5-1, and IEC 62366-1 for quality, software, cybersecurity, and usability. **Action:** Update QMS and DHF to embed cybersecurity and usability standards into lifecycle documentation.

Quality Management Standards



2. Test Grades and Compliance

- New three-tier test grades [A, B, C] introduced, scaling from documentation review to intrusive supervised testing. **Action:** Revise verification protocols; ensure compliance evidence is traceable and declared in technical descriptions.