

ISO/TR 17791:2013-12 (E)

Health informatics - Guidance on standards for enabling safety in health software

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Terms and definitions	1
3	Abbreviated terms	6
4	Health software safety	6
4.1	Health software safety incidents	6
4.2	Health software definitions	7
4.3	Towards safer health software	9
4.4	Health software lifecycle	9
4.5	How standards were selected for assessment	12
4.6	Standards assessed in this Technical Report	13
4.7	Risk management basis	15
4.8	Human factors basis	16
4.9	Granularity	17
5	Standards assessment and guidance	17
5.1	Standards assessment	17
5.2	Standards assessed by lifecycle applicability and software granularity	31
5.3	Standards assessment overlap and gap analysis	33
5.4	Standards for enabling safety in health software -- Implementation and use guidance	36
Annex A (informative)	Patients safety benefits arising from health investments	39
Annex B (informative)	Standards analysis from a software lifecycle perspective	40
Annex C (informative)	Scope information of safety-relevant JTC 1 standards	44
Bibliography		47