

ISO/IEC Guide 63:2019-08 (E)

Guide to the development and inclusion of aspects of safety in International Standards for medical devices

Contents		Page
Foreword		v
Introduction		vii
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Use of the terms "safety", "safe", "effective", and "effectiveness"	4
4.1	Safety	4
4.2	Safe	5
4.3	Effective	5
4.4	Effectiveness	5
5	Principles for including aspects of safety in medical device standards	5
5.1	Scope of medical device standards that include aspects of safety	5
5.2	Objective of medical device standards that include aspects of safety	6
5.3	Types of standards	6
5.3.1	Product standards	6
5.3.2	Process standards	6
5.3.3	Installation and environmental standards	7
5.3.4	In-service standards	7
5.4	Taking a practical view of safety	7
5.5	Coordination of medical device standards	7
5.6	Implications of the regulatory or legal use of standards	8
6	The nature of risk	8
6.1	The elements of risk	8
6.2	Systematic or random nature of risks	9
6.2.1	Types of causes of risks	9
6.2.2	Risks arising from systematic causes	10
6.2.3	Risks arising from random causes	10
7	Risk-based process for developing a medical device standard that includes aspects of safety	10
7.1	General	10
7.2	Preparatory work	11
7.2.1	Identifying the need for a new or revised standard including aspects of safety	11
7.2.2	Establishing the risk management framework under which the standard will be developed	11
7.2.3	Risk acceptability criteria	12
7.3	Drafting	14
7.3.1	General	14
7.3.2	Iterative process of managing risk	14
7.3.3	Intended use and characteristics that can influence safety	16
7.3.4	Identification of hazards and hazardous situations	17
7.3.5	Risk estimation	18
7.3.6	Risk evaluation	19
7.3.7	Identification of risk controls	19

7.3.8	Verification of effectiveness	22
7.3.9	Assessment of residual risks	22
7.3.10	Impact of introduced risk control measures	22
7.3.11	All identified hazards and hazardous situations considered	22
7.4	Validation of the standard	22
7.5	Conclusion	22
8	Overview of the application of medical device standards including aspects of safety in a risk management framework	22
	Annex A (informative) Product and process safety standards	24
	Annex B (informative) Risk information	25
	Bibliography	26