

ISO 22367:2026-04 (E)

Medical laboratories - Application of risk management to medical laboratories

Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Risk management	9
4.1 Risk management process	9
4.2 Management responsibilities	9
4.3 Qualification of personnel	10
4.4 Risk management activities	10
4.4.1 General	10
4.4.2 Foreseeable risk	12
4.4.3 Opportunity	13
4.4.4 Information provided to users	13
5 Proactive risk management	13
5.1 Proactive risk management plan	13
5.2 Scope of the plan	14
5.3 Contents of the plan	14
5.4 Revisions to the plan	14
5.5 Documentation of the risk management plan	15
6 Proactive risk analysis	15
6.1 General	15
6.2 Risk analysis process	15
6.3 Documentation of the risk analysis process	16
6.3.1 General	16
6.3.2 Intended medical laboratory use and reasonably foreseeable misuses	16
6.3.3 Identification of characteristics related to safety	16
6.3.4 Identification of hazards	16
7 Risk evaluation	17
7.1 Overview	17
7.1.1 General	17
7.1.2 Reactive evaluation of risks	17
7.1.3 Proactive evaluation of risks	17
7.2 Benefit-risk analysis	18
7.3 Proactive risk evaluation	18
7.3.1 Risk acceptability criteria	18
7.3.2 Risk reduction	19
8 Risk control	19
8.1 General	19
8.2 Risk control options	20
8.2.1 General	20
8.2.2 Role of standards in risk control	20
8.2.3 Role of IVD medical devices in risk control	20
8.3 Risks external to the laboratory	21
8.4 Risks arising from risk control measures	21
8.5 Residual risk evaluation	21

8.6	Risk control verification	22
9	Risk management review	22
9.1	General.....	22
9.2	Completeness of risk control.....	22
9.3	Evaluation of overall residual risk.....	22
9.4	Risk management report.....	23
10	Risk monitoring, analysis and control activities	23
10.1	Risk monitoring procedure.....	23
10.2	Internal sources of risk information.....	24
10.3	External sources of risk information.....	24
11	Immediate actions to reduce risk.....	24
	Annex A (informative) Implementation of risk management within the management system.....	25
	Annex B (informative) Guidance on establishing risk acceptability criteria	35
	Annex C (informative) Guidance on risk acceptability considerations	37
	Annex D (informative) Identification of characteristics related to safety.....	40
	Annex E (informative) Examples of foreseeable risks, hazards, foreseeable sequences of events and hazardous situations	47
	Annex F (informative) Nonconformities potentially leading to significant risks	55
	Annex G (informative) Risk analysis tools and techniques.....	63
	Annex H (informative) Risk analysis of foreseeable user actions.....	68
	Annex I (informative) Methods of risk assessment, including estimation of probability and severity of harm.....	72
	Annex J (informative) Overall residual risk evaluation and risk management review.....	77
	Annex K (informative) Conducting a benefit-risk analysis.....	79
	Annex L (informative) Residual risks.....	81
	Bibliography.....	82