DIN EN ISO 22367:2026-10 (E)

Medical laboratories - Application of risk management to medical laboratories (ISO 22367:2026)

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