ISO 7101:2023-10 (E)

Healthcare organization management - Management systems for quality in healthcare organizations - Requirements

Contents

Page

Foreword ..... **v**

Introduction ..... **vi**

1 Scope **1**

2 Normative references **1**

3 Terms and definitions **1**

4 Context of the organization **7**
4.1 Understanding the organization and its context 7
4.2 Understanding the needs and expectations of stakeholders 8
4.3 Determining the scope of the management system for quality in healthcare organizations 8
4.4 Management system for quality in healthcare organizations 8

5 Leadership **9**
5.1 Leadership and commitment 9
5.2 Healthcare quality policy 10
5.3 Roles, responsibilities and authorities 10
5.4 Service user focus 10
5.5 Access to care 11

6 Planning **11**
6.1 Actions to address risks and opportunities 11
6.1.1 General 11
6.1.2 Risk culture 12
6.1.3 Risk management processes 12
6.2 Healthcare quality objectives and planning to achieve them 12
6.3 Planning of changes 13

7 Support **13**
7.1 Resources 13
7.2 Competence 14
7.3 Awareness 14
7.4 Communication 14
7.4.1 General 14
7.4.2 Service user communication 15
7.4.3 Clinical communication 15
7.4.4 External communications 15
7.5 Documented information 15
7.5.1 General 15
7.5.2 Creating and updating documented information 16
7.5.3 Control of documented information 16
7.5.4 Information management systems 16
7.5.5 Control and management of electronic information 17
7.5.6 Audit of records 17

8 Operation **18**
8.1 Operational planning and control 18
8.2 Healthcare facilities management and maintenance 18
8.2.1 General 18
8.2.2 Contingency planning for facilities and services 19
8.2.3 Equipment 19

8.3 Waste management 20
8.3.1 General 20
8.3.2 Waste reduction 20
8.3.3 Environmental responsibility 20
8.4 Handling and storage of materials 20
8.5 Service user belongings 21
8.6 Emerging technologies 21
8.7 Service design in healthcare 21
8.8 Supplies and services from external providers 22
8.9 Provision of services 23
8.10 People-centred care 23
8.10.1 General 23
8.10.2 Service user experience 23
8.10.3 Compassionate care 24
8.10.4 Inclusivity and diversity 24
8.10.5 Health literacy 25
8.10.6 Co-production 25
8.10.7 Workforce wellbeing 25
8.11 Ethics 26
8.12 Patient safety 26
8.12.1 General 26
8.12.2 Knowledge and learning in safety 26
8.12.3 Patient identification 26
8.12.4 Medication safety 27
8.12.5 Surgical safety 27
8.12.6 Infection prevention and control (IPC) 27
8.12.7 Prevention of falls, pressure ulcers and thromboembolism 28
8.12.8 Diagnostic safety 28
8.12.9 Blood transfusions 28

9 Performance evaluation 29
9.1 Monitoring, measurement, analysis, and evaluation 29
9.1.1 General 29
9.1.2 Healthcare quality indicators 30
9.1.3 Methods 30
9.1.4 Results 30
9.2 Internal audit 31
9.2.1 General 31
9.2.2 Internal audit programme 31
9.3 Management review 31
9.3.1 General 31
9.3.2 Management review inputs 31
9.3.3 Management review results 32

10 Improvement 32
10.1 Continual improvement 32
10.2 Nonconformity and corrective action 33
10.2.1 General 33
10.2.2 Management of nonconformity and corrective action 33

Bibliography 35