ISO/TS 5137:2026-02 (E)

Medical device maintenance management programme for healthcare delivery organizations (HDO)

Contents

Page

Foreword ..... **v**

Introduction ..... **vi**

1 Scope **1**

2 Normative references **1**

3 Terms and definitions **1**

4 Maintenance management programme **4**
4.1 General requirements 4
4.2 Outsourced activities 4
4.3 Documentation requirements 5
4.3.1 General 5
4.3.2 Control of documents 5
4.3.3 Control of records 5
4.3.4 Maintenance management information system (MMIS) 6
4.3.5 Technical library 6

5 Management responsibility **6**
5.1 Planning 6
5.1.1 Quality objectives 6
5.1.2 Maintenance management programme planning 7
5.2 Responsibility and authority 7
5.3 Biomedical engineering services representative 7

6 Resource management **7**
6.1 Provisions of resources 7
6.2 Human resources 7
6.3 User training 8
6.4 Infrastructure 8
6.5 Contamination control 8

7 Maintenance programme realization **9**
7.1 Planning of maintenance service realization 9
7.1.1 General 9
7.1.2 Maintenance intervals 9
7.1.3 Risk management 9
7.1.4 Release for service 10
7.2 Testing, commissioning and acceptance of new reusable medical devices 10
7.2.1 Testing and commissioning and acceptance 10
7.3 Maintenance services 10
7.3.1 General 10
7.3.2 Identification 10
7.4 Maintenance 11
7.4.1 User maintenance 11
7.4.2 Preventive maintenance 11
7.4.3 Routine inspection 12
7.4.4 Unscheduled maintenance or repair 12
7.4.5 Predictive maintenance 13
7.5 Storage 13
7.6 Decommissioning and disposal of medical devices 13
7.7 Spare parts 14

8 Measurement, analysis, and improvement **14**
8.1 Measurement of maintenance processes 14
8.2 Data analysis 14
8.3 Control of nonconforming medical devices 14
8.3.1 General 14
8.3.2 Actions in response to nonconforming product 15
8.4 Adverse effects and incident investigation and reporting 15
8.5 Alert, safety, field corrective action and recall notices 15
8.6 Internal audit 15
8.7 Medical device replacement plan 16
8.8 Advisory services 16
Bibliography **18**