DIN EN ISO 15189:2024-08 (E)

Medical laboratories - Requirements for quality and competence (ISO 15189:2022)

Contents

Page

European foreword ... 5

[A11] European foreword to the Amendment [A11] ... 6

Annex ZA (informative) [A11] Relationship between this European Standard and the requirements of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93 aimed to be covered [A11] ... 7

Foreword ... 8

Introduction ... 9

1 Scope ... 10

2 Normative references ... 10

3 Terms and definitions ... 10

4 General requirements ... 17
4.1 Impartiality ... 17
4.2 Confidentiality ... 17
4.2.1 Management of information ... 17
4.2.2 Release of information ... 18
4.2.3 Personnel responsibility ... 18
4.3 Requirements regarding patients ... 18

5 Structural and governance requirements ... 18
5.1 Legal entity ... 18
5.2 Laboratory director ... 19
5.2.1 Laboratory director competence ... 19
5.2.2 Laboratory director responsibilities ... 19
5.2.3 Delegation of duties ... 19
5.3 Laboratory activities ... 19
5.3.1 General ... 19
5.3.2 Conformance with requirements ... 19
5.3.3 Advisory activities ... 19
5.4 Structure and authority ... 20
5.4.1 General ... 20
5.4.2 Quality management ... 20
5.5 Objectives and policies ... 20
5.6 Risk management ... 21

6 Resource requirements ... 21
6.1 General ... 21
6.2 Personnel ... 21
6.2.1 General ... 21
6.2.2 Competence requirements ... 21
6.2.3 Authorization ... 22
6.2.4 Continuing education and professional development ... 22
6.2.5 Personnel records ... 22
6.3 Facilities and environmental conditions ... 22
6.3.1 General ... 22
6.3.2 Facility controls ... 23
6.3.3 Storage facilities ... 23
6.3.4 Personnel facilities ... 23
6.3.5 Sample collection facilities ... 23

6.4 Equipment 24
6.4.1 General 24
6.4.2 Equipment requirements 24
6.4.3 Equipment acceptance procedure 24
6.4.4 Equipment instructions for use 24
6.4.5 Equipment maintenance and repair 24
6.4.6 Equipment adverse incident reporting 25
6.4.7 Equipment records 25
6.5 Equipment calibration and metrological traceability 26
6.5.1 General 26
6.5.2 Equipment calibration 26
6.5.3 Metrological traceability of measurement results 26
6.6 Reagents and consumables 27
6.6.1 General 27
6.6.2 Reagents and consumables — Receipt and storage 27
6.6.3 Reagents and consumables — Acceptance testing 27
6.6.4 Reagents and consumables — Inventory management 27
6.6.5 Reagents and consumables — Instructions for use 28
6.6.6 Reagents and consumables — Adverse incident reporting 28
6.6.7 Reagents and consumables — Records 28
6.7 Service agreements 28
6.7.1 Agreements with laboratory users 28
6.7.2 Agreements with POCT operators 28
6.8 Externally provided products and services 29
6.8.1 General 29
6.8.2 Referral laboratories and consultants 29
6.8.3 Review and approval of externally provided products and services 29

7 Process requirements 30
7.1 General 30
7.2 Pre-examination processes 30
7.2.1 General 30
7.2.2 Laboratory information for patients and users 30
7.2.3 Requests for providing laboratory examinations 30
7.2.4 Primary sample collection and handling 31
7.2.5 Sample transportation 32
7.2.6 Sample receipt 33
7.2.7 Pre-examination handling, preparation, and storage 33
7.3 Examination processes 34
7.3.1 General 34
7.3.2 Verification of examination methods 34
7.3.3 Validation of examination methods 34
7.3.4 Evaluation of measurement uncertainty (MU) 35
7.3.5 Biological reference intervals and clinical decision limits 35
7.3.6 Documentation of examination procedures 36
7.3.7 Ensuring the validity of examination results 36
7.4 Post-examination processes 39
7.4.1 Reporting of results 39
7.4.2 Post-examination handling of samples 41
7.5 Nonconforming work 42
7.6 Control of data and information management 42
7.6.1 General 42
7.6.2 Authorities and responsibilities for information management 42
7.6.3 Information systems management 43
7.6.4 Downtime plans 43
7.6.5 Off site management 43
7.7 Complaints 43
7.7.1 Process 43
7.7.2 Receipt of complaint 44

7.7.3 Resolution of complaint **44**
7.8 Continuity and emergency preparedness planning **44**
8 Management system requirements **44**
8.1 General requirements **44**
8.1.1 General **44**
8.1.2 Fulfilment of management system requirements **45**
8.1.3 Management system awareness **45**
8.2 Management system documentation **45**
8.2.1 General **45**
8.2.2 Competence and quality **45**
8.2.3 Evidence of commitment **45**
8.2.4 Documentation **45**
8.2.5 Personnel access **45**
8.3 Control of management system documents **46**
8.3.1 General **46**
8.3.2 Control of documents **46**
8.4 Control of records **46**
8.4.1 Creation of records **46**
8.4.2 Amendment of records **46**
8.4.3 Retention of records **47**
8.5 Actions to address risks and opportunities for improvement **47**
8.5.1 Identification of risks and opportunities for improvement **47**
8.5.2 Acting on risks and opportunities for improvement **47**
8.6 Improvement **48**
8.6.1 Continual improvement **48**
8.6.2 Laboratory patients, user, and personnel feedback **48**
8.7 Nonconformities and corrective actions **48**
8.7.1 Actions when nonconformity occurs **48**
8.7.2 Corrective action effectiveness **49**
8.7.3 Records of nonconformities and corrective actions **49**
8.8 Evaluations **49**
8.8.1 General **49**
8.8.2 Quality indicators **49**
8.8.3 Internal audits **49**
8.9 Management reviews **50**
8.9.1 General **50**
8.9.2 Review input **50**
8.9.3 Review output **50**
Annex A (normative) **Additional requirements for Point-of-Care Testing (POCT)** **52**
Annex B (informative) **Comparison between ISO 9001:2015 and ISO 15189:2022 (this document)** **53**
Annex C (informative) **Comparison between ISO 15189:2012 and ISO 15189:2022 (this document)** **63**
Bibliography **70**