

ISO 15189:2012-11 (E)

Medical laboratories - Requirements for quality and competence

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Management requirements	6
4.1	Organization and management responsibility	6
4.2	Quality management system	10
4.3	Document control	13
4.4	Review of contracts and service agreements	15
4.5	Examination by referral laboratories	16
4.6	External services and supplies	17
4.7	Advisory services	18
4.8	Resolution of complaints	18
4.9	Identification and control of nonconformities	18
4.10	Corrective action	20
4.11	Preventive action	20
4.12	Continual improvement	21
4.13	Quality and technical control of records	22
4.14	Internal evaluation and audits	24
4.15	Management review	26
5	Technical requirements	27
5.1	Personnel	27
5.2	Accommodation and environmental conditions	31
5.3	Laboratory equipment, reagents, and consumables	33
5.4	Pre-examination procedures and processes	39
5.5	Examination procedures and processes	44
5.6	Assuring and ensuring quality of examination procedures and results	48
5.7	Post-examination procedures and processes	51
5.8	Reporting of results	51
5.9	Release of results	54
5.10	Laboratory information management	56
Annex A (informative) Correlation with ISO 9001:2000/2008 and ISO/IEC 17025:2005		58
Annex B (informative) Recommendations for protection of laboratory information systems (LIS)		65
Bibliography		76