

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	9
4.3	Document control	10
4.4	Service agreements	11
4.5	Examination by referral laboratories	12
4.6	External services and supplies	12
4.7	Advisory services	13
4.8	Resolution of complaints	13
4.9	Identification and control of nonconformities	13
4.10	Corrective action	14
4.11	Preventive action	14
4.12	Continual improvement	14
4.13	Control of records	15
4.14	Evaluation and audits	16
4.15	Management review	18
5	Technical requirements	19
5.1	Personnel	19
5.2	Accommodation and environmental conditions	21
5.3	Laboratory equipment, reagents, and consumables	23
5.4	Pre-examination processes	26
5.5	Examination processes	30
5.6	Ensuring quality of examination results	33
5.7	Post-examination processes	35
5.8	Reporting of results	35
5.9	Release of results	37
5.10	Laboratory information management	38
Annex A (informative) Correlation with ISO 9001:2008 and ISO/IEC 17025:2005		40
Bibliography		50