

ISO 15189:2007-04 (E)

Medical laboratories - Particular 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 requirement	4
4.1	Organization and management	4
4.2	Quality management system	5
4.3	Document control	6
4.4	Review of contracts	7
4.5	Examination by referral laboratories	8
4.6	External services and supplies	8
4.7	Advisory services	9
4.8	Resolution of complaints	9
4.9	Identification and control of nonconformities	9
4.10	Corrective action	10
4.11	Preventive action	10
4.12	Continual improvement	10
4.13	Quality and technical records	11
4.14	Internal audits	11
4.15	Management review	12
5	Technical requirements	13
5.1	Personnel	13
5.2	Accommodation and environmental conditions	15
5.3	Laboratory equipment	16
5.4	Pre-examination procedures	18
5.5	Examination procedures	20
5.6	Assuring quality of examination procedures	22
5.7	Post-examination procedures	23
5.8	Reporting of results	23
Annex A (Informative) Correlation with ISO 9001:2000 and ISO/IEC 17025:2005		26
Annex B (informative) Recommendations for protection of laboratory information systems (LIS)		30
Annex C (informative) Ethics in laboratory medicine		34
Bibliography		37