

## \* ISO 15189: 2012

- ISO 9000 - Definition of quality management
- ISO 9001 - How to manage quality of ANY system
- ISO 17025 - How to manage quality of calibration and testing laboratory
- ISO 15189 - How to manage quality of medical testing laboratory

→ ISO 15189: 2012 - is paid document.

- obtain from BIS website

→ Illegal to use - copy of document which we get on internet search  
[it ~~shows~~ is purchased copy & have some information about who have purchased it]

→ It has 5 clause:-

clause 1 - scope

clause 2 - Normative references

clause 3 - Terms & definition

clause 4 - Management requirement

clause 5 - Technical requirement

→ clause 1 - scope:

Has specific requirements for quality & competence in medical laboratories

- Used by NABL for accreditation, accreditation is not mandatory

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## → clause 4<sup>o</sup> - management requirement

- 4.1 - organization & management responsibility
- 4.2 - quality management system
- 4.3 - Document control (S.N.)
- 4.4 - Service agreements
- 4.5 - Examination by referral laboratories
- 4.6 - External services & supplies
- 4.7 - Advisory services
- 4.8 - Resolution of complaints
- 4.9 - Identification & control of nonconformities
- 4.10 - corrective action
- 4.11 - preventive action
- 4.12 - continual improvement
- 4.13 - Control of records
- 4.14 - Evaluation & audits
  - Assessment of user feedback
  - periodic review of request, suitability of procedures & sample requirements
  - Staff suggestion
  - Internal audit
  - Risk management
  - quality indicator
  - Reviews by external organization
- 4.15 - management review

## Clause 5:- Technical requirement

### 5.1 - Personnel

- qualification
- Job description
- Personnel introduction to organizational environment
- Training
- competence assessment
- Review of staff performance
- continuing education & professional development
- personnel record

### 5.2 - Accommodation & environmental condition

### 5.3 - Laboratory equipment, reagent & consumables

### 5.4 - Pre examination processes

### 5.5 - Examination processes

### 5.6 - Ensuring quality of examination results

### 5.7 - Post-examination processes

### 5.8 - Reporting of results

### 5.9 - Release of results

### 5.10 - Laboratory information management