

Check list for laboratories to keep following ready while applying for ISO 15189 2012 accreditation

1. Quality system manual (QSM) duly signed with complete document control and cross references to QP and SOP referred in the QSM
2. Quality system procedures (QSP) Containing procedures followed for all system implementation. This also need to have good document control system in place
3. For all technical activities standard operating procedures department wise and with cross references to all procedures in pre exam examination and post examination areas.
4. Formats for various records as per the requirement of the system this include vendor evaluation reference lab evaluation staff competence evaluation TRF and Report formats to generate minimum of 22 record in both quality and technical areas as per clause 4.13.
5. Latest internal audit report and all related documents
- 6 staff and customer feedback forms and action taken records
7. Equipment maintainance record and Calibration records as per the system requirement
8. Details and the analysis of IQC and EQA
9. Latest management review meeting minutes
10. Staff qualification and other details in the personnel records for all staff as per clause 5.1
11. Waste disposal records and agreement with the agency to whom waste disposal in subcontracted
12. Environmental monitoring process and records
13. All statutory and legal documents to run the laboratory
- 14 Feed back and complaint address