Gap analysis in anticipation of the move to ISO15189

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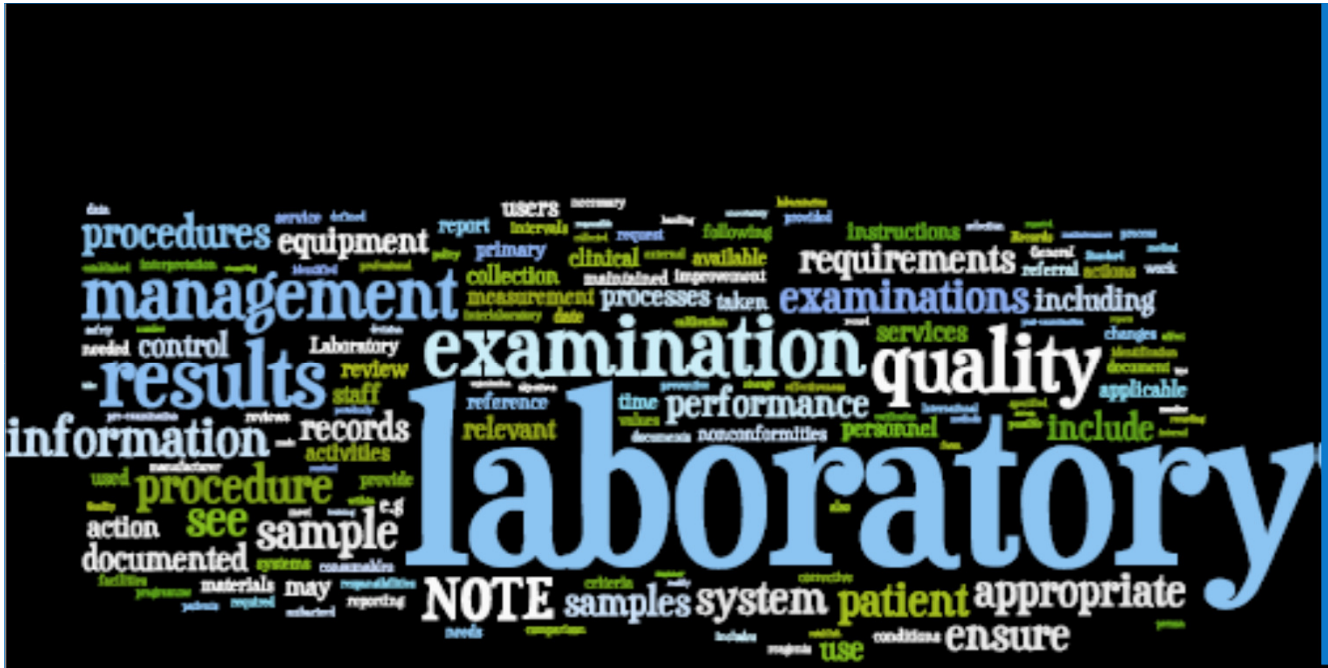
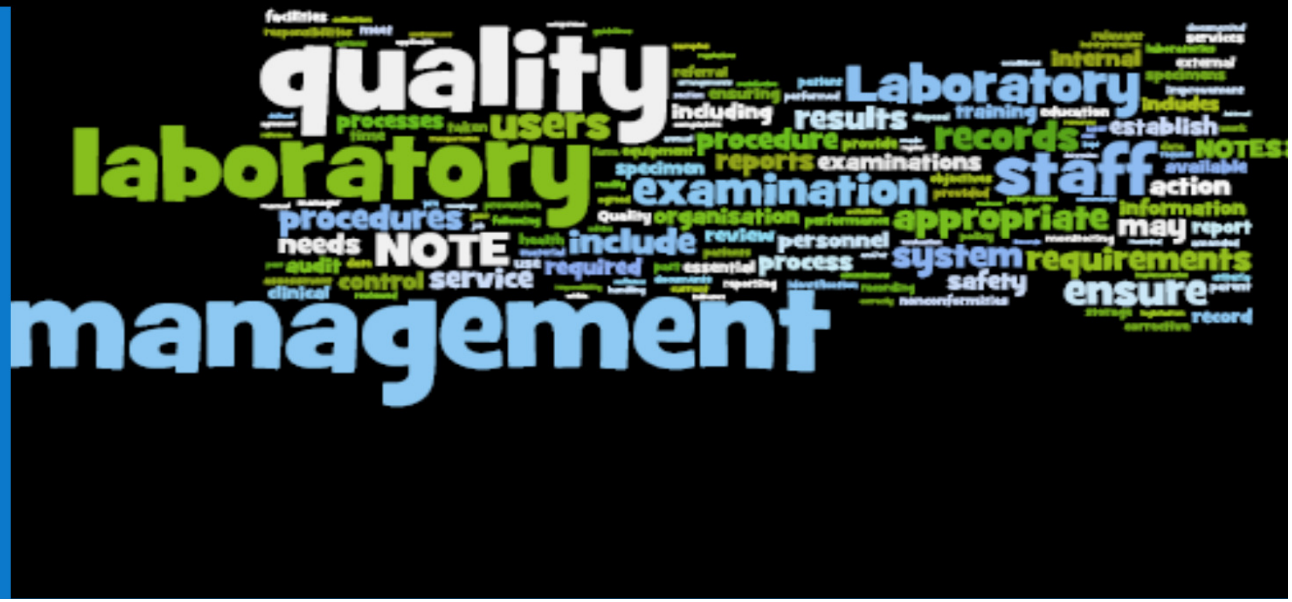


ISO15189:2012

CPA 2010



Clause	Y/N/P/IS	Comments/Actions	Who	Date
2	N	Obtain copies of normative references and other relevant ISO standards	NC	13/10/2013
4.1.1.4	P	Send to Lab Director, concerns over i) and n)	NC	19/07/2013
4.1.2.2	Y	page 14 of Quality Manual WMRG 66;		

Quality Manual

- Developed from Gap analysis
- List the titled clauses e.g. 4.1.1.4 Laboratory Director
- For each clause write a policy statement and a reference to the procedural document
- Get everyone to read it!

Laboratory Director

4.1.1.4

- **Lab Director shall lead and be responsible for services, but also:**
  - **Ensure implementation of Quality Policy**
  - **Select and monitor lab suppliers**
  - **Define, implement and monitor standards of performance**
  - **More emphasis on “continually improve” and “review”**

Service Agreements

- **4.4.1: Each request shall be considered an agreement**
- **Following conditions shall be met:**
  - **Requirements of customers, users and provider (lab) must be understood - evidence**
  - **Capability, including skills/expertise**
  - **Methods fit for purpose**

Purchasing/Suppliers

- **4.5 Examination by referral labs and consultants**
- **Acceptance criteria**
- **Evaluation**
- **Monitoring of performance**
- **Periodic review**
- **4.6 External services & Suppliers**

Staff Suggestions

- **4.14.4 & 4.1.2.6**
- **Communication processes – effective**
- **Staff to be encouraged to make improvement suggestions**
- **Evaluated**
- **Implemented, as appropriate**
- **Feedback**
- **Records maintained**

Internal Auditing

- Clause 4.14.5
- should:
  - be conducted impartially & objectively by trained & experienced personnel
  - (ideally) be independent of the activity to be audited
  - take account of the importance of the processes and technical/management areas

Equipment, Reagents & Consumables

5.3

- Records
  - Contact information for the supplier
  - Date of receipt and date into service
  - Condition when received
  - Inventory
  - Manufacturer instructions
  - Initial acceptability for use; new lot verification of performance
  - On-going acceptability for use

Examination processes

- 5.5.1 Selection, verification and validation
  - All processes
  - Performance characteristics
    - Measurement trueness, accuracy, precision, repeatability, uncertainty, analytical specificity, interfering substances, sensitivity etc
- 5.5.1.4 Measurement uncertainty of measured quantity values

Lab Information Management

- 5.10
- Authorisation for management of information systems, including maintenance and modification
- Define authorities and responsibilities of all personnel who use information systems
- Systems validated by supplier and verified by lab (resultant changes will need to be verified again)
- Safeguarded against tampering

- Environment compliant
- Integrity maintained and system failures documented
- Results and records accurately reproduced
- Contingency plans
- If systems maintained off site, requirements must still be met

Final thoughts!

- Performance should be evaluated at management review; including review of suppliers
- Health and Safety assessment - much reduced
- Objective evidence critical
- CPA top down approach/UKAS bottom up