051-315 WK 08

20 FEBRUARY • THURSDAY

ISO-2012 & 2007 difference

→ NABL use ISO 15189:2012 from October. For already accredited laboratory Knowing difference is important.

Differences

→ General clauses

- Titles of many clauses changed
- Sub clauses given meaningful titles
- More logical flow of ideas
- More relevant to medical laboratory

→ Management clauses

4.1 - Organization & management

- Laboratory is made legally responsible rather than legally identified
- NO explanation for new terminology

4.2 - Quality management system

- Concept of process added
- Suggested contents of quality manual rems

4.4 - Service aggrements

- Switch from Contract to aggrement
- Meaning of aggrement explained in detail

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ISO-2012 & 2007 difference

4.13 - control of records

- New mandatory records:-
  - Receipt of sample
  - Risk management
  - Nonconformance management review

4.14 - Evaluation & audits

- Internal audit is now subclause
- New sub clauses - user feed back
  - staff suggestion
  - Risk management.

Technical clause

5.1 - personnel

Induction program for new staff required

5.2 - Accommodation & environmental condition

- Detailed requirement for following given-
  - laboratory & office
  - staff
  - sample collection facilities

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5.3 - Laboratory equipment, reagent & consumables

- Equipment & reagents described separately
- In house reagent requirement specifically mentioned
- Adverse incident reporting required

5.4 - pre examination process

- Document for information to patients & users
- what information is to be given is described in details.

5.5 - Examination processes

- Verification, Validation & it's documentation required.
- measurement uncertainty mandatory
- SOP require
  - patient preparation
  - Instruction for determining quantitative results when result is not within measuring intervals
  - References.

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5.6 - Ensuring quality of examination results

2020

- procedure to prevent release of results in events of QC failure required.

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5.7 - Post examination procedure

Autoverification requirements described.

5.8 - Reporting of results

- Identification of examination under R & D
- page no or total no of pages.

5.9 - Release of Results

Reports can be released after autoverificatio

5.10 - Laboratory information management

previously an annexture.