

* Identification, control, correction & prevention of nonconformity [In NABL accredited clinical laboratory | requirements in ISO 15189 - 2013]

~~→ Internally audit in NABL accredited clinical laboratory | requirements in ISO 15189 - 2013~~

→ Nonconformity - Nonfulfillment of requirement
Other words - Accident, adverse event, error, event, incident, occurrence

→ Have documented procedure for
identity - find &
manage - control, correct, prevent.

eg. → Identity - technician found that today all glucose are > 200 mg/dl.

Control - Stop glucose analysis

- Stop glucose reporting [if already analysed]

- Take back previous glucose report [if already reported]

Correct - Change reagent [1 day]

- Unstable glucose reagent - change Supplier [1 week]

- Improve criteria for vendor Selection [one month, one year]

→ Define who is responsible to identify & who is authorized to take action

→ Identity: Day-to-day - Calibrations
Lot verification
IQC
EQA, ILC
Staff comments
Report verification

periodic - Internal audit

- Laboratory management reviews

- External audit [NABL assessment]

occasional - clinician complaints

→ control :- No need to know cause

- Find extent of nonconformity

- Take immediate action to reverse harmful effect.

→ correct :- - Evaluating the need.

- Needed most of time

- sometimes, not needed / not possible

- Last bottle of glucose reagent with few ml remaining. New lot starting today.

- Rare nonconformity

- Root causes analysis

- plan action so that n/c do not recur

- Implement action

- Review effectiveness after some time

- make changes in procedure documents, if required.

→ prevention :-

Evaluate the need.

plan preventive action

Implement preventive action

Review effectiveness after sometime

→ Record identification, control, correction & prevention of nonconformity.