↳ To estimate molecular wt of protein By putting standard.

NABL 112 (clause 5.6) Page-2

↓

The lab. shall follow :-

* The rules to follow when 1 level QC is used :-
  1. (1 3S) ⟶ outside 3 SD
  2. (2 2S) ⟶ two consecutive result outside 2SD on same side But ☐in 3SD
  3. 10 x ⟶ 10 consecutive value are above or below the same. But ☐in 2SD

* The rules to be followed when using 2 level QC :-
  1. 1 3S : either QC value is outside 3SD
  2. 2_2S :- both value outside 2SD on same side
  3. R_4S :- diff. B/w both QC is >4SD that is one level QC is >2SD and other level is <2SD
  4. 10x :- 5 consecutive value of one level QC & 5 consecutive value of another level QC are >/< than mean But ☐in 4SD.

⟶ Now search for recent event that could have changed causing changes

⟶ See environment condi^n

⟶ Follow manufacturer's troubleshooting guide

⟶ Refer to manufacturer's of equipment, reagent or QC/calibrator

(7) → NABL 112 also describe checklist for collection centers.

(8) → It's annexure describes routine & special tests. (pg - 51)

(5.6) Assuring quality of examination procedure

Page (1)

→ Laboratory must have procedure for monitoring & evaluating analysis or testing procedures for resolving 'out of control' situations

→ Lab. should use control material similar to or identical to pt. sample matrix

→ Lab. shall incorporate multi-QC rule used to detect systemic and random errors.

→ If no: of pt. sample analysed for any parameter exceeds

- 25/day → Lab. shall employ 2 level QC once a day for such parameters
- < 25/day → one level QC once a day
- > 75/day → 2 level QC at least twice a day at appropriate Intervals.

→ Daily QC values shall be documented along with calculation of CV % from monthly QC data.

→ Lab. shall maintain control chart to demonstrate stability of the analytical measuring system.

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(5.6) Page (1)

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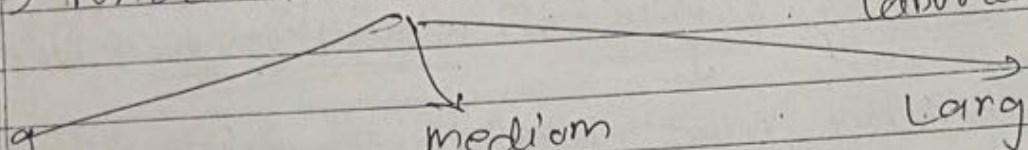
NABL ISO 112 → specific criteria for med. testing lab.

Prepared By NABL over & above

→ Specific criteria of the ISO 15189.
→ To be used together ISO 15189:2012
→ requirement of ISO 15189 are general & require some clarificaⁿ in Indian context — They are described in NABL 112.
→ In addiⁿ, certain specific requirement is described in NABL 112.
→ NABL 112 has described size of laboratory



① ↓ 100 samples ↓ 100-400 ↓ >400 sample.

② → It has defined period for retenⁿ of records, pt reports, retenⁿ period of sample

③ → It has described qualification of personnel for being authorized signatory for various speciality for medical laboratory

④ → It has also defined qualificaⁿ of various techwical staff

⑤ → NABL 112 also defines calibration frequency of various equipment

~~→ It has etc~~

⑥ → NABL 112 also defines various QC rule to be followed & number of QC sample to be analysed ~~per~~ based on sample workload (pg-35 of NABL 112)

(1) No subcause - Neum titl
meaning ful →

(2) 5.8 < 5.8 / 5.9

(3) LIS
as → 5.10
Annex - Inform

(4) Ethics
as → Ethics as
Annexure a Mang. Clause
(4.1)

(5) Detail prescrip'd with cpms removed

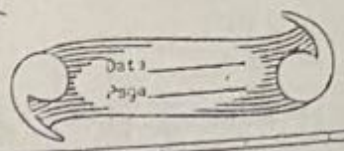
(6) (+) Risk mani. (4.14.6)

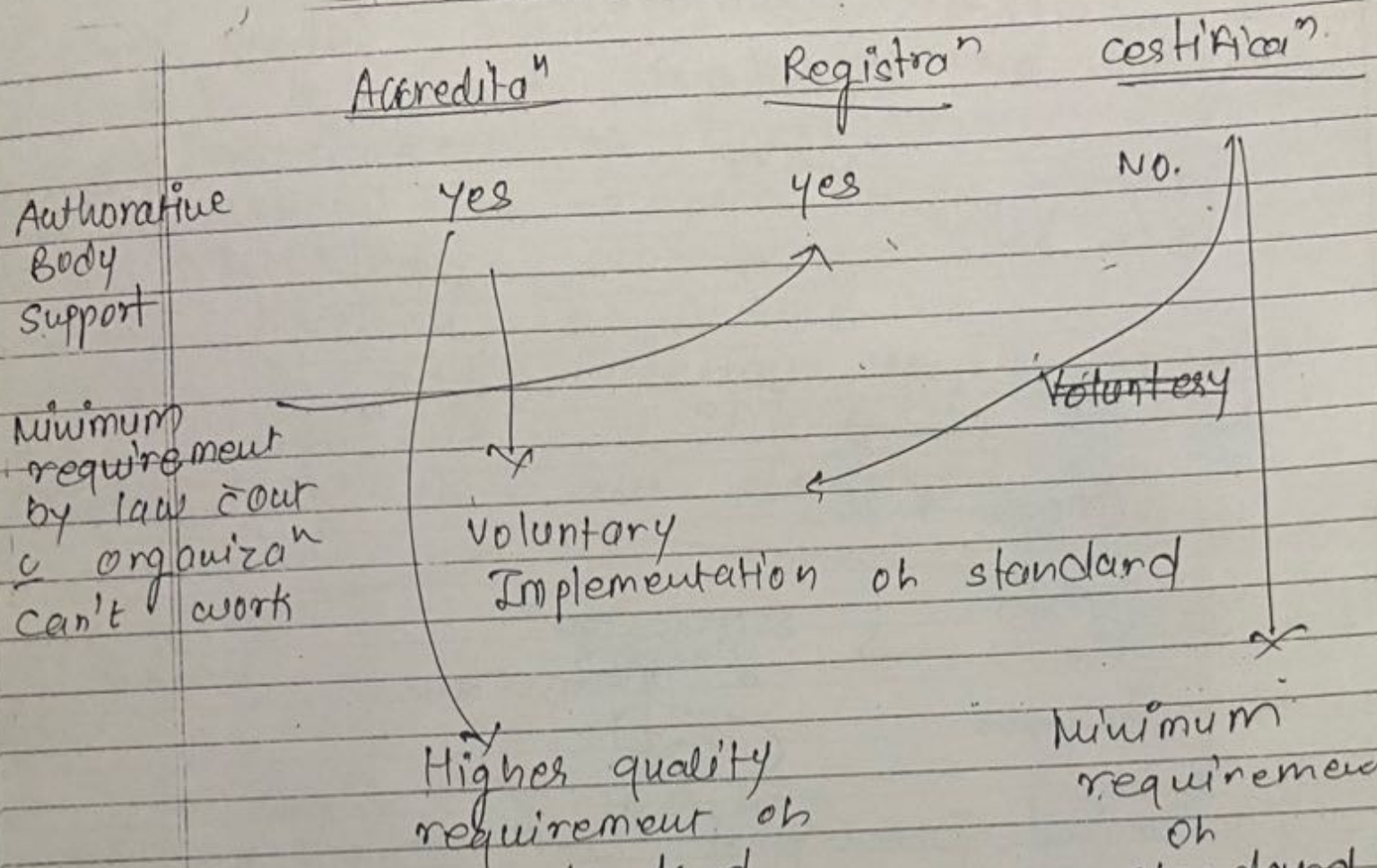
(7) Primary Samp Colle a was details & ~~prescripn~~ is 2 not. Cause related
but such dele
dlin 2012

(8) valid & valif 5 open in 2 or if an part my other
claus

(9) Pilot draft NABL new not revdt NABL 112 to synchronize with
ISO → 2012

Registration :- Basic requirement





Imp.

⑥. * Document control procedure

Countries where ISO 15189 is compulsory :-

ISO 9001 :- Quality Management System

→ 5 sections
2 Annexures

* CLIA is a law for foreign Act supported by govt

Clinical establishment Act ; 2010

(1) Scope
(2) Normative reference :-
Refered those Document refered by ISO 15189 : 2012 for developing standard
↓
- ISO 17025 : 2005

(3) Terms & definations :-
those terms which have special meaning is described

Like accreditation

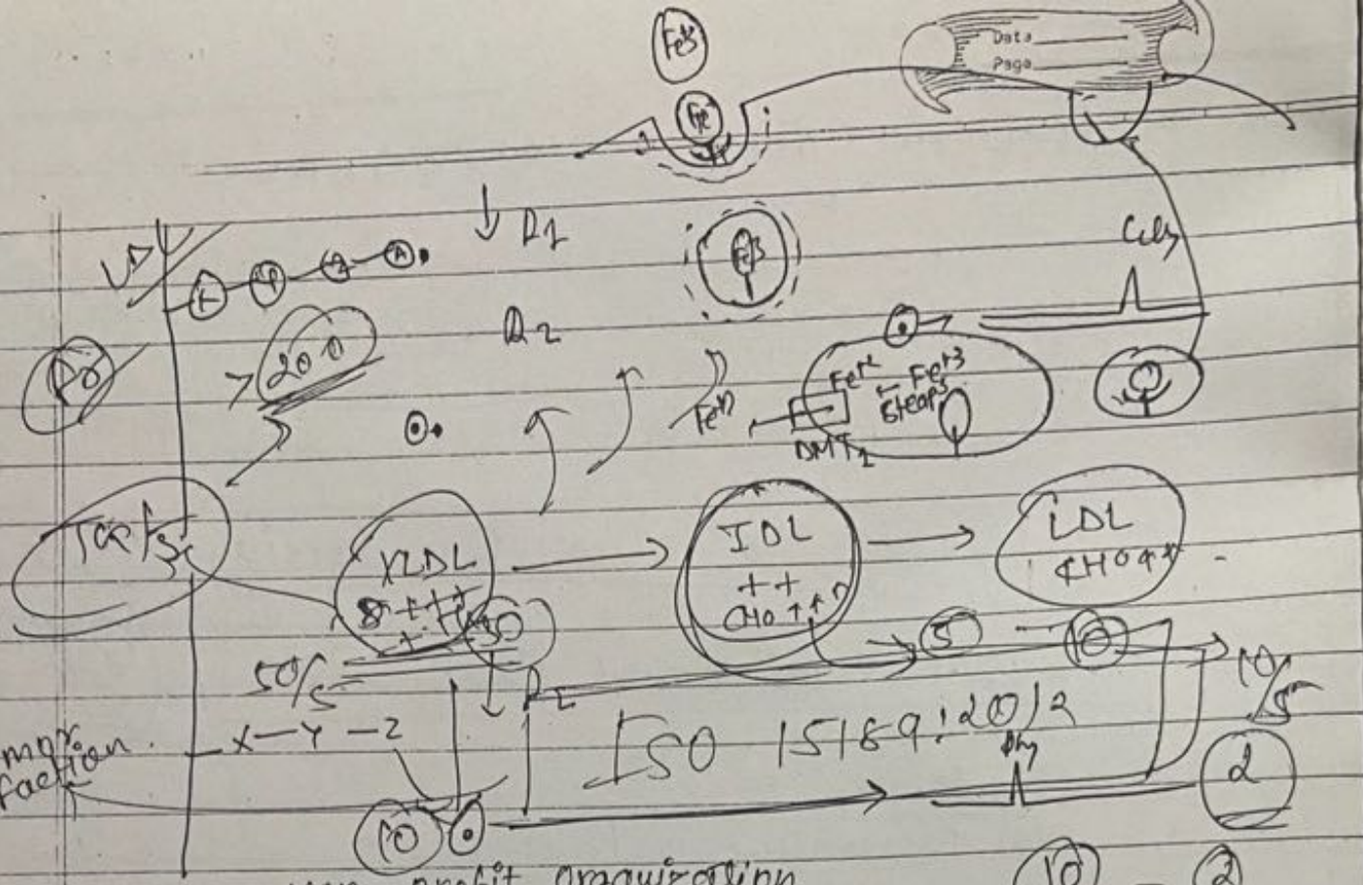
Prime ministers

ILAC is not authority Body

Under ↓

Health Ministries ← Family Of Health welfare ← QCI ← NABL

(4) Managem
↳ where various requirement related to



(A) ISO → Non profit organization for all laboratory

ISO 17025 :—

(1) ISO 15189 : 2003 → 2007 → 2012 latest.

(2) 15189 : 2012 → By NABL as based document in India

(3) NABL 112 → Criteria over & above the ISO 15189:2012.

(4) Scope :— ISO :— Document for process of improvement

↓

Can be used for competence

Can be used By Lab., customers, Regulatory authority

- Regulatory authority : Government
- Accredited Bodies : NABL
- standard to be followed By Laboratory, customer, or lab itself

10 - 2

LDL → 10

LDL → 2