* Measurement uncertainity

- Determine measurement uncertainty for each measurement procedure in examination phase used to report measured quantity values on patient sample.

→ Define performance requirement for measurement uncertainty of each measurement procedure & regularly review estimates of measurement uncertainty.

e.g. → Precision/imprecision is one of component.
↳ obtained by running stable controls with frequency described under each discipline.
- Calculate SD & CV% from laboratory mean. [Not from control's target value assigned by manufacturer]
- Actual CV% up to first place of decimal for each parameter shall be used for calculation.

- As IQC material may not totally reflect analytical behavior of patient samples, derive imprecision from long term IQC data - Calculate SD / CV%.

→ For measurement uncertainity
$= k \times \%CV$

k is coverage factor ?
at 95% confidence interval - it equals to ± 1.96 approximated to ± 2.

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→ Uncertainty of measurement set as

↓

- %CV [Coefficient of variation]
- uncertainity of measurement would be $\pm 1.96 \times \%CV \approx \pm 2 \times CV\%$.

→ Minimum 6 month IQC data should be used to calculate routine imprecision

→ For non quantitative set of tests, laboratory shall enlist factors which could contribute to uncertainty of results & also ensure that they were given due attention while performing the test.