PTB

INTERNATIONAL
KNOWLEDGE
TRANSFER

Contents

- ISO/IEC 17025:2017 Requirements
- Foundations of a Quality Control Programme
- Internal QC:
  - ✓ Use of Check Standards
  - ✓ Control Charts
  - ✓ Intra-laboratory Comparisons
- External QC:
  - ✓ PTs/ILCs

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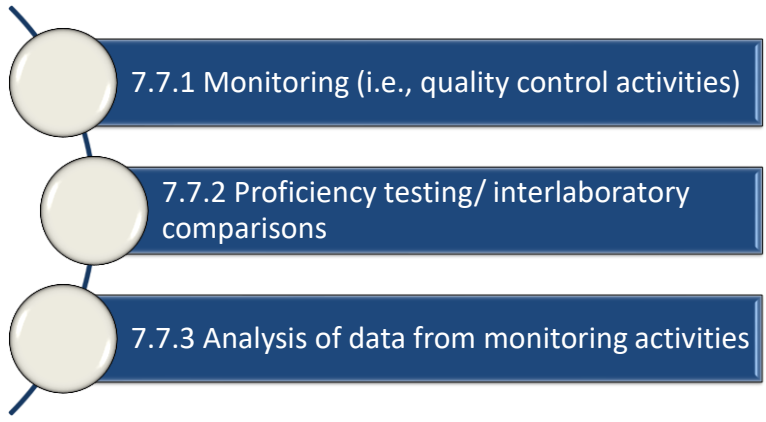
ISO/IEC 17025:2017 clause 7.7

- 3 sub-clauses:



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Sub-clause 7.7.1

Requires a procedure

Record data

- Detect trends
- Apply statistical techniques, where practicable

Review and monitoring

- Monitoring shall include, where appropriate: a) to k)

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Sub-clause 7.7.1

Monitoring activities for ensuring validity of results

- a) use of reference materials or quality control materials;
- b) use of alternative instrumentation that has been calibrated to provide traceable results;
- c) functional check(s) of measuring and testing equipment;
- d) use of check or working standards with control charts, where applicable;
- e) intermediate checks on measuring equipment;
- f) replicate tests or calibrations using the same or different methods;
- g) retesting or recalibration of retained items;
- h) correlation of results for different characteristics of an item;
- i) review of reported results;
- j) intralaboratory comparisons;
- k) testing of blind sample(s)

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Sub-clause 7.7.2

Monitor performance by comparison with results of other laboratories

- Proficiency testing (PT)
- Interlaboratory comparisons (ILCs)

Benefits of participation:

- Supplements internal QC activities
- Added confidence
- Comparison of performance

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PTs- ILAC P9

P9: ILAC Policy for Participation in Proficiency Testing Activities

Minimum PT activity for labs:

- Evidence of satisfactory participation prior to gaining accreditation
- Further and ongoing activity that is appropriate to the scope of accreditation and consistent with the PT participation plan

… And the requirements of the Accreditation Body

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Most crucial points of ABs' requirements

- Reference to the importance of PTs as a tool to demonstrate technical competence
- Requirements concerning i) the minimum level and frequency of participation and ii) need for planning participation
- How PT participation and performance will be reviewed and used during assessments.

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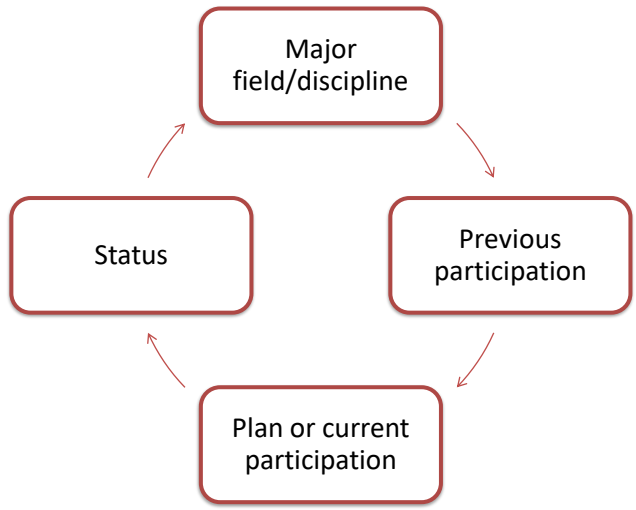
PTs- ILAC P9

PT Participation Plan



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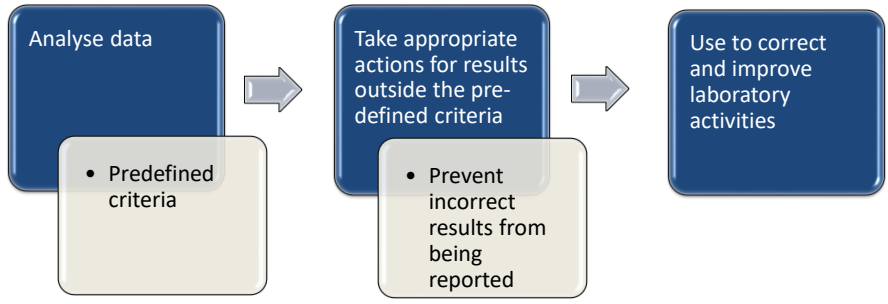
Sub-clause 7.7.3



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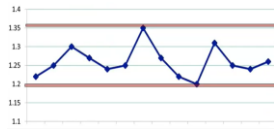
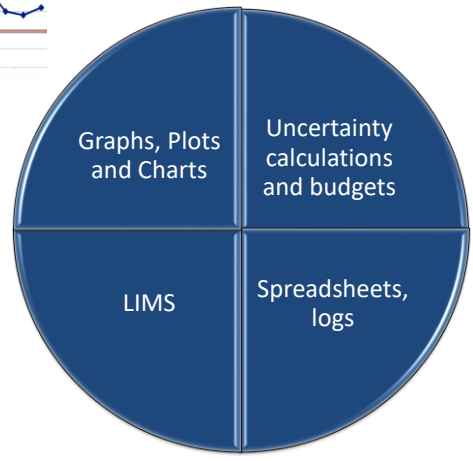
Sub-clause 7.7.3- Recording and Analysing Data





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Foundations of a Quality Control Programme

Internal Quality Control	• Based on day-to-day and item to item monitoring of performance
External Quality Control	• Based on the laboratories ' performance in interlaboratory comparisons and proficiency testing programs

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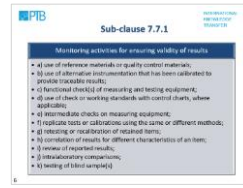
Evaluation of internally obtained measurement assurance data

These data can be obtained through:



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Evaluation of internally obtained measurement assurance data (cont'd)

Each measurement parameter in the laboratory's scope of activities must be reviewed and analyzed to determine the validity of the measurement process.

- The standards and the measurement process for each parameter must be in a state of statistical control.
- Statistical control means that the variability of the measurement process is known, stable and observed values are adequately close to reference values, within the chosen statistical limits.
- When a process is in statistical control and the reference values are within suitable limits, we can assume that the reported measurement uncertainties are valid.

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Evaluation of internally obtained measurement assurance data

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Minimizing risks of measurement errors includes all the following laboratory functions:

a. Training staff and evaluating effectiveness and proficiency

b. Monitoring the laboratory environment to minimize potential errors or excess variation

c. Maintaining suitable equipment (including installation, monitoring, approvals, and integrated software)

d. Selecting and calibrating standards

e. Ensuring suitable suppliers for materials and calibrations

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Evaluation of internally obtained measurement assurance data (cont'd)

INTERNATIONAL KNOWLEDGE TRANSFER

Minimizing risks of measurement errors includes all the following laboratory functions:

f. Selecting and validating procedures with evaluation of accuracy/bias and precision

g. Ensuring proper care and handling of laboratory standards, equipment, and items submitted for calibration

h. Accurately and effectively calculating, evaluating, and reporting measurement uncertainty

i. Participating in inter- and intra-laboratory comparisons

j. Creating and reviewing calibration certificates to ensure accuracy of measurement results and the effective communication of results

k. Controlling data – information management (including software and information technology controls).

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Evaluation of externally obtained measurement assurance data

These data can be obtained through:

a. Evaluation of the calibration history of reference standards, working standards, and check standards

b. Evaluation of before/after calibrations within a laboratory to compare and evaluate results obtained from an external calibration provider

c. Review of historical calibration data for items calibrated having demonstrated stability

d. Comparison of all calibration results and calibration history on control charts for working standards and check standards with results from external calibration sources

e. Participation in proficiency testing using the same procedures and handling methods used for routine laboratory calibrations

f. Use of externally obtained data from calibrations, PTs, and ILCs in the assessment of errors and bias in measurement results

g. Participation in ILCs other than proficiency testing (e.g., for method validation or as a training activity)

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Combining Data from Multiple Sources

Measurement results collected over several years may be statistically evaluated with current results being compared to results from previous years.

- Any observed problems or changes in the measurement results are investigated- corrective action taken
- Ongoing monitoring establishes a continuous and comprehensive internal laboratory measurement assurance program

Data from internal measurement assurance programs should be compared to the results of calibration history assessments, interlaboratory comparisons or proficiency tests, and other external sources of data

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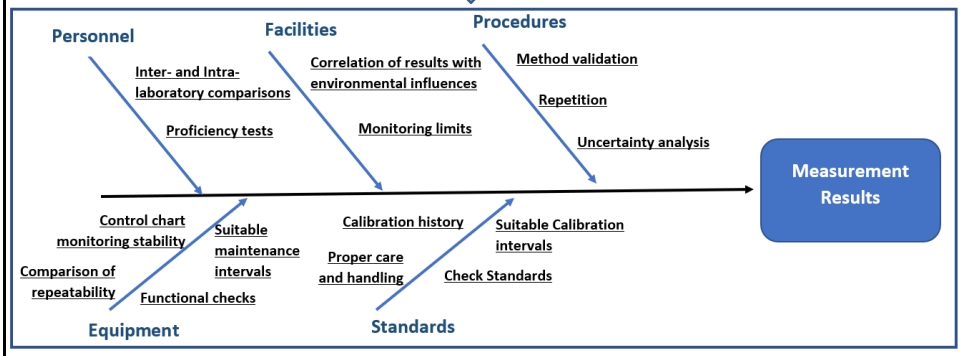
Analysis of results

Objectives to evaluate the entire measurement process, as a system, will consider:

a. Personnel;
b. Facility/accommodations;
c. Procedures and method validation;
d. Equipment; and
e. Standards.



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Analysis of results

Definition of the criteria against which the measurement assurance results are assessed and evaluated.

Data from all the measurement assurance activities are analysed and monitored to both control and improve the laboratory's activities.

When the results of the data analyses from monitoring activities are found to be outside the pre-defined criteria, appropriate actions are taken to prevent incorrect results from being reported to the customer.

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Internal QC- Use of Check Standards- Summary

- Regular checks of check standards (where possible), in order to ensure the reliability of the process of calibration according to the calibration procedures.
- An appropriate check standard (or control standard) is incorporated into the measurement process and measured at established intervals.
- The check standard can be either substituted for, or measured as, the item being calibrated.
- The results of the check standard measurements are recorded, charted, and analysed to establish the measurement capability and to set process control and warning limits.
- The limits are used to establish process uncertainties and to control future measurement performance.

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Internal QC- Use of Check Standards- Summary

A check standard must be stable and is normally comparable to the reference standard or to the typical item submitted for calibration, depending on what is being monitored (standards or process).

For lower order calibrations, it should simulate the laboratory's reference or working standards (to the extent feasible).

It should be calibrated using a better procedure than the one being monitored to ensure that the expanded uncertainty is equal to or better than the uncertainty achievable with the process being monitored.

All check standards should be cared for in the same way as reference standards to prevent their damage or deterioration.

Lower order check standards should be recalibrated at regular intervals, according to the laboratory's policy on re-calibration intervals.

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Internal QC- Use of Check Standards- Summary

- Control measurements of the check standard are graphed on control charts ($\bar{x}$ and standard deviation charts) for visual examination of process performance and are evaluated against statistical control limits.

$\bar{x}$ control chart

- Monitors the process with respect to both the standard and the variability
- A central line is drawn, indicating the mean ($\bar{x}$) of the measured values and control limits are indicated within which the results of measurements are expected to be randomly distributed, based on statistical considerations.
- The control limits consist of the "action" and "warning" limits that represent probabilistic limits for the distribution of results around the central line.

standard deviation chart

- monitors the short term precision of the process

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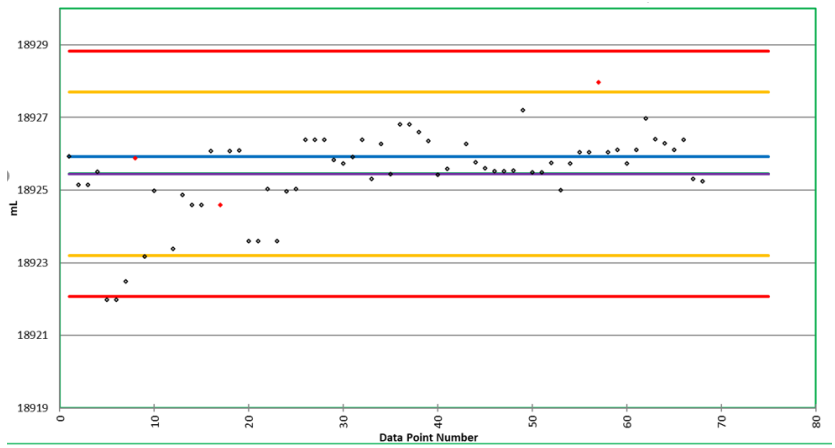
Internal QC- Use of Check Standards- Summary



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Internal QC- Use of Check Standards- Summary

The system is in statistical control when the individual values are within the designated statistical limits.

- The statistical information on which the control limits are based can be used to calculate confidence limits for measurements made while the system is demonstrated to be stable and in a state of statistical control.
- The standard deviation of the measurement process may be included in uncertainty calculations

The system is out of control if:

- values are present outside established limits for which no reasonable and correctable cause have been determined and corrected
- unusual trends are observed
- the mean exceeds the control limits

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Internal QC- Use of Check Standards Requirements

Check Standards:

- Must **represent the standard and/or the items to be calibrated**.
- Must be **stable**, and their **values should be established with accuracy**, since they will be used to control the uncertainty in the calibration process
- Their reference values and uncertainty must be **determined by a higher level of calibration than the procedure being monitored**, and preferably using an **independent standard, process, or laboratory competent** to work at that level
- As a minimum, they may be calibrated within the laboratory only **if qualified to work at the next higher level and using a procedure one level higher** than the calibration process to be controlled

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Internal QC- Use of Check Standards Additional Requirements

- Experienced operators
- A calculating system for statistical control that calculates standard deviations, control limits, F-tests, t-tests, root-sum-of-the-squares (RSS), and creates control charts

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Check Standards- Terms used in Control Charts

- bias - expresses the difference between the mean value of the measured quantity and the “known" value (the result of the most recent calibration).
- short-term variability- often referred to by the term repeatability and expresses the ability of the device/system to produce under clearly defined measuring conditions the same measurement result.
  - ✓ Repeatability is determined by the standard deviation of a series of repeated measurements.
  - ✓ This standard deviation is a measure of the variability of the measurement process over a short period of time, usually the time necessary to complete one calibration using a particular sequence of measurements called a statistical design. It is called the "within standard deviation” s_w.

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Check Standards- Terms used in Control Charts

- long-term variability - associated with changes in existing environmental conditions of the laboratory or in the measurement performance.
  - ✓ Often referred to by the term reproducibility and expresses the ability of a process to produce under non-identical measurement conditions the same result.
  - ✓ It is also referred to as a "between" standard deviation, s_b, meaning between calibrations, and is attributed to changes in the calibration process from day-to-day (environmental changes that are not accounted for by modelling, changes in artifact alignment relative to the standard , and other fluctuations that are not reflected in the within standard deviation.

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Check Standards- Terms used in Control Charts

- Total standard deviation- includes both the "within" and "between" components of variability

$$s_c = \sqrt{s_w^2 + s_b^2}$$

  - ✓ It reflects both the short-term and long-term random errors that affect the measurement process.

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Check Standards- Objectives of QC

- QC is used for defining, measuring, analysing, improving, and controlling the **measurement process and uncertainty** as the calibration is performed through the use of suitable check standards.
- The uncertainty includes effects of the measurement instrument, the operator, the procedure, the standards, and the environment over time.
- Each process is modelled to determine and control:
  - ✓ 1) the measurement process;
  - ✓ 2) the calibration and check standards; or
  - ✓ 3) a balance of both the process and the standards.

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Check Standards- Objectives of QC

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- The objectives will establish the value of the check standard, the check standard measurement procedure, and influence the frequency of control measurements of the check standard.
- **Objectives** may be:
  - ✓ 1) Determine the standard deviation of the process (s_p);
  - ✓ 2) Determine the expanded uncertainty, U;
  - ✓ 3) Measure the value of the calibration standard uncertainty (u_s).

  The model may allow any one objective or a combination of the objectives to be established

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Check Standards- Methodology

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- The check standard is selected to evaluate the standard deviation of the process, s_p, other process uncertainties, u_o, and possible bias, u_d of the process.
- Initial measurements for the check standard should be performed immediately after calibrating the reference or working standards and after the servicing of the measurement instrument.

Symbol	Description
S_c	Control measurement of check standard
S_{cs}	Accepted value of check standard
U	Expanded Uncertainty (of the process)
u_c	Combined standard uncertainty
u_s	Standard uncertainty of the standard
u_o	Standard uncertainty of other factors
u_d	Standard uncertainty of differences
s_p	Standard deviation of the process
k	Coverage factor

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Check Standards- Obtain Initial Measurements to Establish Control Charts

- To establish a new control chart, a minimum of 12 or more, independent measurements of the check standard should be made, using the same standards, equipment, procedure, and under the same conditions that will be used to make routine measurements.
- A calibration is defined as the result of replicate measurements as required by the respective SOP (i.e., a complete test consists of the number of runs specified in the SOP).
- No two measurements may be made on the same day.
- The time of day should be varied as would be typical during routine laboratory operations. This is necessary to estimate the long-term standard deviation to the extent feasible. To make statistically valid decisions or calculate uncertainties based on this data, 25 to 30 points are necessary.

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Check Standards- Obtain Initial Measurements to Establish Control Charts

a) A database is created. This database is the statistical population from which the quality parameters of the measuring process (bias, long and short-term variability) can be identified and quantified.

b) Using statistical criteria, the compatibility of the latest measurements with the defined quality parameters of the process is examined (process monitoring)

- The quality parameters are adjusted at regular intervals (every 12 measurements) to reflect the most recent state of the measuring processes.

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Check Standards- Obtain Initial Measurements to Establish Control Charts

- **Conditions:**

a) data belong to the statistical distribution (population).

b) the distribution is normal

c) the measuring errors are uncorrelated over time.

- ***n* daily (*n*≥4) iterations during *m* days (*n* is the same for all the daily repetitions).**
- Each point in the database is denoted by X_{ij} (i=1,…m; j=1,…n) The average of the n iterations of the i-day equals:

$$\overline{X}_i = \frac{1}{n}\sum_{j=1}^{n} X_{i,j}$$

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Check Standards- Calculations for Construction of Control Charts

- A standard deviation may be calculated for each set of runs according to the appropriate SOP.
- Standard deviation of the n repetitions for $v=n-1$ degrees of freedom (short-term variability of the measuring system):

$$s_i = s_C = \sqrt{\sum_{j=1}^{n}\left(X_{i,j} - \overline{X}_i\right)^2 \frac{1}{n-1}}$$

- A pooled standard deviation is then determined for the measurement process.
- Pooled standard deviation: a better estimation of the repeatability of the measurement process and requires the combination of the m daily standard deviations ($v= m(n-1)$ degrees of freedom):

$$s_p = \sqrt{\frac{1}{m}\sum_{i=1}^{m} s_i^2}$$

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Check Standards- Calculations Related to Control Charts

- Standard deviation of the m values of the check standard: expresses the long-term variability of the process (v= m-1 degrees of freedom):

$$s_{chkstd} = \sqrt{\frac{1}{m-1}\sum_{i=1}^{m}\left(\overline{X}_i - \overline{X}\right)^2}$$

- General mean value of all the measurements that refer to the check standard

$$\overline{X} = \frac{1}{m}\sum_{i=1}^{m}\overline{X}_i$$

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Check Standards- Calculations Related to Control Charts

- **Control of the long-term variability of the process: *t*-test**
- Checks whether the measurement difference Δy_{check} from the latest quality control measurement is not essentially different from the overall average of the differences from the previous control measurements.
- A test statistic is computed from the current check standard measurement, the accepted value of the check standard, and the total standard deviation.

$$t = \frac{\left|\Delta y_{check} - \overline{\Delta y}_{check}\right|}{s_{chkstd}}$$

y: measurand

The calibration process is under statistical control if:

$t \leq$ critical value of t-distribution with n degrees of freedom

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Check Standards- Calculations Related to Control Charts

- **Control of the long-term variability of the process: *t*-test**
- Critical value $t_{\alpha/2}(\nu)$- ν Dof: depends on ν and on $\alpha/2$, the significance level (probability of mistakenly flagging a check standard measurement as out-of-control).
- Critical values for a two-sided t test with α=0,05:

Degrees of freedom	Critical value	Degrees of freedom	Critical value
1	12,706	14	2,145
2	4,303	15	2,131
3	3,182	19	2,093
4	2,776	24	2,064
5	2,571	29	2,045
6	2,447	34	2,032
7	2,365	39	2,023
8	2,306	44	2,015
9	2,262	49	2,010
10	2,228	50	2,009

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Check Standards- Calculations Related to Control Charts

- **Control of the short-term variability of the process: F-test**
- If the measurement sequence allows for a within standard deviation, the ratio of this within standard deviation to the pooled standard deviation s_p is compared to F(critical value).

$$F = \frac{s_i^2}{s_p^2} \qquad s_i = s_C = \sqrt{\sum_{j=1}^{n} (X_{i,j} - \overline{X}_i)^2 \frac{1}{n-1}} \qquad s_p = \sqrt{\frac{1}{m}\sum_{i=1}^{m} s_i^2}$$

- The repeatability is under statistical control when:

$F \leq$ critical value of F-distribution with ν degrees of freedom for s_i and $m \cdot \nu$ for s_p

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Check Standards- Calculations Related to Control Charts

- **Control of the short-term variability of the process: F-test**

Critical values of F-distribution so that $s_{new}(v) \leq s_p(m \cdot v)$ for one-sided test with α=0,05:

m·v	v=1	2	3	4	5	6	7	8	9	10
1	161,45	199,50	215,71	224,58	230,16	233,99	236,77	238,88	240,54	241,88
10	4,965	4,103	3,708	3,478	3,326	3,217	3,135	3,072	3,020	2,978
16	4,494	3,634	3,239	3,007	2,852	2,741	2,657	2,591	2,538	2,494
20	4,351	3,493	3,098	2,866	2,711	2,599	2,514	2,447	2,393	2,348
26	4,225	3,369	2,975	2,743	2,587	2,474	2,388	2,321	2,265	2,220
30	4,171	3,316	2,922	2,690	2,534	2,421	2,334	2,266	2,211	2,165
36	4,113	3,259	2,866	2,634	2,477	2,364	2,277	2,209	2,153	2,106
40	4,085	3,232	2,839	2,606	2,449	2,336	2,249	2,180	2,124	2,077
45	4,057	3,204	2,812	2,579	2,422	2,308	2,221	2,152	2,096	2,049
50	4,034	3,183	2,790	2,557	2,400	2,286	2,199	2,130	2,073	2,026
60	4,001	3,150	2,758	2,525	2,368	2,254	2,167	2,097	2,040	1,993
70	3,978	3,128	2,736	2,503	2,346	2,231	2,143	2,074	2,017	1,969
80	3,960	3,111	2,719	2,486	2,329	2,214	2,126	2,056	1,999	1,951
90	3,947	3,098	2,706	2,473	2,316	2,201	2,113	2,043	1,986	1,938
100	3,936	3,087	2,696	2,463	2,305	2,191	2,103	2,032	1,975	1,927

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Check Standards- Calculations Related to Control Charts

- **Shewhart Control Charts: Bias and long-term variability**
- Control chart parameters: are evaluated based on a reasonable number of initial measurements and updated as additional measurement data are accumulated.
- A known value is based on a higher-level calibration of the check standard that is preferably independent of the measurement system being monitored.
- The central line is established by the mean of measurements.
- If no higher-level calibration is available, the central line may be used as the known value, but this is not recommended since it will allow no evaluation of measurement accuracy or bias.
- Upper and lower control limits should be fixed, and adjusted after periodic evaluation when/if appropriate.

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Check Standards- Calculations Related to Control Charts

Shewhart Control Charts: Bias and long-term variability ($\overline{X}_i$ vs time)

Construction of $\overline{x}$ control chart:

- Calculate the mean (central line), $\overline{X}$, and $s = s_{chkstd}$

$$\overline{X} = \frac{1}{m}\sum_{i=1}^{m}\overline{X}_i \qquad s_{chkstd} = \sqrt{\frac{1}{m-1}\sum_{i=1}^{m}\left(\overline{X}_i - \overline{X}\right)^2}$$

- Establish the control chart parameters as follows:

Control Chart Parameter	Value
Central Line	$\bar{x}$
Upper Control/Action Limit (UCL)	$\bar{x} + 3s$
Upper Warning Limit (UWL)	$\bar{x} + 2s$
Lower Warning Limit (LWL)	$\bar{x} - 2s$
Lower Control/Action Limit (LCL)	$\bar{x} - 3s$

$s = s_{chkstd}$

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Check Standards- Analyse Data of Control Charts

Standard Deviation Control Charts: Short-term variability (s_i vs time)

- This chart is characterized by the central reference line and the upper control limit.
- This is due to the fact that the deterioration of the short-term variability of the measurement process is expressed only by the increase of the standard deviation of repeated measurements.
- The central/base line is the pooled standard deviation s_p
- Upper control limit: $UCL = s_p\sqrt{F_a\left(n-1; m(n-1)\right)}$

- α is chosen based on the desired limits (e.g., 0.05 for 95 %).
- n-1 represents the degrees of freedom from the replicates.
- $m(n$-$1)$ represents the DoF corresponding to s_p.

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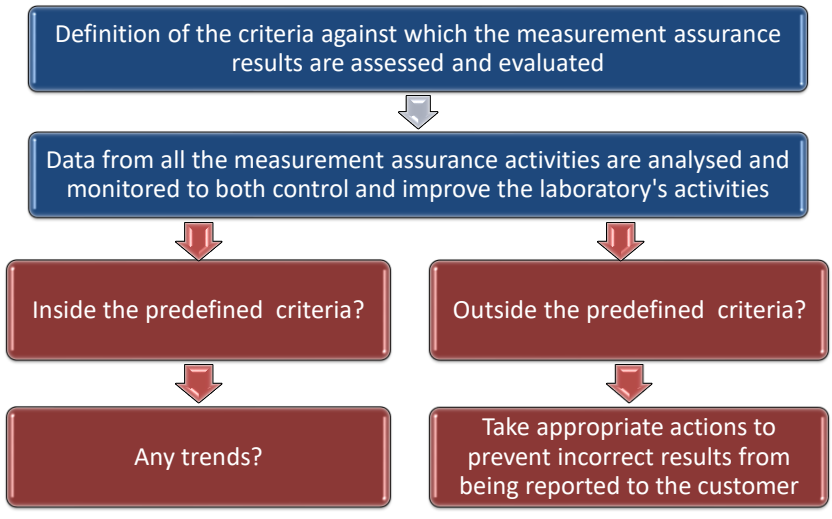
Check Standards- Analyse Data of Control Charts

Flowchart



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Check Standards- Analyse Data of Control Charts: Outline

If plotted points are stable and randomly distributed within the warning limits, the system is in control.

In case of normal process statistic, this means that 99.73 % of the points will fall within the control/action limits.

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PTB

INTERNATIONAL KNOWLEDGE TRANSFER

Check Standards- Analyse Data of Control Charts: Outline

Observations outside the limits, or systematic patterns within, should be investigated and corrected as appropriate or possible

If a plotted point is outside the warning limits but within the control limits, investigate the presence of calculation errors.

If none were made, re-measure the check standard

The re-measured value must be within the warning limits to merit the decision of "in control".

If the re-measured results are not within limits, consider the measurement process "out of control"

Reject all data obtained since the last "in-control" measurement and take corrective action.

Keep the "out of control" data in the chart and flag it as problematic. In control again: 2 successive measurements within the control limits

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PTB

INTERNATIONAL KNOWLEDGE TRANSFER

Check Standards- Analyse Data of Control Charts: Outline

If a plotted point is outside the control limits and arithmetically correct, the system is out of control.

Data are rejected

Corrective actions must be taken

Re-attainment of statistical control must be demonstrated before data are accepted.

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INTERNATIONAL KNOWLEDGE TRANSFER

Check Standards- Analyse Data of Control Charts

- Additional guidelines for the evaluation of control charts based on probability statistics should be used to evaluate the presence of drift, shifts, and possible bias. Examples:
  - ✓ Any single point or series of points outside of 3*s* (keeping in mind the probability that a 3*s* limit could reasonably expect to allow 3 points out of 1000 to be outside these limits);
  - ✓ 2 of the last 3 points are above (or below) 2*s*;
  - ✓ 4 of the last 5 points are above (or below) 1*s*;
  - ✓ 8 consecutive points are on one side of the mean or reference value;
  - ✓ 6 points in a row are trending up (or down); and
  - ✓ 14 points are alternating up and down (sawtooth pattern) about the mean or reference value.

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INTERNATIONAL KNOWLEDGE TRANSFER

Check Standards- Analyse Data of Control Charts

Nelson Rules

Rule 1	One point is more than 3 standard deviations from the mean.
Rule 2	Nine (or more) points in a row are on the same side of the mean.
Rule 3	Six (or more) points in a row are continually increasing (or decreasing).
Rule 4	Fourteen (or more) points in a row alternate in direction, increasing then decreasing.
Rule 5	Two (or three) out of three points in a row are more than 2 standard deviations from the mean in the same direction.
Rule 6	Four (or five) out of five points in a row are more than 1 standard deviation from the mean in the same direction.
Rule 7	Fifteen points in a row are all within 1 standard deviation of the mean on either side of the mean.
Rule 8	Eight points in a row exist, but none within 1 standard deviation of the mean, and the points are in both directions from the mean.

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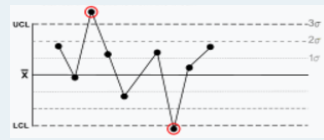
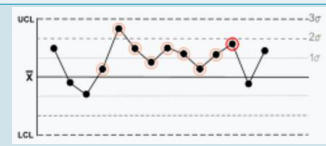
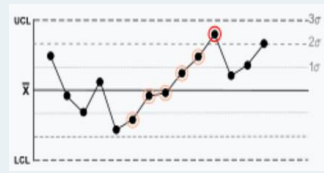
PTB

INTERNATIONAL KNOWLEDGE TRANSFER

Check Standards- Analyse Data of Control Charts

Nelson Rules

Rule 1	One point is more than 3 standard deviations from the mean.		Tests for stability. This is the strongest evidence of lack of control. One sample (two shown in this case) is grossly out of control.
Rule 2	Nine (or more) points in a row are on the same side of the mean.		Tests for stability. This can be used to supplement rule 1. Some prolonged bias exists.
Rule 3	Six (or more) points in a row are continually increasing (or decreasing).		A trend exists

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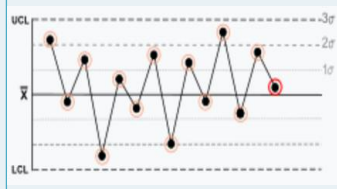
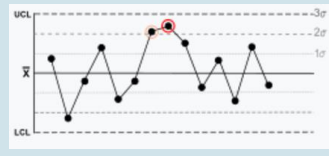
Check Standards- Analyse Data of Control Charts

Nelson Rules

Rule 4	Fourteen (or more) points in a row alternate in direction, increasing then decreasing.		Tests for a systematic variable. The pattern of variation should be random, but is predictable if failing rule 4. This much oscillation is beyond noise. Note that the rule is concerned with directionality only. The position of the mean and the size of the standard deviation have no bearing.
Rule 5	Two (or three) out of three points in a row are more than 2 standard deviations from the mean in the same direction.		Tests for small shifts in the data. There is a medium tendency for samples to be out of control. The side of the mean for the third point is unspecified.

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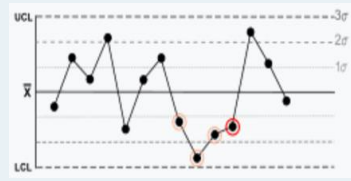
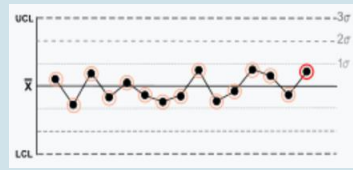
INTERNATIONAL KNOWLEDGE TRANSFER

Check Standards- Analyse Data of Control Charts

Nelson Rules

Rule 6	Four (or five) out of five points in a row are more than 1 standard deviation from the mean in the same direction.		Tests for small shifts in the data. There is a strong tendency for samples to be slightly out of control. The side of the mean for the fifth point is unspecified.
Rule 7	Fifteen points in a row are all within 1 standard deviation of the mean on either side of the mean.		Tests for stratification, which can be misinterpreted as good process control. Within 1 standard deviation, greater variation would be expected.

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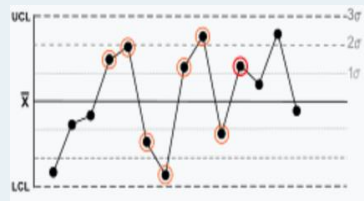
INTERNATIONAL KNOWLEDGE TRANSFER

Check Standards- Analyse Data of Control Charts

Nelson Rules

Rule 8	Eight points in a row exist, but none within 1 standard deviation of the mean, and the points are in both directions from the mean.		Tests for mixture, which is when the data avoids the centre line and lies near the control limits. Jumping from above to below whilst missing the first standard deviation band is rarely random.

http://asq.org/learn-about-quality/data-collection-analysis-tools/overview/control-chart.html

http://www.itl.nist.gov/div898/handbook/pmc/section3/pmc3.htm

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INTERNATIONAL KNOWLEDGE TRANSFER

Check Standards- Analyse Data of Control Charts

Even while the system is in an apparent state of control, incipient troubles may be indicated when the control data show **short or long term trends, shifts, or runs**.(Use F and t-tests to estimate their significance)

If the values plotted on the standard deviation chart fall outside of the control limits, a **decrease in precision is indicated**. Problems with the standards or process will need to be investigated

If the plotted value of $\bar{x}$ lies outside of the control limits and the corresponding value on the standard deviation chart is within the control limits, a source of **systematic error** is suspected.

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INTERNATIONAL KNOWLEDGE TRANSFER

Check Standards- Analyse Data of Control Charts

- Demonstration of "in control" indicates that the calibration process is consistent with the past experience of the laboratory. There is no reason to believe that excessive changes in precision have occurred.
- To the extent appropriate, the indicated measurement precision of the calibration of the measured type of standards may be extended to the calibration of other standards of similar type, capacity and design.

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PTB

INTERNATIONAL KNOWLEDGE TRANSFER

Check Standards- Analyse Reference Values

When the system remains in control: Absence of a significant difference between the central line and the accepted reference value for the check standard

→ May be considered evidence of insignificant bias at the level of confidence of the statistical test used.

On occasion, small differences (less than one standard deviation) from unknown sources will become obvious over time and the value observed for the bias may be incorporated into the uncertainty.

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PTB

INTERNATIONAL KNOWLEDGE TRANSFER

Check Standards- Analyse Reference Values

When a Reference Value for the check standard is more than one standard deviation from the mean value:

→ it may necessitate obtaining an updated calibration or evaluating the bias or deviation further to determine the cause and correct it.

The deviation or offset must be considered with respect to the reported uncertainty for the reference value as well as the measurement process being used to evaluate the value.

Where tolerances are very large, a measurement process offset might be quite small compared to the tolerance → the offset can be used as an uncorrected systematic error in the uncertainty calculations

Where tolerances are small or uncertainty requirements stringent → updated calibrations may be required

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PTB

INTERNATIONAL KNOWLEDGE TRANSFER

Check Standards- Analyse Reference Values

- The Normalized Error, E_n, may be used to compare the mean value of the check standard, S_c to the calibrated reference value, S_{cs} (once adequate metrological traceability for the reference value is ensured).
- Expanded uncertainty of the reference value from the calibration certificate.

- Uncertainty of the mean value of the check standard :

$$u_c = \sqrt{\frac{s_p^2}{n} + u_s^2 + u_0^2} \qquad U_{\overline{S_c}} = k \times u_c$$

- s_p: standard deviation of the process from the control chart,
- n the number of relevant data points;
- u_s:standard uncertainty of the standard
- u_o :any other critical components to be considered.

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PTB

INTERNATIONAL KNOWLEDGE TRANSFER

Check Standards- Analyse Reference Values

$$E_n = \frac{|\overline{S_c} - S_{cs}|}{\sqrt{U_{\overline{S_c}}^2 + U_{S_{cs}}^2}}$$

- $|E_n| \leq 1$ to pass
- If $|E_n| > 1$, corrective action is required.

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INTERNATIONAL KNOWLEDGE TRANSFER

Check Standards- Improve the Process

During analysis of the measurement process or the reference and check standards, opportunities for corrective action and improvement action may be identified.

Control charts or values that do not have normal distributions or which have significant differences between observed measurement results and reference values are cause for action of some type.

During review of the charts, the first step is to identify the source/cause of the concern, and the associated actions will generally follow.

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INTERNATIONAL KNOWLEDGE TRANSFER

Check Standards- Improve the Process

- Examples:

Assignable Cause – Source of Problem	Example Action Item
Standard deviation has increased after new staff member is hired	Staff might need training, instruction, or oversight; uncertainties may need to be increased
Standard deviation has increased over the past year	Devices may need service; uncertainties may need to be increased
Standard deviation has gotten smaller over the past few months (due to staff training or devices service)	Uncertainties may benefit from being reduced (may also not matter if tolerances are large enough)
Observed values of the check standards suddenly changed. Possibilities might be standards were switched, standards were damaged, values of standards after calibration were not updated properly, new software was implemented without proper validation, standards recently returned from calibration and the provider cleaned them (weights).	Identify root cause – take appropriate action. For example, replace standards, update values of standards, validate software, contact calibration provider. Evaluate whether the shift corresponds in direction and magnitude to changes in the calibration value of standards used.
Standard values are demonstrating a drift over time. Possibilities may be that standards were not equilibrated long enough before being placed into service; standard or check standard type and design might be inherently unstable.	Allow standards to equilibrate longer; replace unstable standards or check standards.

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INTERNATIONAL KNOWLEDGE TRANSFER

Check Standards- Updating Control Chart Parameters

- Update control chart parameters when:
  - ✓ a significant amount of additional data is available, or
  - ✓ the previously determined parameters are no longer relevant due to changes in the system.

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INTERNATIONAL KNOWLEDGE TRANSFER

Check Standards- Updating Control Chart Parameters

IF:	THEN:
The tests fail and results are significantly different	Determine the reason for the difference, if possible, and decide whether corrective action is required.
Data do not agree within statistical limits	Establish new parameters and limits using the most recent data and note the reasons for not using previous data or correct the causes of variation.
Portions of the process or standard variations pass	Be sure to note the degrees of freedom to support uncertainty analyses and coverage factors.
No significant differences between the data sets are found	Pool all data and calculate new control chart parameters based on all existing data.

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PTB

INTERNATIONAL KNOWLEDGE TRANSFER

Check Standards- Control the Process

- How frequently should the check standard be measured and plotted?
  - ✓ Sufficient frequency to minimize the risk of loss of data during the period from last-known-in to first-known-out of control condition.
- Good practice: measure the check standard at least once during each period when a set of calibration measurements is made.
- For critical calibrations or those of highest accuracy, it is desirable to alternate measurements of calibration items and check standards.
- For real-time evaluation it is preferable to incorporate the check standard in the calibration design (SOP).

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PTB

INTERNATIONAL KNOWLEDGE TRANSFER

Check Standards- Control the Process

- Whenever there has been a long period of inactivity, it is good practice to make a series of measurements of the check standard and to plot the results on a control chart to demonstrate attainment of statistical control prior to resuming measurements with that specific calibration system.
- Check standard measurements should be plotted in control charts as close to real time as feasible to effectively monitor the measurement process and to prevent the possible release of questionable data that may result in the recall of laboratory work.

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PTB

INTERNATIONAL KNOWLEDGE TRANSFER

Check Standards- Checklist for Creation or Evaluation of Control Charts

Control Charts cover entire scope (are available for each measurement parameter).	
Control charts have titles (or otherwise include)	
	Laboratory name or other identifying information
	SOP(s) used to generate measurement result
	Equipment
	Standard Identification, Check standard Identification
	Nominal value
	Dates/chronology/time periods if not used on the x axis
	Legends if multiple series and extra information are plotted (to avoid confusion)
Control charts have x and y axis with labels and	
	All measurement values have units of measure associated with them
Control charts have	
	Mean value (and units)
	Standard deviation (and units)
	Degrees of freedom or number of points noted (if not obvious or if small number)
	Alternative summaries of this information and suitable references (e.g., tables)
	Printed summary reports of control data with the charts
	Reference values and source and bias if appropriate/available

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PTB

INTERNATIONAL KNOWLEDGE TRANSFER

Check Standards- Checklist for Creation or Evaluation of Control Charts

Control charts have limits that are based on	
	Statistical controls of:
	Warning limits (i.e., two standard deviations) and
	Action/control limits (i.e., three standard deviations)
	Or, specification limits (e.g., tolerances or smaller ratios of tolerances)
Good Items (on chart or in spreadsheet or database table summaries). Control charts have (when applicable and meaningful if not otherwise noted, e.g., in a table)	
	Tolerances: when applicable
	Uncertainties: for the reference value, check standard, and the process output
	Equipment information: device readability, configuration (stability settings/timing)
	Standard information: calibration date and interval information
	Responsible staff: need on chart or in database
	Status of control: in control, out of control with latest date of review
	History: previous limits and history of the chart/data with F-test and/or t-test results

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INTERNATIONAL KNOWLEDGE TRANSFER

Check Standards- Transfer of Statistics

- The estimate of the standard deviation of the process, s_p, used to establish the control limits may be used to calculate confidence intervals for all related measurements made while the system is in control.
- The value of the item being calibrated is said to be within the limits if the combined mean of the measurements on the calibration item and the expanded uncertainty are within limits.

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INTERNATIONAL KNOWLEDGE TRANSFER

Check Standards- Control Charts-Further Thoughts

Shewhart control chart:

✓easy to be constructed and applied

✓ability to detect large changes

the decision regarding the state of control of the process at any time depends solely on the most recent measurement from the process and the degree of "trueness" of the estimates of the control limits from historical data

limited ability to detect small changes (at the level of ½ to 1 st. dev.)

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INTERNATIONAL KNOWLEDGE TRANSFER

Check Standards- EWMA Control Charts

- **Exponentially Weighted Moving Average (EWMA)** is a statistic for monitoring the process that averages the data in a way that gives less and less weight to data as they are further removed in time.
- The decision depends on the EWMA statistic, which is an exponentially weighted average of all prior data, including the most recent measurement.
- By the choice of weighting factor, λ, the EWMA control procedure can be made sensitive to a small or gradual drift in the process, whereas the Shewhart control procedure can only react when the last data point is outside a control limit.

Lucas, J. M. and Saccucci, M. S. (1990). "Exponentially weighted moving average control schemes: Properties and enhancements", *Technometrics 32*, 1-29.

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INTERNATIONAL KNOWLEDGE TRANSFER

Check Standards- EWMA Control Charts

- The EWMA control chart is characterized by a central reference line that results from the average of all values in the control template database and from two bounding lines, UCL and LCL:
- $EWMA_t = \lambda Y_t + (1-\lambda) EWMA_{t-1} \;\; for\; t = 1,2 \ldots, n$
- $s^2_{EWMA} = \frac{\lambda}{2-\lambda} s^2$
- $UCL = EWMA_0 + k s_{EWMA}$
- $LCL = EWMA_0 - k s_{EWMA}$
- k usually =3

- $EWMA_0$ is the mean of historical data (target)
- Y_t is the observation at time t
- n is the number of observations to be monitored including $EWMA_0$
- $0 < \lambda \leq 1$ is a constant that determines the depth of memory of the EWMA
- s is standard deviation calculated from the historical data

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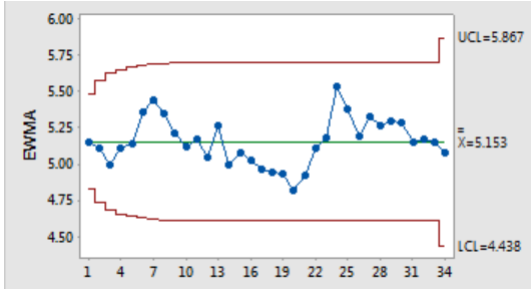
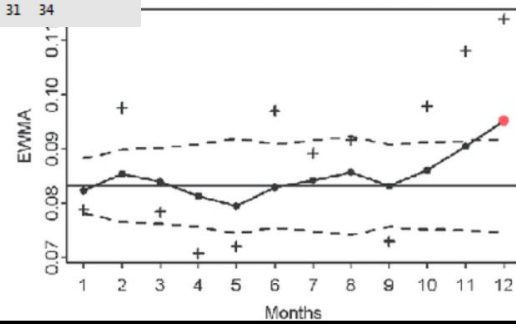
INTERNATIONAL KNOWLEDGE TRANSFER

Check Standards- EWMA Control Charts





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INTERNATIONAL KNOWLEDGE TRANSFER

Contents

- ISO/IEC 17025:2017 Requirements
- Foundations of a Quality Control Programme
- **Internal QC:**
  - ✓ Use of Check Standards
  - ✓ Control Charts
  - ✓ **Intra-laboratory Comparisons**
- External QC:
  - ✓ PTs/ILCs

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INTERNATIONAL KNOWLEDGE TRANSFER

Internal QC- Intra-laboratory Comparisons

- An intra-laboratory comparison is conducted when:
  - ✓ Several technicians within an organization perform calibrations on the same or similar artifact, using the same method, under specified, controlled conditions.
  - ✓ The same artifact is measured by using different methods or different calibration systems.
- The data resulting from these activities shall be analysed for statistical validity

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INTERNATIONAL KNOWLEDGE TRANSFER

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PTB

INTERNATIONAL KNOWLEDGE TRANSFER

External QC- Participation in PTs/ILCs

REMINDER

Use of PTs/ILCs:

a. Evaluating laboratory performance of specific measurement scope capabilities and monitoring continuing performance

b. Identifying problems and initiating corrective action.

c. Establishing the effectiveness and comparability of measurement methods (e.g., method validation).

d. Evaluating method performance characteristics (e.g., method validation).

e. Providing additional confidence to laboratory customers

f. Identifying of differences among laboratories

g. Educating participating laboratories based on comparison outcomes

h. Validating uncertainty claims.

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PTB

INTERNATIONAL KNOWLEDGE TRANSFER

External QC- Participation in PTs/ILCs

PT plans and schedules shall be developed and updated at least annually to determine if the participation frequency is appropriate and adequate.

Usual Minimum requirements: Each laboratory shall participate in one PT per major sub-area of their accredited or recognized scope every five years.

Recommendation: organizations participate in PT activities for each specific measurement parameter and calibration method that the laboratory employs as a part of ongoing QC program.

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INTERNATIONAL KNOWLEDGE TRANSFER

External QC- Participation in PTs/ILCs- Assessment of Results

Evaluation of PT/ILC results for calibration laboratories:

- **Bias (Difference):** $x_{lab} - X_{ref}$

  This value is not used as a pass/fail statistic, but is used in the initial assessment of data by the PT provider to review the overall data for obvious blunders and outliers.

  The laboratory may use this value as a part of its follow-up assessments of laboratory bias, accuracy goals, and plans for recalibration limits. (For precision calibrations, a laboratory might want to set recalibration goals such that whenever the bias/offset exceeds some ratio of its reported uncertainty, a recalibration or interim assessment of metrological traceability is conducted).

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INTERNATIONAL KNOWLEDGE TRANSFER

External QC- Participation in PTs/ILCs- Assessment of Results

Evaluation of PT/ILC results for calibration laboratories:

- Normalized Error E_n: $E_n = \left| \frac{x_{lab} - X_{ref}}{\sqrt{U_{lab}^2 \pm U_{ref}^2}} \right| < 1$ to pass

When + ?
When - ?

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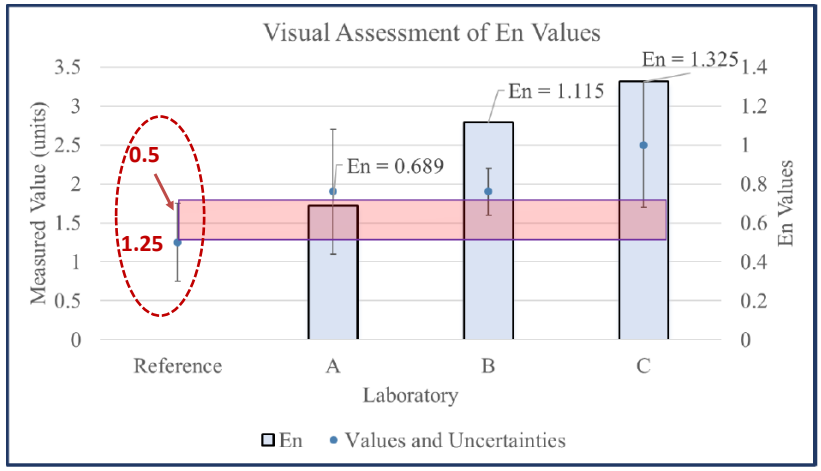
INTERNATIONAL KNOWLEDGE TRANSFER

External QC- Participation in PTs/ILCs- Assessment of Results

Interpretation of E_n

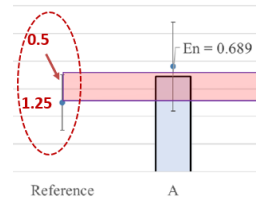


Source: NIST

INTERNATIONAL KNOWLEDGE TRANSFER

External QC- Participation in PTs/ILCs- Assessment of Results

- **Lab A:**
  - ✓ The value submitted is outside the uncertainty of the reference value
  - ✓ Its uncertainty overlaps the reference value.
  - ✓ Visually, there is a good amount of overlap of the uncertainty bars.
  - ✓ E_n (=0.689) < 1 Pass.



- **Interpretation**:

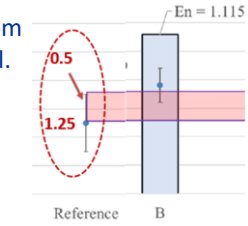
  An E_n value of 0.689 might still justify further assessment of the laboratory accuracy by determining if the Bias (Difference) that is shown has been consistent in previous PTs or is observed in a laboratory control chart. Further evaluation would depend on the applicable tolerances for the application and the desired level of accuracy needed by the laboratory

PTB

INTERNATIONAL KNOWLEDGE TRANSFER

External QC- Participation in PTs/ILCs- Assessment of Results

- **Lab B:**
  - ✓ The value submitted is identical to the value from lab A, thus the Bias (Difference) is also identical.
  - ✓ $U_B < U_A$ and $U_B < U_{ref}$
  - ✓ While the uncertainties still overlap slightly, U_B does not overlap the reference value, U_{ref} does not overlap the submitted lab B value
  - ✓ E_n (=1.115) > 1 Fail.



- **Interpretation**:

The Bias (Difference) for both labs A and B are identical, but U_B does not support this level of bias. Either the uncertainty is too small if all other laboratories performed the same procedure and submitted uncertainties comparable to Labs A and C (likely) or the laboratory needs to identify the root cause of this failure (e.g., a systematic error of some type or the need for recalibration of standards to bring values closer to the reference value).

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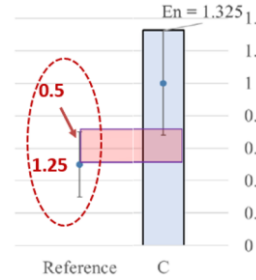
PTB

INTERNATIONAL KNOWLEDGE TRANSFER

External QC- Participation in PTs/ILCs- Assessment of Results

- **Lab C:**
  - ✓ The value submitted is not inside reference value uncertainty.
  - ✓ $U_C = U_A$
  - ✓ There is very minor overlap of uncertainty values, but the overlap is not enough.
  - ✓ E_n (=1.325) > 1 Fail.



- **Interpretation**:

Some laboratories working with larger tolerances might suggest that the offset does not matter and the failure is not significant, which is counter to the purpose of PTs. If the tolerances are significantly larger than the offset shown, a larger uncertainty to cover the gap and pass the E_n assessment is likely warranted.

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INTERNATIONAL KNOWLEDGE TRANSFER

External QC- Participation in PTs/ILCs- Follow-up Actions

- Pass/fail status of each standard evaluated in the PT is not the only thing a laboratory should consider when participating in a PT.
- **Recommendation**: Prepare a thorough follow up assessment that creates an Executive Summary that can be used in a Management Review as well as guiding the laboratory in performing a thorough assessment of the report, even when all indicators were successful.

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INTERNATIONAL KNOWLEDGE TRANSFER

External QC- Participation in PTs/ILCs- Follow-up Actions

- Example of Executive Summary Report:

Assessment	Results and Evidence
1. Executive Summary	
2. PT Failures	
3. Analysis and Action Plan	
4. Deadlines	
5. Uncertainties (7.6., 7.8.6).	
6. Uncertainty versus Applicable Tolerances (7.8.6).	
7. Offset/Bias Assessment (7.7)	
8. Records (7.5, 7.8, 8.4).	
9. Non-Measurement Result Observations or Failures	

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PTB

INTERNATIONAL KNOWLEDGE TRANSFER

External QC- Participation in PTs/ILCs- Follow-up Actions

- Example of Executive Summary Report:

1.Executive Summary:	Include summary and highlight the PT findings that can be used in the Management Review. (For example, total number of points, number passing/failing percentages, lessons learned, opportunities, corrective action already taken, etc.)
2. PT Failures:	Describe all laboratory failures that were identified in the final PT report (or additional failures or concerns identified outside the report).
3.Analysis and Action Plan:	Describe the analysis and investigation of Root Cause Analysis, Risk/Opportunities, Improvement Action(s), and Corrective Action(s). (Section 8.5, 8.6, 8.7)

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PTB

INTERNATIONAL KNOWLEDGE TRANSFER

External QC- Participation in PTs/ILCs- Follow-up Actions

- Example of Executive Summary Report:

4. Deadlines:	List the deadlines for the completion of each action item and identify the personnel responsible for implementing and monitoring the results of each action.
5. Uncertainties (7.6., 7.8.6):	 Describe the uncertainty assessment.
6. Uncertainty versus Applicable Tolerances (7.8.6).:	 Describe the Precision assessment results for this proficiency test. This assessment reviews the laboratory Uncertainty compared to the applicable Tolerances.

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- Example of Executive Summary Report:

5. Uncertainties (7.6., 7.8.6). Questions to consider include:

How did the reported uncertainty compare to other participating laboratory values?

Was the correct k factor used?

If the laboratory (or laboratory participant(s)) uncertainty value(s) were at the high end of the uncertainties, explain why. Could a better procedure or instrument have been used?

If at the low end, was the value calculated correctly? Why is it smaller than the values reported by other laboratories?

Explain if all appropriate uncertainty components were included (or why they were not included). Describe the planned measurement process and/or actual procedure used for the PT (higher/lower level procedure).

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- Example of Executive Summary Report:

6. Uncertainty versus Applicable Tolerances (7.8.6). Questions to consider include:

Was a precision test conducted as a part of the analysis? If yes, explain why there any ranges with unacceptable results. If no, conduct the precision analysis now.

The calculation evaluates the reported uncertainty(expanded at k=2) against the tolerances required for the equipment with any uncertainty to tolerance ratios considered. Was the uncertainty reported acceptable/appropriate for the level of work? Could the uncertainty be improved with different equipment or procedures?

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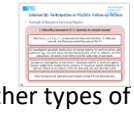
- Example of Executive Summary Report:



7. Offset/Bias Assessment (7.7).:	Was bias observed in the PT also observed in other types of measurement assurance charts in the laboratory? Describe or summarize the bias and offset of the laboratory PT.
8. Records (7.5, 7.8, 8.4):	Describe the assessment in place to track PT data over time within the laboratory and evaluate the data against previous results and other data. Ensure that the final results were entered in laboratory PT log and identify the summary data that will be included in the Management Review (8.9).
9. Non-Measurement Result Observations or Failures:	Describe any additional feedback related to the PT planning, scheduling, evaluation (e.g., delays) or reporting results (e.g., calibration certificate review, 7.8) that were provided as a part of this PT.

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- Example of Executive Summary Report:

7. Offset/Bias Assessment (7.7). Questions to consider include:

Was the E_n > 1? If E_n > 1, a measurement bias was indicated. If a bias was present, are there any overriding reasons for it?

An investigation generally needs to be conducted looking for common errors and problems: e.g., incorrect values for the standard used, errors in software used for calculations, deviations from SOPs, need for calibration of standards.

Conduct an investigation of bias (even if values passed the E_n analyses) against internal calibrations, control charts, previous PT results or recent calibrations to find out if there is correlation of the ILC data with internal laboratory data.

Was the bias for all laboratory participants similar? If not, describe why.

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Conclusions

- The major advantage of a successful system of Quality Control is the ability to evaluate the reference standards and the measurement process over time, providing ongoing assurance regarding accuracy and traceability of the reference standards for both the laboratory and its customers.
- When a process is in statistical control and the reference values are within suitable limits, we can assume that the reported measurement uncertainties are valid.
- Ongoing evaluation of the measurement process provides the laboratory with data that can be used to establish or adjust calibration intervals for reference standards.
- The measurement assurance program is also critical for defining and reporting realistic uncertainties.

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References

- ISO/IEC 17025:2017: General requirements for the competence of testing and calibration laboratories.
- JCGM 100:2008 “Guide to the expression of uncertainty in measurement”
- M. Grabe, “Principles of Metrological Statistics”, Metrologia 23, (1986/1987), 213.
- K.Weise and W. Woeger, “A Bayesian Theory of Measurement Uncertainty”, Meas. Sci. Tech. 3, (1992), 11.
- C. Eisenhart, “Realistic Evaluation of the Precision and Accuracy of Instrument Calibration Systems”, NBS Special Publication 300, vol. I, H.H. Ku editor, Washington DC 1969, pp. 21-48.

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References

- A.J. Duncan, "Quality Control and Industrial Statistics", 5th ed., Irwin, Homewood, IL, 1986.
- Bucher, J.L., "Quality Calibration Handbook—Developing and Managing a Calibration Program", ISA Publication, ASQ Quality Press, 2007.
- J.K. Taylor and H.V. Oppermann, "Handbook for the Quality Assurance of Metrological Measurements", NBS Handbook 145, Gaithersburg, 1986.
- NIST/SEMATECH e-Handbook of Statistical Methods, http://www.itl.nist.gov/div898/handbook/, January 19, 2019

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