L17 Quality Control and Proficiency Tests

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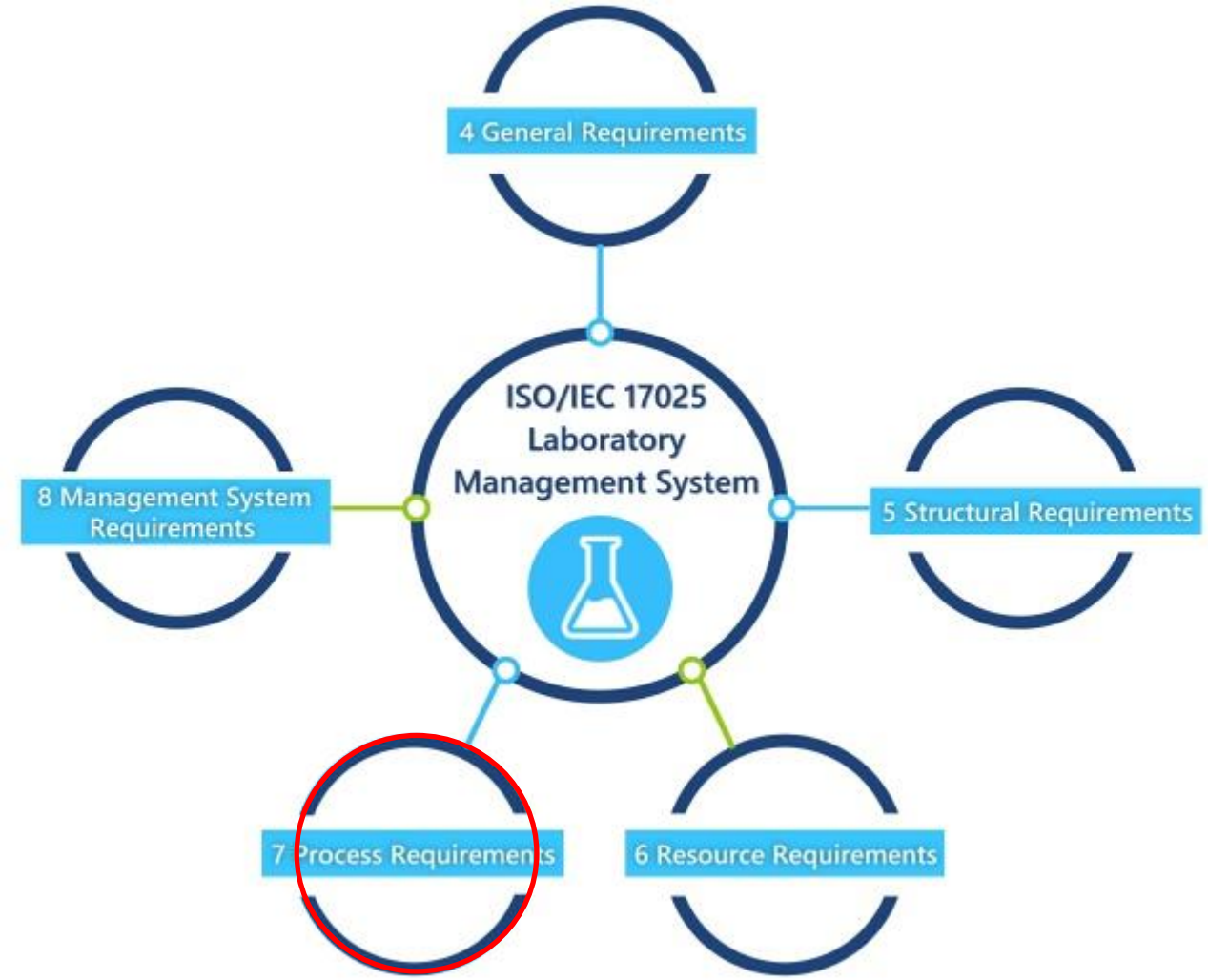
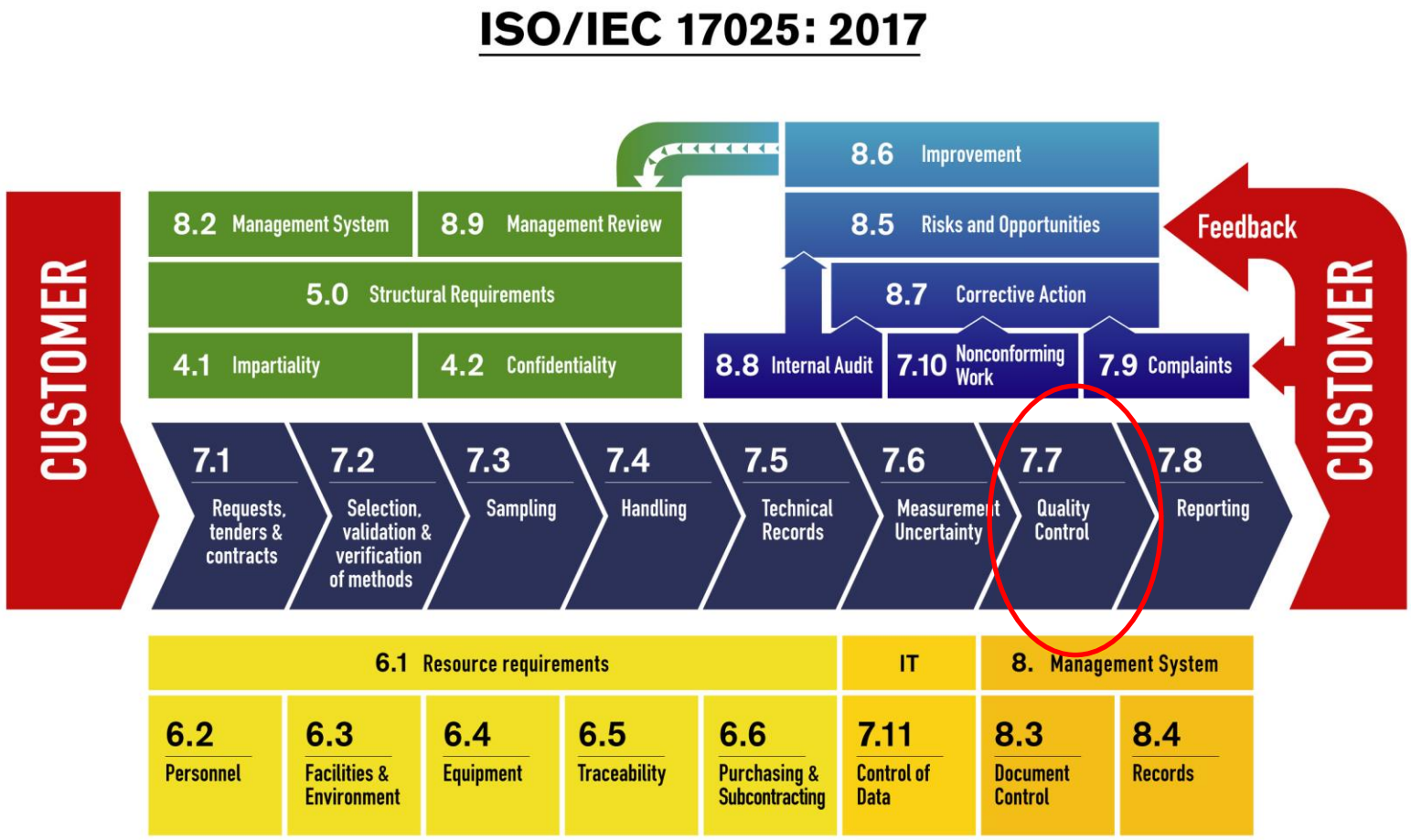
International Atomic Energy Agency

7 Process Requirements



Structure


ISO/IEC 17025: 2017
8.6 Improvement
8.2 Management System
8.9 Management Review
8.5 Risks and Opportunities
Feedback
5.0 Structural Requirements
8.7 Corrective Action
CUSTOMER
4.1 Impartiality
4.2 Confidentiality
8.8 Internal Audit
7.10 Nonconforming Work
7.9 Complaints
CUSTOMER
7.1 Requests, tenders & contracts
7.2 Selection, validation & verification of methods
7.3 Sampling
7.4 Handling
7.5 Technical Records
7.6 Measurement Uncertainty
7.7 Quality Control
7.8 Reporting
6.1 Resource requirements
IT
8. Management System
6.2 Personnel
6.3 Facilities & Environment
6.4 Equipment
6.5 Traceability
6.6 Purchasing & Subcontracting
7.11 Control of Data
8.3 Document Control
8.4 Records

Objectives

In this lecture we will:

- Discuss the importance of control of measurement instruments and quality control of methods; and
- Learn how to implement them in testing and calibration laboratories

7.7 Ensuring the validity of results

7.7.1 Document procedure for monitoring the validity of results. The resulting data is recorded and trends are detectable, use statistical techniques is applied to review results. The monitoring to be planned and reviewed and include:

- use of reference materials or quality control materials;
- use of alternative instrumentation that has been calibrated to provide traceable results;
- functional check(s) of measuring and testing equipment;
- use of check or working standards with control charts, where applicable;

7.7 Ensuring the validity of results (2)

- intermediate checks on measuring equipment;
- replicate tests or calibrations using the same or different methods;
- retesting or recalibration of retained items;
- correlation of results for different characteristics of an item;
- review of reported results;
- intra-laboratory comparisons;
- testing of blind sample(s).

7.7 Ensuring the validity of results (3)

7.7.2 Monitor laboratory performance by comparison with results of other laboratories, where available and appropriate:

- participation in proficiency testing;
- participation in inter-laboratory comparisons other than proficiency testing

Participating in PT's (Proficiency Tests) and/or ILC's (inter-laboratory comparisons) is expected where available and appropriate

7.7.3 Data from monitoring activities is analyzed and used to control. If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action taken to prevent incorrect results from being reported.

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Quality Control

- The data obtained over long periods may be used to feed QC charts, where acceptance, action and rejection levels have been considered.
- In this way, trends can be observed and corrected, if necessary.
- The overall performance of the service should be periodically checked. Participation in national and international comparison exercises is a useful and very much needed test of the performance.
- The performance of the service for routine measurements is assessed under normal workplace conditions
- Don’t forget also to check your background level

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QC: example for IMS

- Daily performance check of your reader using e.g. Sr-source or reference light
- Monthly - internally:
  - Verification using your own irradiator at e.g. 1 mSv to monitor stability of the reader and the dosimetric analytical process
  - Travel/Witness & Transport dosemeters – blind with known irradiated dose and blank dosemeter per site/region
  - Background dosemeters at your reader location
  - Check of your irradiator using ionization chamber
- Minimum two-yearly: ECC and RCF redetermination

The aim and the tools of Quality Control (QC)

- Aim: keep the process under control – to verify the validity of the results, of the validation that was carried out initially and the calibrations that are carried out.
- Why? The product is intangible and can not be verified
- How? We want to detect and prevent errors through the introduction of internal quality control samples simultaneously with every batch of real samples in all critical phases of the analytical process. The QC procedures should include the frequency and the acceptance criteria and the procedures one needs to take in the case the criteria are not met.

Control charts

- Control charts are very useful in the quality control.
- They gave the users a very quick overview of the results from the quality control measurements.

- All control charts have three basic components:
  - A centerline that represents the level around which the plotted statistic may be expected to vary
  - Two horizontal lines, called the upper control limit (UCL) and the lower control limit (LCL) that define a band within which the statistic of the process may be expected to lie randomly when the process is in control
  - Performance data plotted over time.

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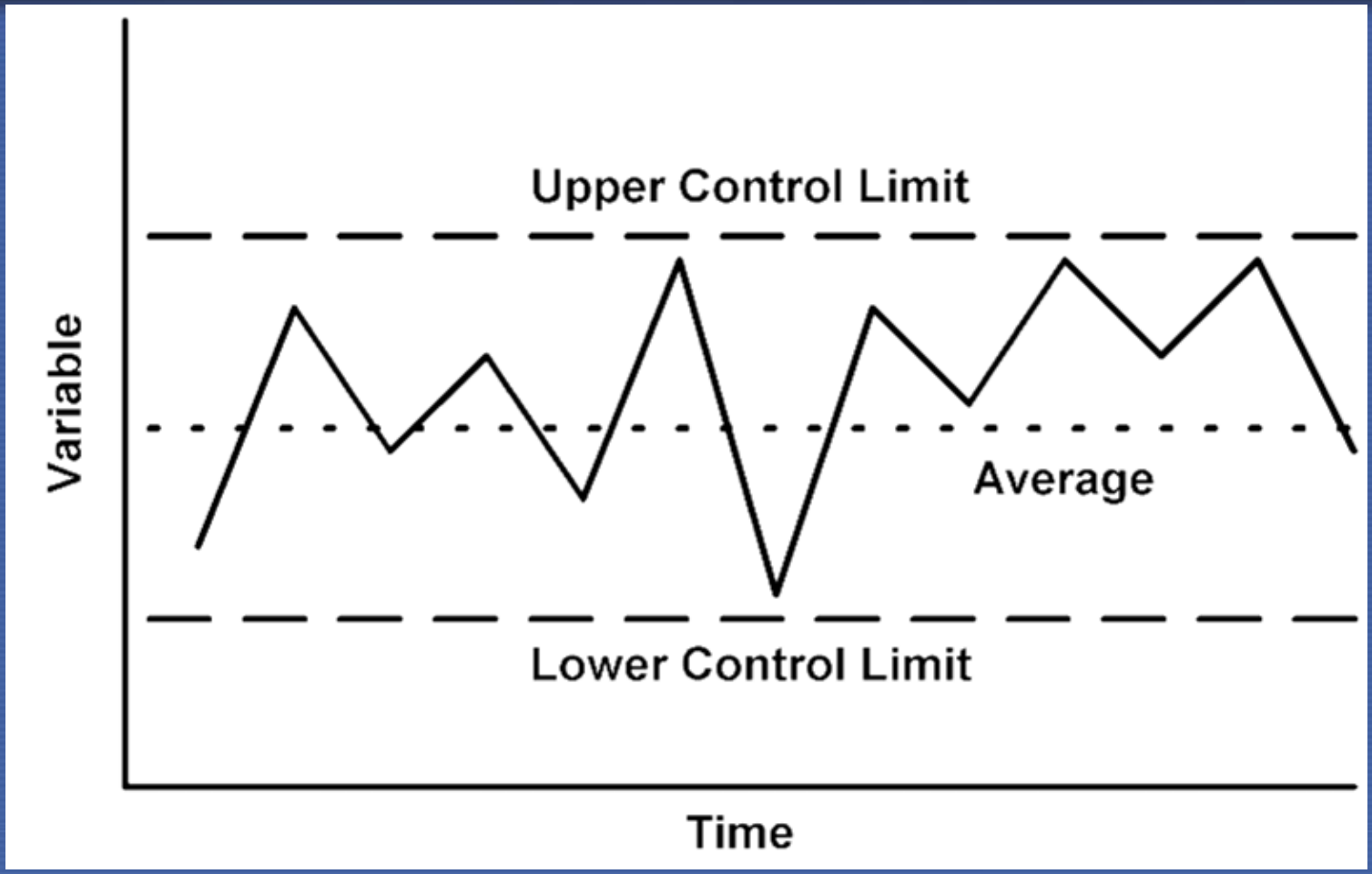
Basic control chart



A demonstration of a control chart for a variant over time with the average as dotted line and the upper and lower level as slashed lines.

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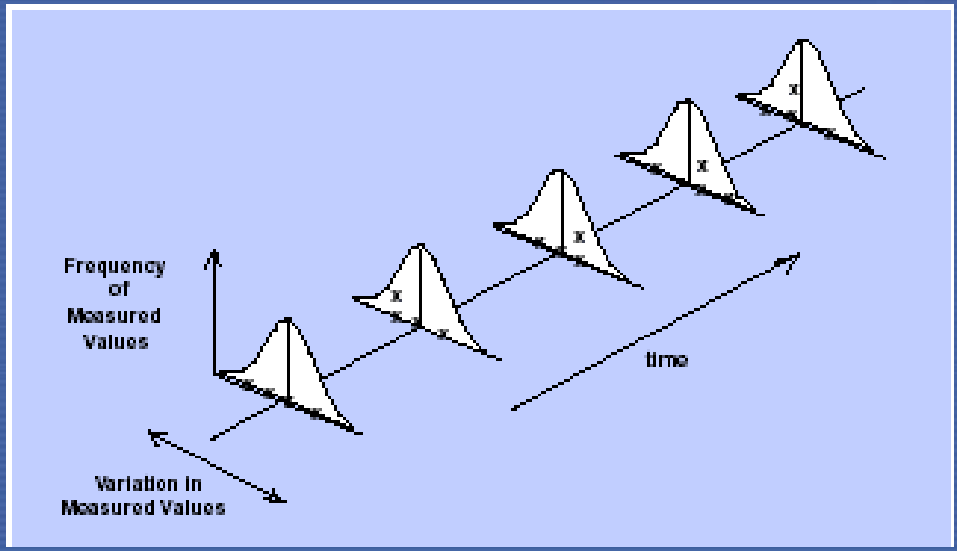
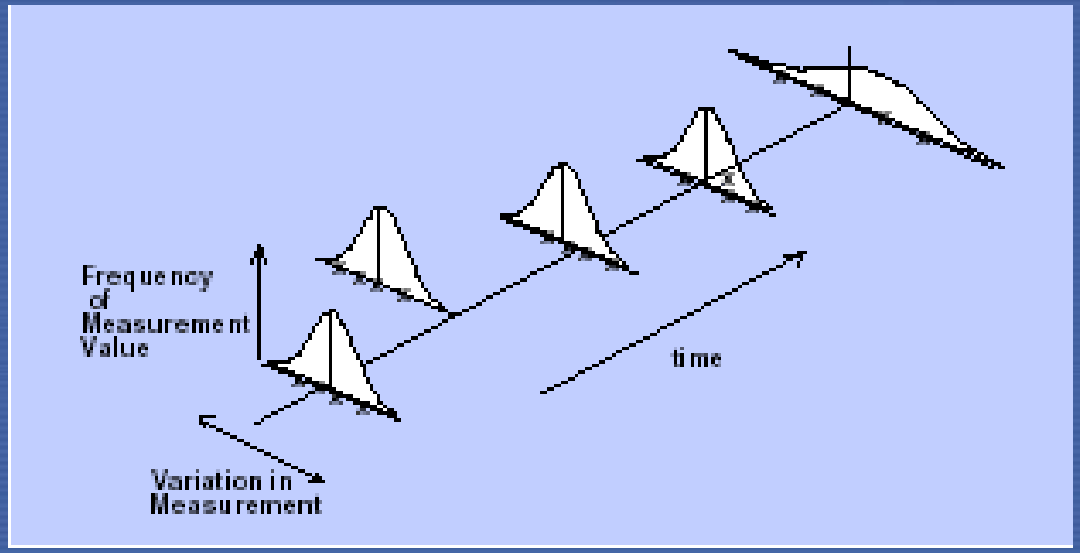
Process in control

A process is said to be **in control** when it is subject only to **random variation** (or **common cause** variation) that is variation due to “normal” or inherent interaction among process components (people, instrumentation, environment, and methods).

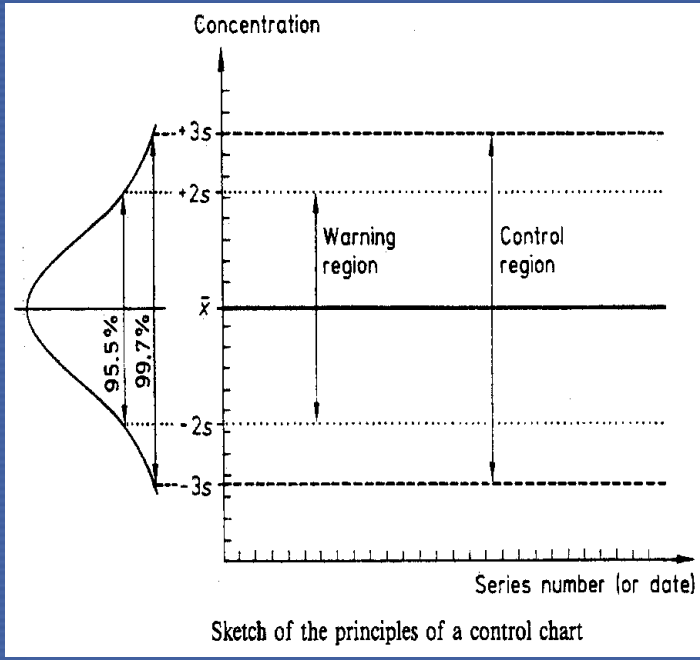


Process out-of-control

A process is said to be **out-of-control** when it is subject also to **variation due to assignable causes** that is variation due to events that are not part of the normal process and represents sudden or persistent abnormal changes.



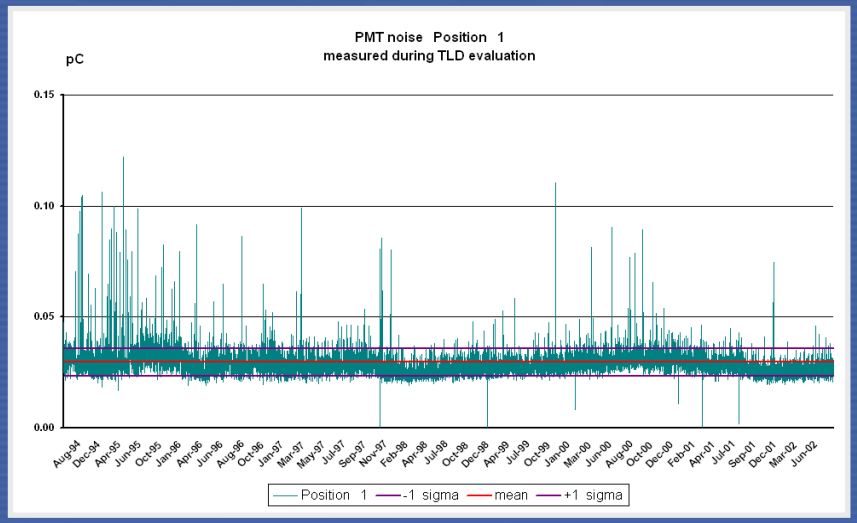
Warning and control limits

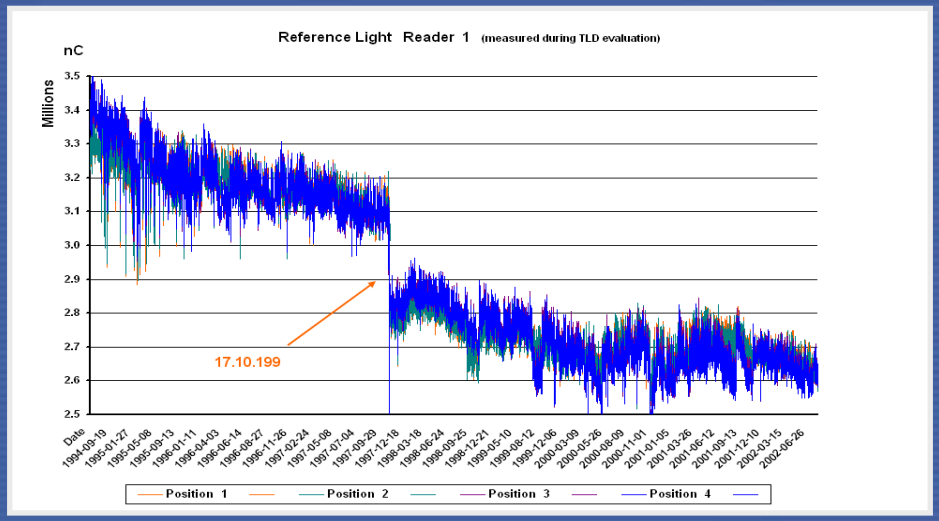


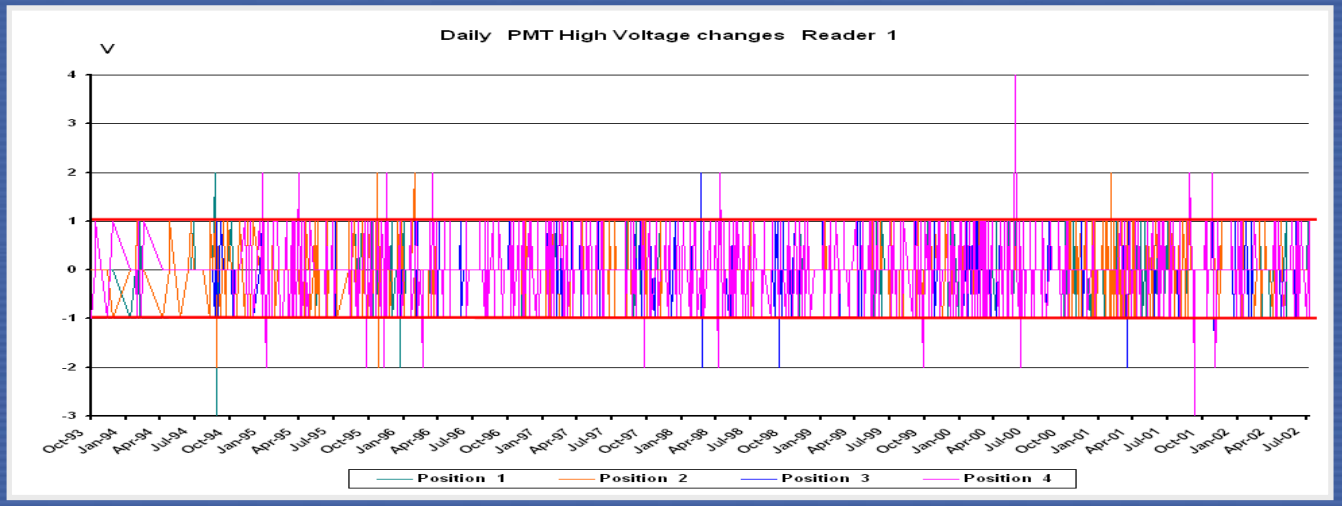
Sketch of the principles of a control chart

A control chart is a means of ensuring that the method remains in 'control' - continues to perform in accordance with expectations. This usually means that results from analysing QC material fall within ± **2 standard deviations of the accepted value** (within the warning level). Any results appearing outside the alarmlevel **(± 3 standard deviations**) indicate that the method is not longer in control and requires investigation.

Reader Stability Check: daily in principle







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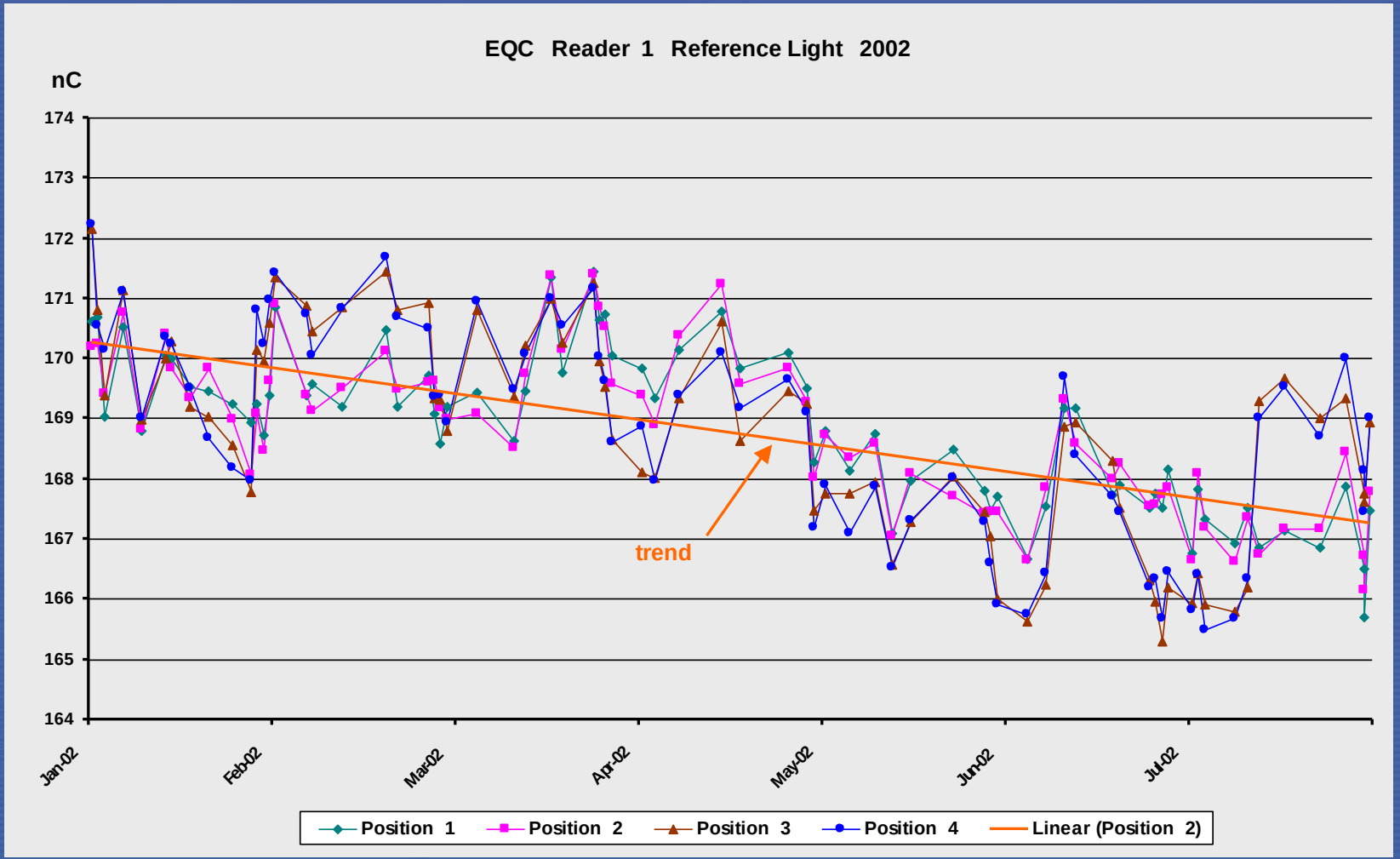
Methods: Instrument control charts



Methods: Instrument control Charts

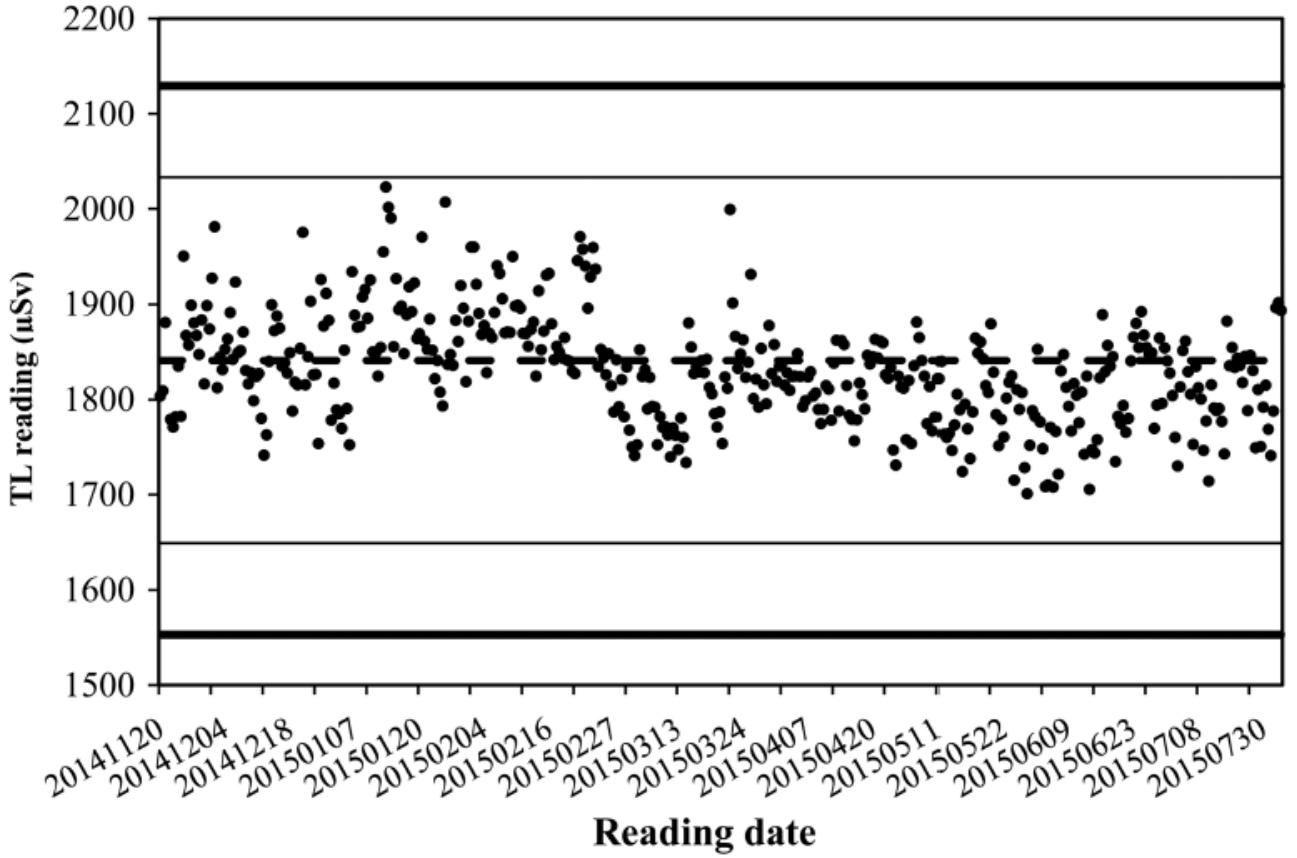
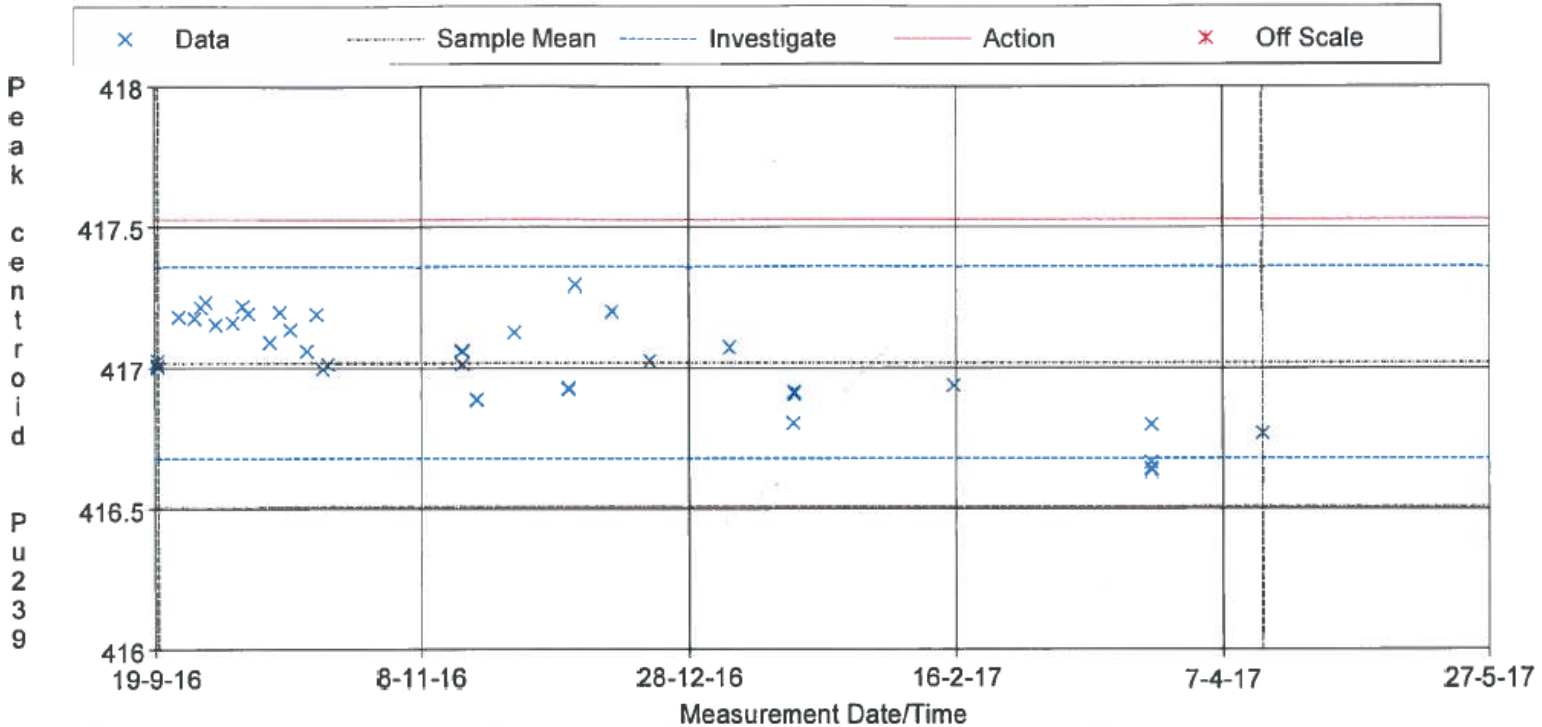


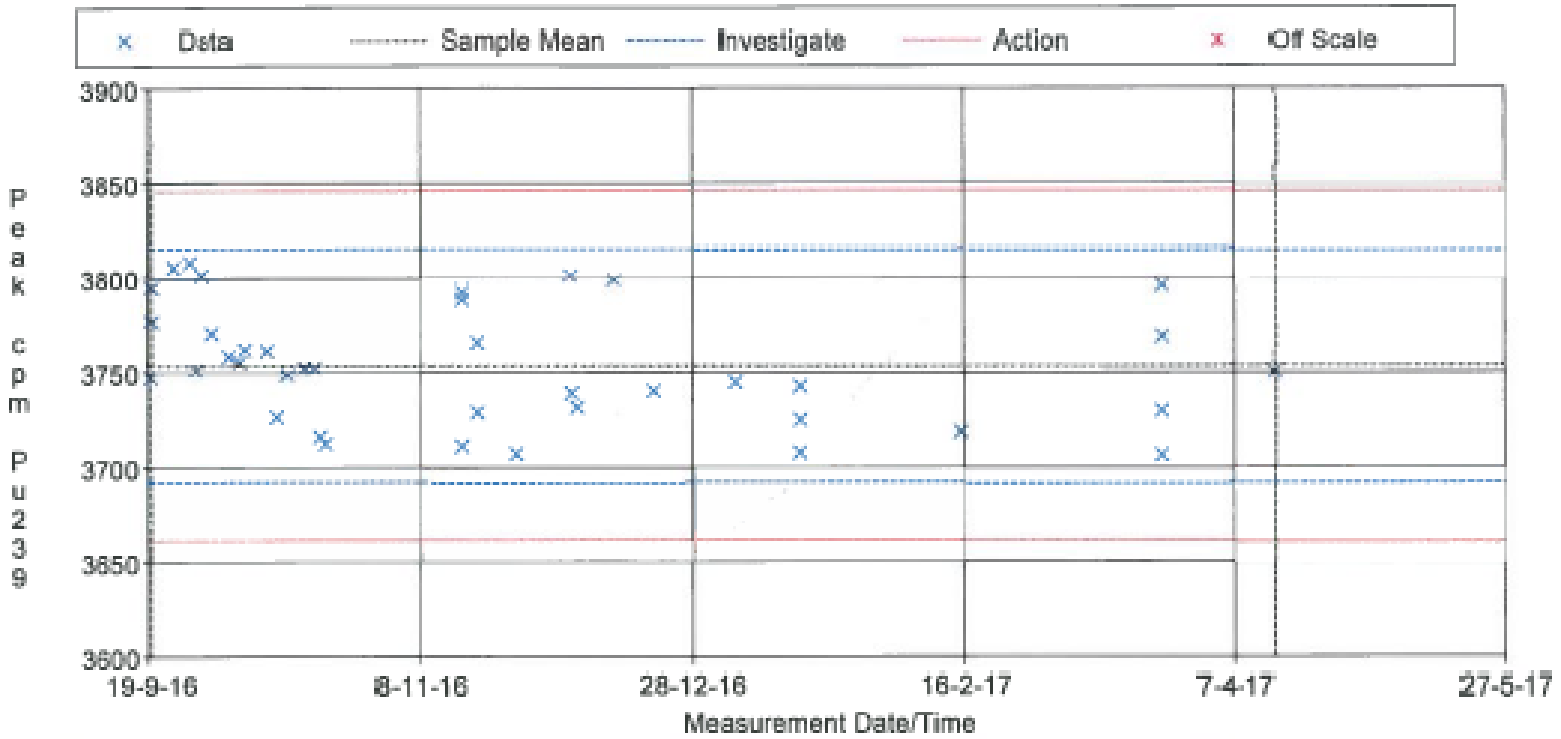
Figure 1. Evaluation of quality control cards in order to check the stability of the reader.

Example of Shewart Control Chart



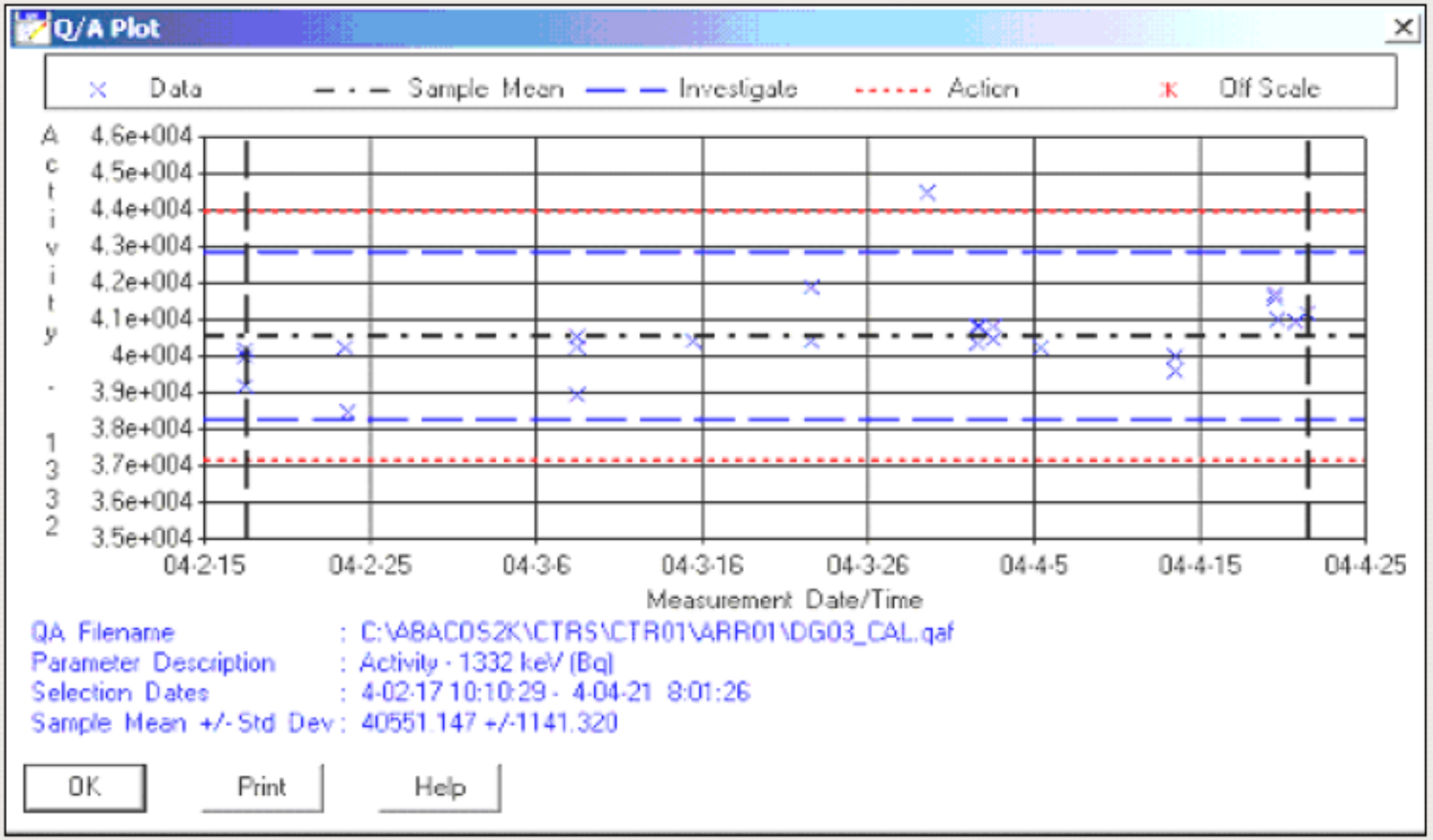
QA Filename : C:\Canberra\ApexAlpha\Root\QA\109090_13001357A_C1026_CALCHK.QCK
Parameter Description : Peak centroid Pu239 (ch)
Selection Dates : 19-09-16 11:35:14 - 14-04-17 10:07:19
Sample Mean +/- Std Dev : 417.018 +/- 0.170

Example of Shewart Control Chart



QA Filename : C:\Canberra\ApexAlpha\Root\QA\109090_13001357A_C1026_CALCHK.QCK
Parameter Description : Peak cpm Pu239 (cpm)
Selection Dates : 19-09-16 11:35:14 - 14-04-17 10:07:19
Sample Mean +/- Std Dev : 3753.714 +/- 30.829

Example of Shewart Control Chart



Gamma-spectrometric detector (broad energy germanium)

What is an Interlaboratory Study or a Proficiency Test?

"Organization, performance and evaluation of tests on the same or similar test items by two or more laboratories in accordance with predetermined conditions"

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Proficiency Schemes – Why?

Participation in proficiency testing schemes offers the following benefits:

- Independent and objective evaluation of performance - Show labs how well they compare with others and evaluates the analytical methods/techniques
- Help them to reduce the overall variability in testing;
- Give the regulatory authorities and consumers confidence that their quality criteria are meaningful
- To determine the performance characteristics of a method
- To assign values to reference materials (RMs) and assess their suitability for use in specific tests or measurement processes
- To demonstrate competence of staff or for education and training purposes
- To identify analytical problems and initiate remedial actions
- A necessity in order to get accredited

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Proficiency Schemes – How

Organisers of such schemes must ensure that:

- All participating labs receive identical, homogeneous, stable samples;
- They are competent – ISO/IEC 17043?
- Good design of the study
- Clearly defined procedures and protocols
- A ‘true’ value is assigned for the result of a test (for example it may be the mean of all participants’ results);
- Participants do not know the ‘true’ result before they do the test.
- There is an effective communication between organizer and participants

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Proficiency testing – some rules

- Use same methodology
- Use same personnel
- Use your normal procedure as for real samples – it should involve the whole process (sample preparation, weighing, storage, dilution, extraction, …), if you follow your normal procedure

- If you have sufficient material you can use other personnel or other method, not for reporting but for method validation or for qualification

After the PT

- Main purpose: to LEARN
- In a QA-system a good score is the AIM, however a bad score is NOT a problem, not taking any corrective action is the PROBLEM
- Scoring a PASSED or REJECTED is not enough, you should look closer
- Analyses according to daily conditions, by regular staff, not analyses with the best measurement capabilities, by most experienced staff, with 10 replicates, different techniques, different sample preparation steps the your normal method. But, it is allowed to test several analysts using the same measurement procedure
- Always bear in mind: An Interlaboratory Study is a “snapshot” of laboratory performance

Accreditation and PT

ILAC recommends:

- …one PT activity prior to gaining accreditation and one activity relating to each major sub-area of major disciplines of a laboratory's scope of accreditation at least once during the accreditation cycle
- … you should decide on the frequency depending on risks, number of samples, availability, other forms of QC, previous performance

Statistical treatment

- **ISO 17043:2010** Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes
- **ISO 13528: 2015** Statistical Methods for Use in Proficiency Testing by Interlaboratory Comparisons
- ISO 14146:2018: Radiological protection — Criteria and performance limits for the periodic evaluation of dosimetry services – the trumpet curve

Laboratory Performance Studies

- Deviation or bias (or % bias)
- The bias between the Lab/Analyst's value and the Target/Reference value expressed as a Absolute value or as a Percentage:
- x_i = Analist/Lab result
- x_{pt} = Target value.

$$D_i = x_i - x_{pt}$$

$$D_i\% = 100(x_i - x_{pt}) / x_{pt}$$

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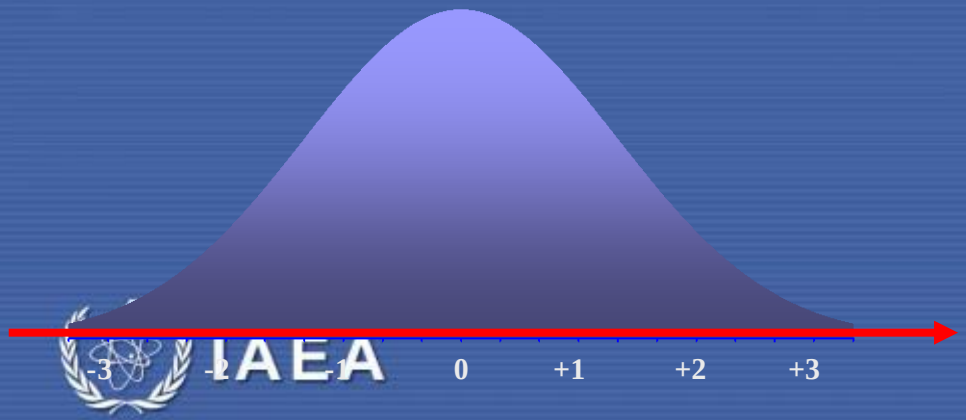
Scoring: z-score

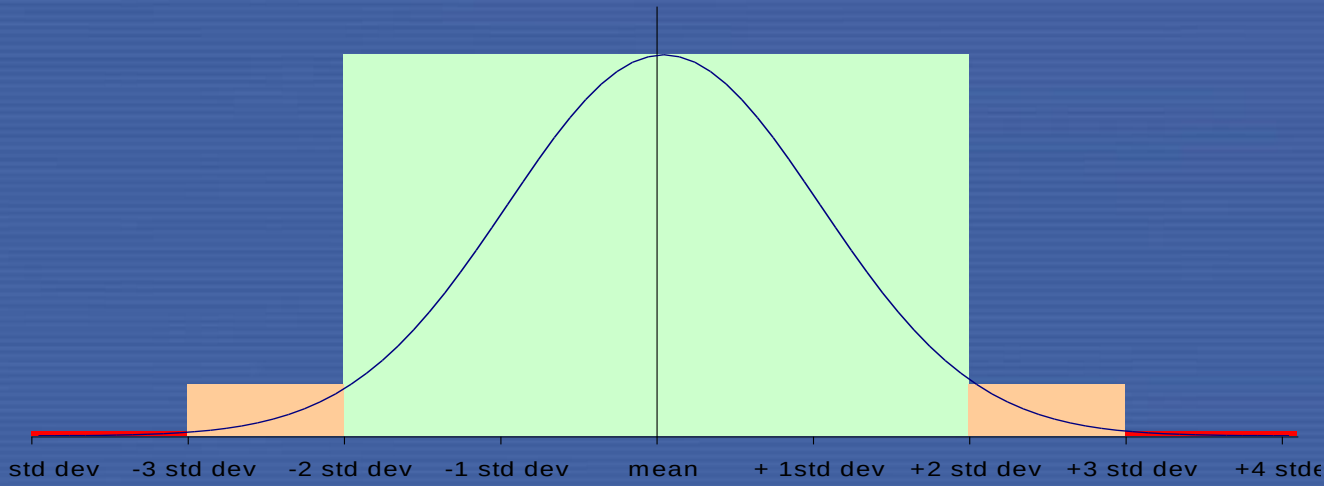
$$z_i = (x_i - x_{pt}) / \sigma_{pt}$$

So, z is in fact a normalised result of your bias during the proficiency test

- x_i = Analist/Lab result
- x_{pt} = Target/Assigned value
- σ_{pt} = is assigned by the organizer according to the analyte and its concentration level.
  - *Predefined*
  - *Empirical (Horwitz, …)*
  - *Your own precision*
  - *The SD of all labs*



Interpretation of z-Scores



- z-scores can be interpreted as:
  |z| <= 2 ‘satisfactory’
  2< |z| <= 3 ‘questionable’
  |z| > 3 ‘unsatisfactory’

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Target Standard Deviation

standard deviation for proficiency assessment, σ_p

- σ_p defined by 'fitness-for-purpose'

  balance between increasing cost of analysis vs consequences of an inaccurate result

- σ_p set objectively, independent of observed spread of results

  e.g. from reproducibility data from method performance studies or from ISO 14146

Zeta-scoring

- E_n:

$$E_{n,i} = \frac{x_i - x_{pt}}{\sqrt{U_{x_i}^2 + U_{x_{pt}}^2}}$$

- ζ:

$$\zeta_i = \frac{x_i - x_{pt}}{\sqrt{u_{x_i}^2 + u_{x_{pt}}^2}}$$

- u_{x_i} = standard uncertainty of the lab , U_{x_i} = expanded uncertainty of the lab
- $u_{x_{PT}}$= standard uncertainty of the assigned value, $U_{x_{PT}}$= expanded uncertainty of the assigned value

$\zeta < 2$; OK
$2 < \zeta < 3$: ??
$\zeta > 3$: not OK

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Trendanalysis – for dosimetry – the trumpetcurve