



Understanding of ISO/IEC 17025

Jing Wang

ISO/IEC 17025 is divided into 5 clauses, 2 annexes, and 1 bibliography section:

Clause 1: Scope

Clause 2: Normative References

Clause 3: Terms and Definitions

Clause 4: Management Requirements

Clause 5: Technical Requirements

Annex A: Cross References to ISO 9001:2000

Annex B: Guidelines for Establishing Applications for Specific Fields

Bibliography

The most important clauses are clause 4 and 5, describing management and technical requirements. In addition to official requirements, these clauses also include notes with further explanations and recommendations.

The structure of technical management

1. What need to be considered?

- The scale of laboratory
- Professional structure
- Capability of personnel
- Resources have
- Business

The structure of technical management

2. Structure of technical management

- Mechanism
- Functions
- Levels
- Operation model

Technical control in the process of achieving the data and test results

Accommodation and Environmental Conditions

- Verify the environmental conditions
- When there are any specific requirements to the environmental conditions, the laboratory shall verify if it could meet those requirements
 - Verify plan
 - Record test results and data analysis
 - Evaluation of the test results

Accommodation and Environmental Conditions

- Monitor and record of environmental conditions
 - Requirements from standards, specifications (include the environmental conditions of the usage of equipment)
 - When the environmental condition may affect the test results

When use non-automatic recording device, it should specify the recording timing

Control of test method

- Management of the standards, and documents used for testing
 - Establish a stable and effective track for standards
 - Establish the list(s) of controlled documents and standards
 - There should be a unique identification for a self-developed document (for example: work instruction). There is a instruction for how to identify the documents.
 - All the documents under controlled shall be approved before issued.
 - Review the testing related document (internal, external) at a regular period, and revise as necessary.

Control of test method

- Management of the standards, and documents used for testing
 - Invalid or obsolete documents are promptly removed from all points of issue of use
 - Obsolete documents retained for either legal or knowledge preservation purpose are suitably marked

Control of test method

- Select of test method
 - Methods published in international, regional or national standards shall be preferably be used.
 - The laboratory shall confirm that it can proper operate standard methods before introducing the test. If the standard method changes, the confirmation shall be repeated.

Control of test method

- The laboratory shall confirm that it can properly operate standard methods before introducing the test. If the standard method changes, the confirmation shall be repeated.
 - The analysis on the differences of new and old standard
 - Evaluation on human resources, conduct training and evaluation if necessary
 - Evaluation on equipment, purchasing new equipment if necessary
 - Review and revise the work instruction
 - Review of the record form and test report form
 - Participate in IC or retesting, if there are large differences between the new and old standard

Control of test method

- Deviations of standard method
 - In order to ensure the correct implementation of standard method, the laboratory shall provide effective control to the deviation of standard method.
 - The laboratory shall document the content, scope and testing steps of deviations.
 - Using an effective method to make a technical evaluation, until it shows that the deviation does not affect the test requirements
 - Authorization
 - Agreed by customer
 - The deviation from the standard method, should be clearly stated in its test report

Control of test method

- Validation of non-standard method
 - Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled
 - Validation method: 1) calibration using reference standards or reference materials; 2) comparison of results achieved with other methods; 3) IC; 4) systematic assessment of the factors influencing the results; 5) assessment of uncertainty of the results based on scientific understanding of the theoretical principals of the method and practical experience

Control of test method

- Validation of non-standard method
 - Validation requirement:
 - The scope and accurate of the test results obtained meet the particular requirements for a specific indented use
 - The validation is as much completed as possible
 - Record any results and method used for validation
 - Conclusion of the validation
 - When some changes are made in validation, he influence of such changes should be documented and, if appropriate, a new validation should be carried out.

Control of test method

- Development of work instruction
 - Why to develop the work instruction?
 - in which cases, it will need to develop work instruction?
 - The standards or manual is not very clear for operation
 - The detailed document is missing which may affect the test results during the operation

Control of test method

- Development of work instruction
 - The common work instruction may include
 - Operating instruction of the equipments (including maintenance)
 - Sample preparation
 - Testing
 - Self-calibration
 - Intermediate checks
 - Evaluation of uncertainty

Control of test method

- Development of work instruction
 - Operating instruction manual of the equipment includes:
 - Accommodations and environmental conditions
 - Preparation and precautions
 - Start, initial commissioning or self-checking steps
 - The necessary preheating operation and the preparation steps for the measurement
 - The adjustment of the measurement range and the method of reducing the indication error
 - Read timing of the measured value
 - Preparation before shutdown and shutdown steps
 - Equipment maintenance requirements (maintenance plan) and storage conditions

Control of test method

- Development of work instruction
 - The testing method is not clear in the standard, it needs to further detail, otherwise it would bring different operations
 - It does not specify the test method in the existing standards, it would need to refer to the generally used test method standard or the standard of a similar product (same type or same group)
 - There is no test method, and it would need to refer to reputable technical organization, or in relevant scientific texts or journal, or as specified by the manufacturer of the equipment

Control of test method

- Development of work instruction
 - In a standard, it defines many test methods, while in the laboratory it only can use one of them
 - The deviation to the standard method
 - Self-developed testing method

Control of test method

- Development of work instruction
 - The content of the work instruction:
 - Title
 - Scope
 - Reference standard
 - The type of products applied to
 - Testing items
 - Testing equipment
 - Environmental conditions
 - Test conditions (e.g. timing, frequency)
 - Testing steps
 - Security measures
 - Handling of anomalies
 - Data analysis (if necessary, provide the evaluation of uncertainty)
 - Evaluation of test results

Control of test method

- Development of work instruction
 - Development of intermediate checks instruction
 - Title
 - Scope
 - Intermediate check items
 - Technical requirements
 - Referenced standard
 - Operation steps
 - Data analysis
 - Conclusions
 - Period

Control of evaluation of uncertainty

- The uncertainty evaluation procedure
 - Establish the mathematic model (determine the functional relationships between outputs and inputs)

$$y = f(x_1, x_2, \dots, x_n)$$

- Identify the components of uncertainty
- Calculate the best estimate of the measured value

Calculate the best estimate of x

- Equally accurate measurement (at same test conditions)

$$\bar{x} = \frac{1}{n} (x_1 + x_2 + \dots + x_n) = \frac{1}{n} \sum_{i=1}^n x_i$$

- Unequally accurate measurement (at different test conditions, or different testing times)

$$\bar{x}_p = \frac{p_1 x_1 + p_2 x_2 + \dots + p_n x_n}{p_1 + p_2 + \dots + p_n}$$

$$P_i = \frac{C}{\sigma_i^2}$$

Pi: The weights of the measured values, are inversely proportional to their own variances

C: coefficient, normally is 1

Calculate the best estimate of y

- If there is only one direct input,

$$Y=cx$$

- If there are several indirect input, means, y is calculated by x_i , $y = f(x_1, x_2 \dots \dots x_n)$

$$y = \frac{1}{n} \sum_{k=1}^n y_k = \frac{1}{n} \sum f(x_{1k}, x_{2k}, \dots, x_{Nk})$$

$$y = f(\overline{x_1}, \overline{x_2} \dots \dots \overline{x_n})$$

Control of evaluation of uncertainty

- The uncertainty evaluation procedure
 - Listed the calculate formulation of the uncertainty
 - Evaluate the uncertainty one by one

Control of evaluation of uncertainty

- A type uncertainty

(1). Calculate the σ of each measurement

$$\sigma = \sqrt{\frac{\frac{n}{\sum (x_i - \bar{x})^2}}{n - 1}}$$

(2). Calculate the σ arithmetic mean of measurement values

$$\sigma_{\bar{x}} = \frac{\sigma}{\sqrt{n}} = \sqrt{\frac{\frac{n}{\sum (x_i - \bar{x})^2}}{n(n - 1)}}$$

Example

Times	x_i (%)	U_i (%)	Times	x_i (%)	U_i (%)
1	0.42	0.016	9	0.40	0.004
2	0.43	0.026	10	0.43	0.026
3	0.40	0.004	11	0.42	0.016
4	0.43	0.026	12	0.41	0.006
5	0.42	0.016	13	0.39	-0.014
6	0.43	0.026	14	0.39	-0.014
7	0.39	-0.014	15	0.40	0.004
8	0.30	-0.104	Mean	0.404	

$$\bar{x} = \frac{\sum_{i=1}^{15} x_i}{15} = 0.404\%$$

$$\sigma = \sqrt{\frac{\sum_{i=1}^{15} (x_i - \bar{x})^2}{15-1}} = 0.033\%$$

$$\sigma_{\bar{x}} = \frac{\sigma}{\sqrt{15}} = 0.009\%$$

Control of evaluation of uncertainty

- Key points

A.If one test is not the routine test in the laboratory, then A type uncertainty should be evaluated along with the testing.

B.If the laboratory use the same equipment and same method, at the same conditions to conduct the normal test, there is no need to evaluate A type uncertainty at each test, but can use the value that evaluated before.

Control of evaluation of uncertainty

- If test m times for the customer, then the A type uncertainty is

$$u(x) = \frac{\sigma}{\sqrt{m}}$$

- If test 1 time for the customer, then the A type uncertainty is

$$u(x) = T \cdot \sigma = 1.06 \sqrt{\frac{\sum_{i=1}^n (x_i - \bar{x})^2}{n-1}}$$

T-----t-distribution correction factor

If $k=1, n=10, T=1.06;$

If $k=1, n=5, T=1.14;$

T correction factor table

<i>n</i>	<i>k=1</i>	<i>k=2</i>	<i>k=3</i>	<i>n</i>	<i>k=1</i>	<i>k=2</i>	<i>k=3</i>
3	1.32	2.27		12	1.05	1.13	1.28
4	1.20	1.66	3.07	13	1.04	1.12	1.25
5	1.14	1.44	2.21	14	1.04	1.11	1.23
6	1.11	1.33	1.84	15	1.03	1.10	1.21
7	1.09	1.26	1.63	16	1.03	1.09	1.20
8	1.08	1.22	1.51	17	1.03	1.09	1.18
9	1.07	1.19	1.43	18	1.03	1.08	1.17
10	1.06	1.16	1.36	19	1.03	1.08	1.16
11	1.05	1.14	1.32	20	1.03	1.07	1.15

An example

Current Test: $n=10$, $s(x)=0.074\text{mA}$

Measured value

Times	1	2	3	4	5	6	7	8	9	10	Mean
Value (mA)	46.4	46.5	46.4	46.3	46.5	46.3	46.3	46.4	46.4	46.4	46.39

① $n'=1$, $x'=46.3\text{mA}$, Calculate - $u(x)$

$$u(x) = T \cdot s(x) = 1.06 \times 0.074 = 0.078\text{mA}$$

Test result: 46.3mA

An example

Current Test: $n=10$, $s(x)=0.074\text{mA}$

Measured value

Times	1	2	3	4	5	6	7	8	9	10	Mean
Value (mA)	46.4	46.5	46.4	46.3	46.5	46.3	46.3	46.4	46.4	46.4	46.39

② $n'=3$, $\bar{x} = \frac{45.4 + 45.3 + 45.5}{3} = 45.4$, Calculate - $u(x)$ 。

$$u(\bar{x}) = \frac{s(x)}{\sqrt{n'}} = \frac{0.074\text{mA}}{\sqrt{3}} = 0.043\text{mA}$$

Test result: 45.4mA

Control of evaluation of uncertainty

- Key points

- C. If the testing times are too small, it will bring the uncertainty itself.

If the measurement system is stable, and it would not be able to increase the testing times at the same conditions, it could adopt the combination of standard deviations of the samples in order to obtain more reliable standard deviation for one measurement.

Control of evaluation of uncertainty

- An example

Testing m samples for n times of each, the combination variance $s_p^2(x_i)$ is the average of each sample's variance $s_j^2(x_i)$

$$s_p^2(x_i) = \frac{\sum_1^n s_j^2(x_i)}{m} \qquad s_j^2(x_i) = \frac{\sum_1^n (x_{ji} - \bar{x}_j)^2}{n - 1}$$

$$s_p^2(x_i) = \frac{1}{m(n-1)} \sum_{j=1}^m \sum_{ii=1}^n (x_{ji} - \bar{x}_j)^2$$

$$u = \sqrt{\frac{s_p^2(x_i)}{n}}$$

Control of evaluation of uncertainty

- Key points

- D. If there is an unexpected event or human error in the measurement process, an abnormal value may appear in the measurement column, and its presence will distort the measurement and should be removed. There are many ways to determine the outliers..

Control of evaluation of uncertainty

- **1. Laiyin Da guidelines:** If there is a maximum residual in the measurement column $|v_i| > 3\sigma$, the value is recalculated without this data
- **2. Grubbs' Criterion:** If there is a maximum residual in the measurement column $|v_i| > g(\alpha, n)\sigma$, the value is recalculated without this data

Control of evaluation of uncertainty

- $g(\alpha, n)$, α significance level, σ standard deviation of one measurement

n	$g(\alpha, n)$		n	$g(\alpha, n)$		n	$g(\alpha, n)$	
	$\alpha = 0.01$	$\alpha = 0.05$		$\alpha = 0.01$	$\alpha = 0.05$		$\alpha = 0.01$	$\alpha = 0.05$
3	1.15	1.15	12	2.55	2.29	21	2.91	2.58
4	1.49	1.46	13	2.61	2.33	22	2.94	2.60
5	1.75	1.67	14	2.66	2.37	23	2.96	2.62
6	1.91	1.82	15	2.70	2.41	24	2.99	2.64
7	2.10	1.94	16	2.74	2.44	25	3.01	2.66
8	2.22	2.03	17	2.78	2.47	30	3.10	2.74
9	2.32	2.11	18	2.82	2.50	35	3.18	2.81
10	2.41	2.18	19	2.85	2.53	40	3.24	2.87
11	2.48	2.24	20	2.88	2.56	50	3.34	2.96

An example

n	x_i (%)	U_i (%)	n	x_i (%)	U_i (%)
1	0.42	0.016	9	0.40	0.004
2	0.43	0.026	10	0.43	0.026
3	0.40	0.004	11	0.42	0.016
4	0.43	0.026	12	0.41	0.006
5	0.42	0.016	13	0.39	-0.014
6	0.43	0.026	14	0.39	-0.014
7	0.39	-0.014	15	0.40	0.004
8	0.30	-0.104	平均值	0.404	

σ : 0.033% U_8 max

• **Laiyin Da guidelines:** $3\sigma = 0.099\%$ $U_8 > 3\sigma$, taking out 8, and recalculate the following 14 results, until there is no abnormal value

• **Grubbs' Criterion:** if $\alpha = 0.05$ $g(\alpha, n)$: 2.41,

$$g(\alpha, n) \cdot \sigma = 2.41 \times 0.033\% = 0.079\%$$

It still need to take out 8, and recalculate

Note: in each time, it can only take out one abnormal value. If the testing is too small, it would not use Laiyin Da guidelines.

Evaluation of A type uncertainty

	Steps	Formula
1	Correction of all measurement results	
2	Calculate the mean of the corrected measurement results. That is, the sum of the measured results after the correction divide the measurement times n	$\bar{x} = \frac{\sum_{i=1}^n x_i}{n}$
3	Calculate the residual of each measurement result, which means each measurement minus its average	$v_i = (x_i - \bar{x})$
4	Calculate the square sum for results, and then calculate the square residuals and then divide n-1. called variance V.	$V = \frac{\sum_{i=1}^n (x_i - \bar{x})^2}{n-1}$
5	The positive square root gives the standard deviation of a set of measurements	$\sigma(x) = \sqrt{V} = \sqrt{\frac{\sum_{i=1}^n (x_i - \bar{x})^2}{n-1}}$
6	Calculate the standard deviation of the mean Standard uncertainty synthesis	$u(x) = \frac{\sigma(x)}{\sqrt{n}} = \sqrt{\frac{1}{n(n-1)} \sum_{i=1}^n (x_i - \bar{x})^2}$

If there is any abnormal results, it needs to be taken out

Control of evaluation of uncertainty

- B type uncertainty

Useful information

- Pervious testing data
- Relevant documents, and knowledge and experience on the equipment characteristics
- Specification or manual
- Calibration certificate or other technical documents
- Standard data and its uncertainty
- The repetitive or reproducible limits given by the testing method technical document

.....

Examples

Components	Distribution	Half-width a	Coverage factor k
Calibration certificate: U, p	Normal	U	k_p
Calibration certificate: U, k	Normal	U	k
Calibration certificate: U, p, ν	t	U	$t_p(\nu)$
Equipment Resolution: R	Evenly	$R / 2$	$\sqrt{3}$
Repeatability limits of two measurements: r	Normal	$r / \sqrt{2}$	2
Reproducibility limits of two measurements: R	Normal	$R / \sqrt{2}$	

Commonly used distribution, and relationship with k and u

Distribution	p(%)	k	Uncertainty u
Normal	99.73	3	$\alpha / 3$
t		$t_{p(\gamma)}$	$\alpha / t_{p(\gamma)}$
Rectangle (even)	100	$\sqrt{3}$	$\alpha / \sqrt{3}$
Anti-sine	100	$\sqrt{2}$	$\alpha / \sqrt{2}$
Triangle	100	$\sqrt{6}$	$\alpha / \sqrt{6}$
Two points	100	1	α
Trapezoid $\beta = 0.71$	100	2	α

Control of evaluation of uncertainty

Example:

For a equipment, maximum allowable error is $\pm 1\%$, and the errors of all the measured values located within $[-0.01, +0.01]$ with the rectangular distribution

$$k = \sqrt{3}$$

$$a = 0.01(1\%)$$

Therefore

$$u(x_i) = \frac{a}{k} = \frac{1.0\%}{\sqrt{3}} = 0.58\%$$

Control of evaluation of uncertainty

- Synthetic uncertainty

If the measurement uncertainty has several components, the total uncertainty should be composed of all the uncertainty components (A type and B type) to synthesis, known as the synthetic uncertainty. The synthetic uncertainty is, given by the square root of the synthetic variance.

Control of evaluation of uncertainty

- Synthetic uncertainty

According to the mathematical model, it can list uncertainty component expression of input

$$u_i(y) = \left| \frac{\partial f}{\partial x_i} \right| u(x_i)$$

Control of evaluation of uncertainty

- **Evaluation of the direct measurement**

Direct measurement $y = x$ $u(y) = u(x)$

If $y = cx$, c : constant $u(y) = |c|u(x)$

C is the sensitivity coefficient, indicating that the contribution of x to the uncertainty of y is $|c|$ times .

Control of evaluation of uncertainty

- **An example: Calibrating an energy meter with a standard energy meter**

According to the mathematic model $\gamma_H = \gamma_{WO}$

γ_H Related error of Energy meter --- output

γ_{WO} Related error of Standard Energy meter --- input

Uncertainty components of γ_{WO} includes:

- ① u_A ;
 - ② The error of standard energy meter u_{B1} ;
 - ③ The resolution of standard energy meter u_{B2} .
- u_A , u_{B1} and u_{B2} are independent

$$u_c(\gamma_{WO}) = \sqrt{u_A^2 + u_{B1}^2 + u_{B2}^2}$$

- **Evaluation of the indirect measurement**

1) Inputs are not relevant

y is obtained by measuring the input

$$y = f(x_1, x_2, \dots, x_n)$$

$$u_a^2(y) = \sum_1^n \left(\frac{\partial f}{\partial x_i} \right)^2 u^2(x_i) = \sum_1^n c_i^2 u^2(x_i)$$

$$\frac{\partial f}{\partial x_i}$$

Uncertainty propagation coefficient or sensitivity coefficient, expressed as c. The meaning is change of y caused by the unit change of the input x_i. If C_i is different, the contribution of each input x_i to the y uncertainty is also different.

- **Evaluation of the indirect measurement**

1) Inputs are not relevant

Calculate the each uncertainty value $u(x_i)$

then calculate c_i

then calculate

$$u_i(y) = |c_i| = \left| \frac{\partial f}{\partial x_i} \right| u(x_i)$$

i) Rule 1: if $y = C_1x_1 - C_2x_2$ use the absolute uncertainty $u(x_i)$

$$u^2(y) = C_1^2 u^2(x_1) + C_2^2 u^2(x_2)$$

Example: $y=(p-q+r)$, 其中 $p=6.02$, $q=6.45$, $r=9.04$;
 $u(p)=0.13$, $u(q)=0.05$, $u(r)=0.22$.

Then $y=6.02-6.45+9.04=7.61$

$$u(y) = \sqrt{0.13^2 + 0.05^2 + 0.22^2} = 0.26$$

ii) Rule 2: if $y = \frac{x_1^2 x_2}{x_3}$, use the relative uncertainty $u_{rel}(y)$

$$u_{crel}^2(y) = 2^2 u_{1rel}^2(x_1) + u_{2rel}^2(x_2) + u_{3rel}^2(x_3)$$

- An example

$$\sigma = \frac{F}{A} = \frac{F}{\frac{1}{4}\pi d^2} = \frac{4F}{\pi d^2}$$

$$\frac{u_c(\sigma)}{\sigma} = \sqrt{\left(\frac{u(F)}{F}\right)^2 + \left(-2\frac{u(d)}{d}\right)^2} = \sqrt{\left[\frac{u(F)}{F}\right]^2 + 4\left[\frac{u(d)}{d}\right]^2}$$

- **Evaluation of the indirect measurement**

2) Inputs are relevant

y is obtained by measuring the input

$$y = f(x_1, x_2, \dots, x_n)$$

$$u_c^2(y) = \sum_{i=1}^n \sum_{j=1}^n \frac{\partial f}{\partial x_i} \cdot \frac{\partial f}{\partial x_j} \cdot u(x_i, x_j)$$

$$= \sum_1^n \left(\frac{\partial f}{\partial x_i} \right)^2 u^2(x_i) + 2 \sum_{i=1}^{n-1} \sum_{j=i+1}^n \frac{\partial f}{\partial x_i} \cdot \frac{\partial f}{\partial x_j} \cdot u(x_i, x_j)$$

$$r(x_i, x_j) = \frac{u(x_i, x_j)}{u(x_i) \cdot u(x_j)}$$

If r: Correlation coefficient

$$u_c^2(y) = \sum_1^n \left(\frac{\partial f}{\partial x_i} \right)^2 u^2(x_i) + 2 \sum_{i=1}^{n-1} \sum_{j=i+1}^n \frac{\partial f}{\partial x_i} \cdot \frac{\partial f}{\partial x_j} \cdot u(x_i) \cdot u(x_j) \cdot r(x_i, x_j)$$

- **Evaluation of the indirect measurement**

2) Inputs are relevant

If $y = x_1 + x_2$

Then $u_c^2 = u_1^2 + u_2^2 + 2 u_1 u_2 \cdot r(1,2)$

- **Evaluation of the indirect measurement**

- 2) Inputs are relevant

Standard deviation $u_c = \sqrt{u_1^2 + u_2^2 + 2u_1u_2 \cdot r(1,2)}$

If $r=0$ $u_c = \sqrt{u_1^2 + u_2^2}$

If $r=1$ $u_c = \sqrt{(u_1 + u_2)^2}$

If $r=-1$ $u_c = \sqrt{(u_1 - u_2)^2}$

- **Evaluation of the indirect measurement**

- 2) Inputs are relevant

x_1 and x_2 has been tested independently for n times, then the Covariance

$$u(\bar{x}_1, \bar{x}_2) = \frac{\sum_{k=1}^n (x_{1k} - \bar{x}_1)(x_{2k} - \bar{x}_2)}{n(n-1)}$$

and

$$r(\bar{x}_1, \bar{x}_2) = \frac{u(\bar{x}_1, \bar{x}_2)}{u(\bar{x}_1)u(\bar{x}_2)}$$

Control of Equipment

- Development of operation instruction
- Intermediate checks
 - key performance
 - poor stability
 - high frequency of use
 - poor environment of use
 - Returning back

Control of Equipment

- Evaluation of Intermediate checks
 - One person, use the intermediate check instruction

$$E_n = \frac{|x_1 - x_2|}{\sqrt{2U}}$$

$E_n \leq 1$, satisfactory

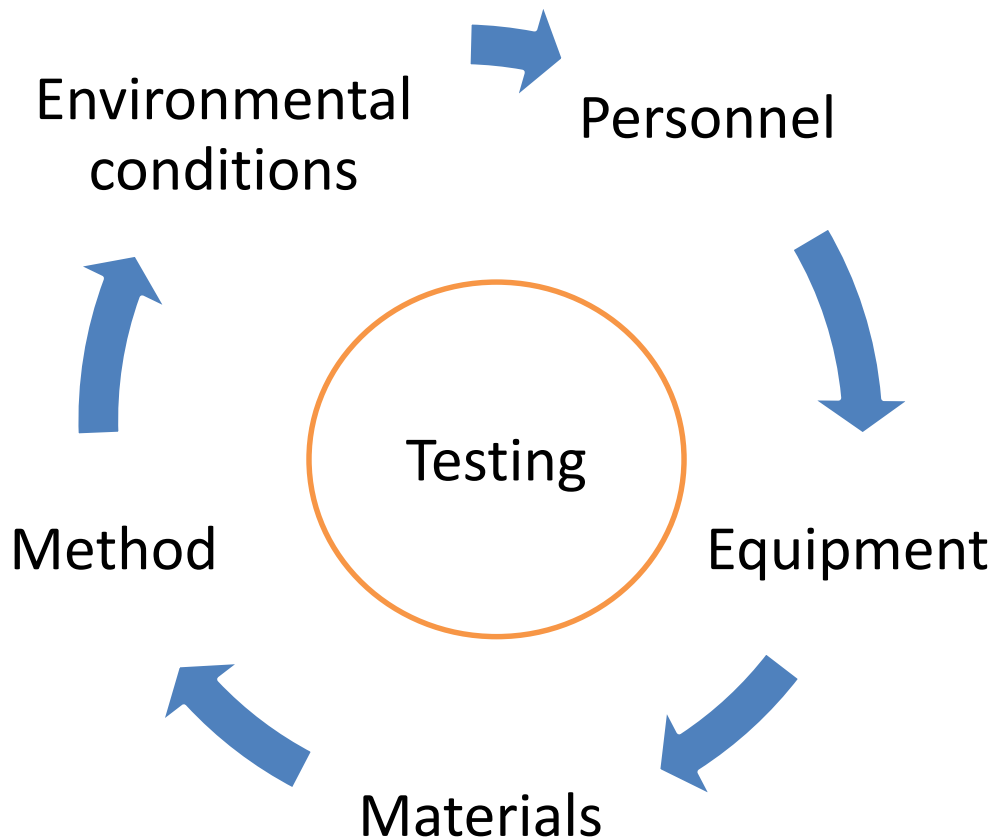
$E_n > 1$, need to be calibrated or repaired

Control of Equipment

- Intermediate checks is not calibration, and can not replace calibration
- The period is not always the same, should be determined according to the usage frequency

Assuring the quality of testing results

- The application of statistical process control



Consistent with the statistical laws of random phenomena

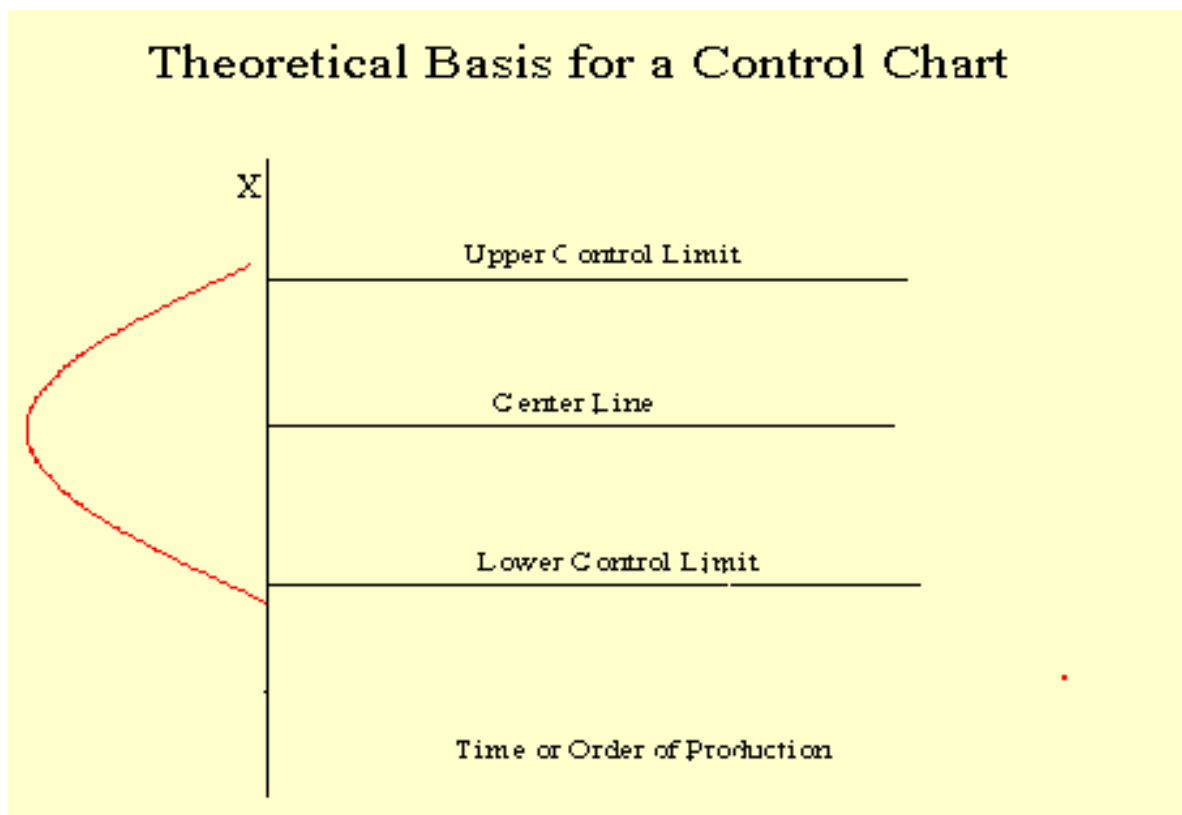
Assuring the quality of testing results

- 1. usage of control charts

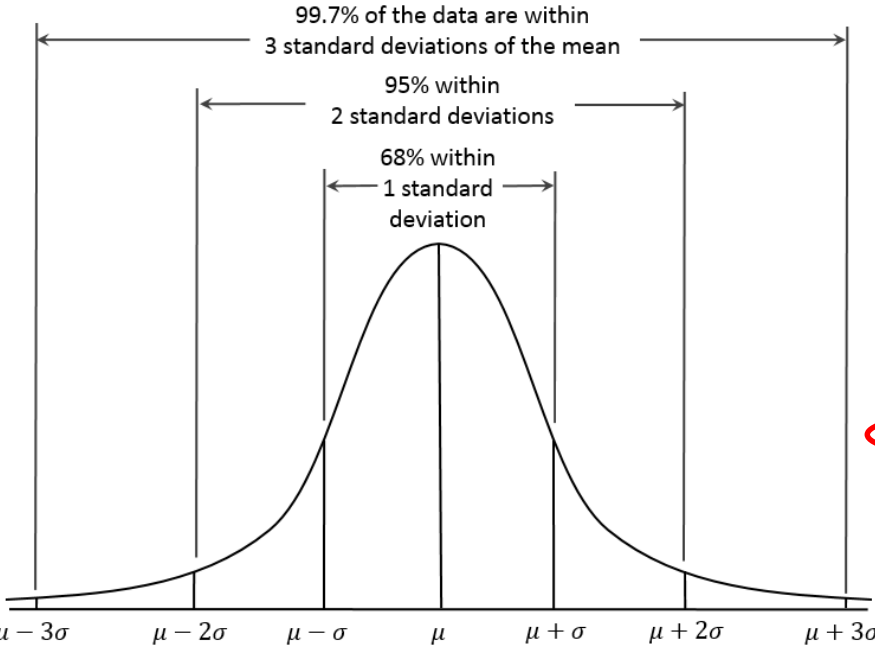
The control chart is a graph used to study how a process changes over time. Data are plotted in time order. A control chart always has a central line for the average, an upper line for the upper control limit and a lower line for the lower control limit. These lines are determined from historical data. By comparing current data to these lines, you can draw conclusions about whether the process variation is consistent (in control) or is unpredictable (out of control, affected by special causes of variation)

Assuring the quality of testing results

- 1. usage of control charts



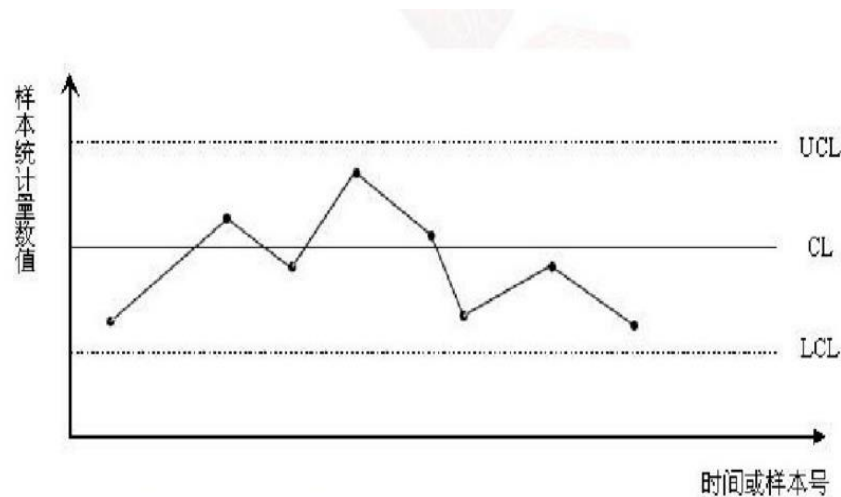
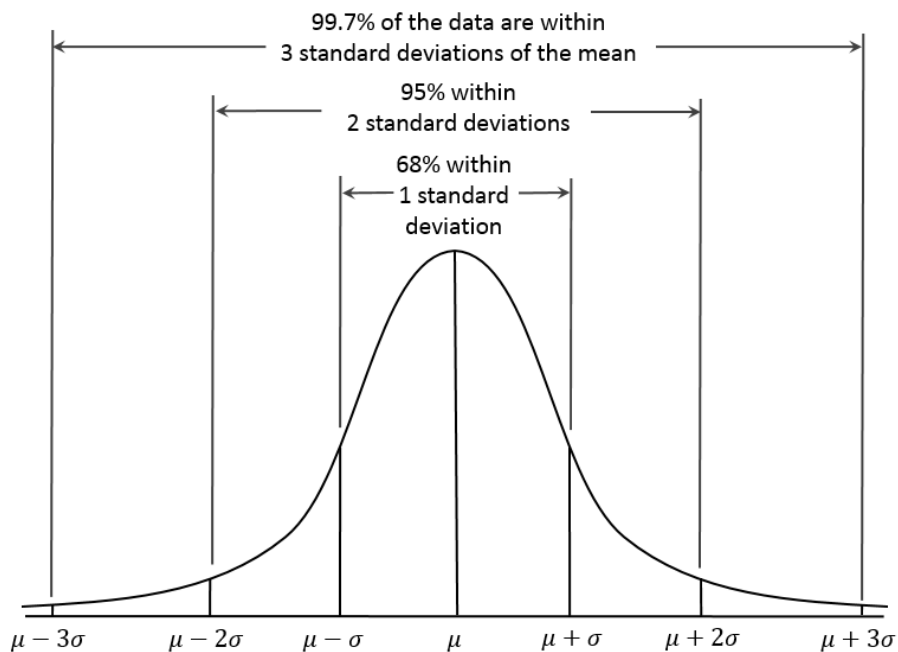
Assuring the quality of testing results



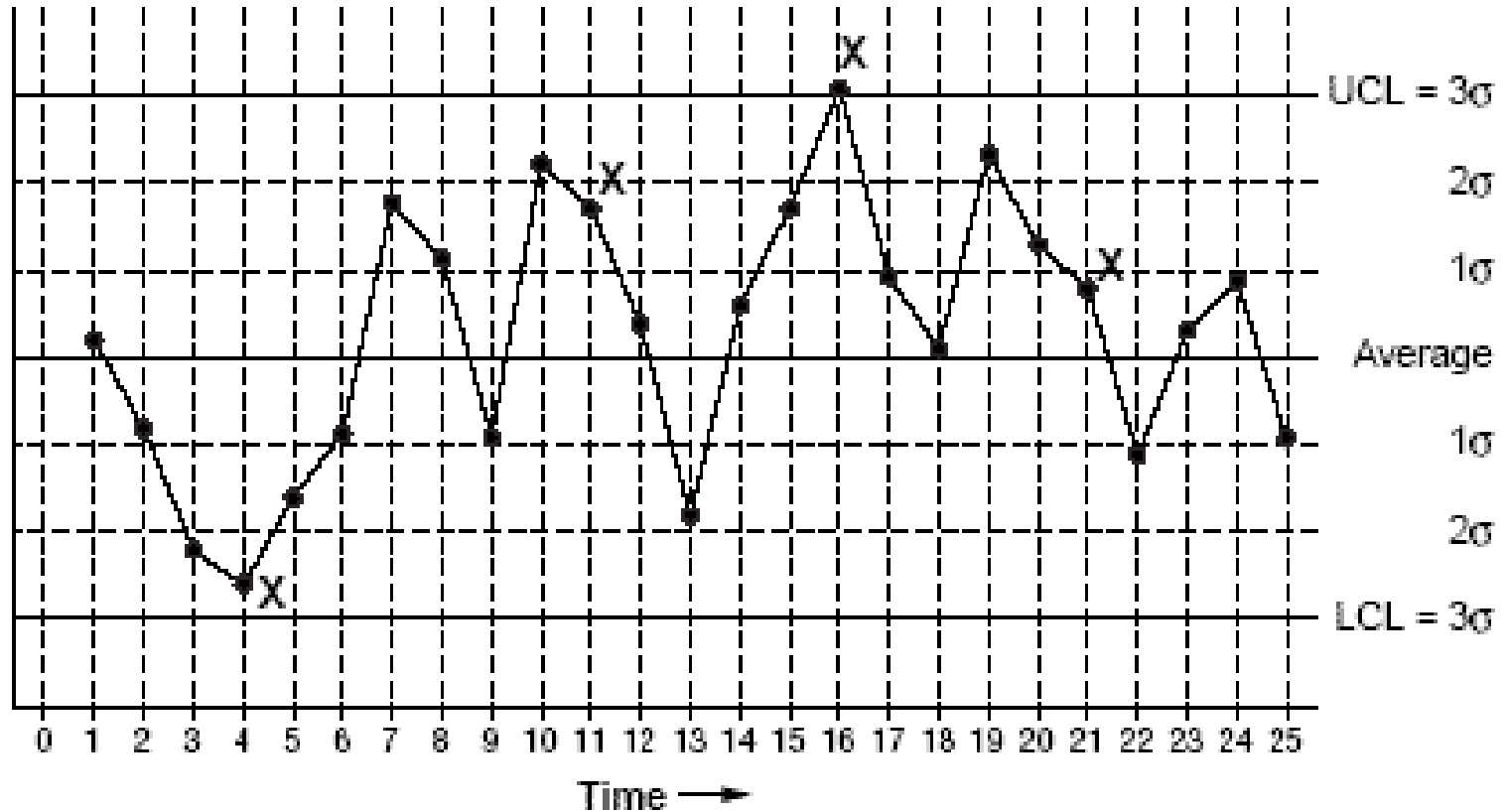
界限	界内概率	界外概率
$\pm 0.67\sigma$	50.00%	50.00%
$\pm 1.00\sigma$	68.26%	31.74%
$\pm 2.00\sigma$	95.45%	4.55%
$\pm 3.00\sigma$	99.73%	0.27%
$\pm 6.00\sigma$	99.99966%	0.00034%

Assuring the quality of testing results

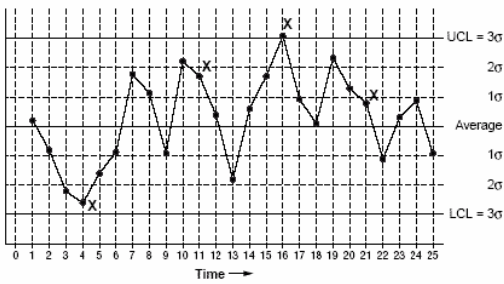
- 1. usage of control charts



Assuring the quality of testing results



Control Chart: Out-of-Control Signals

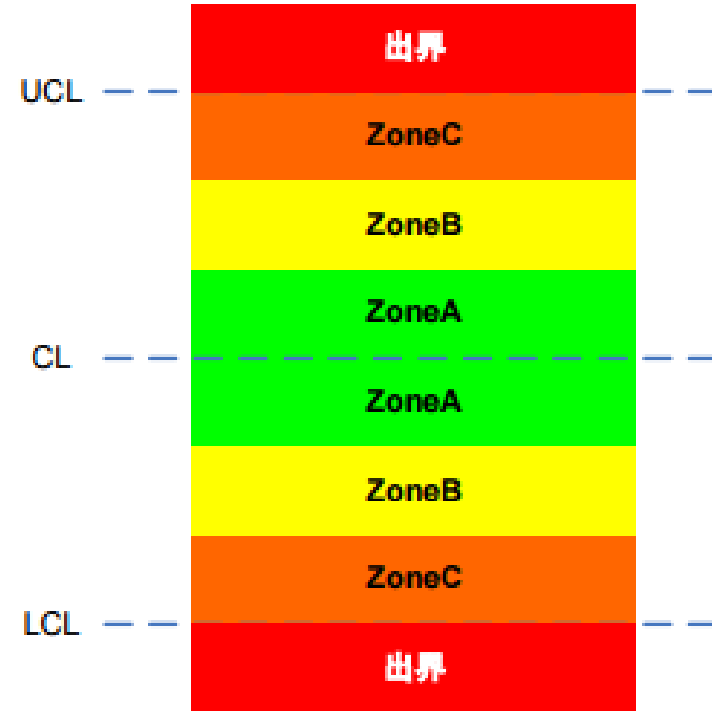
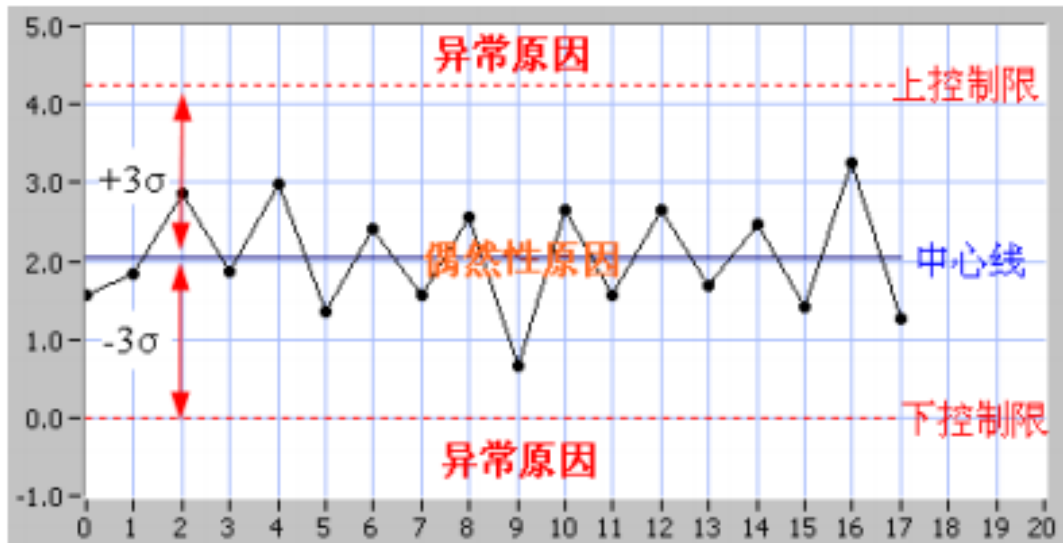


Assuring the quality of testing results

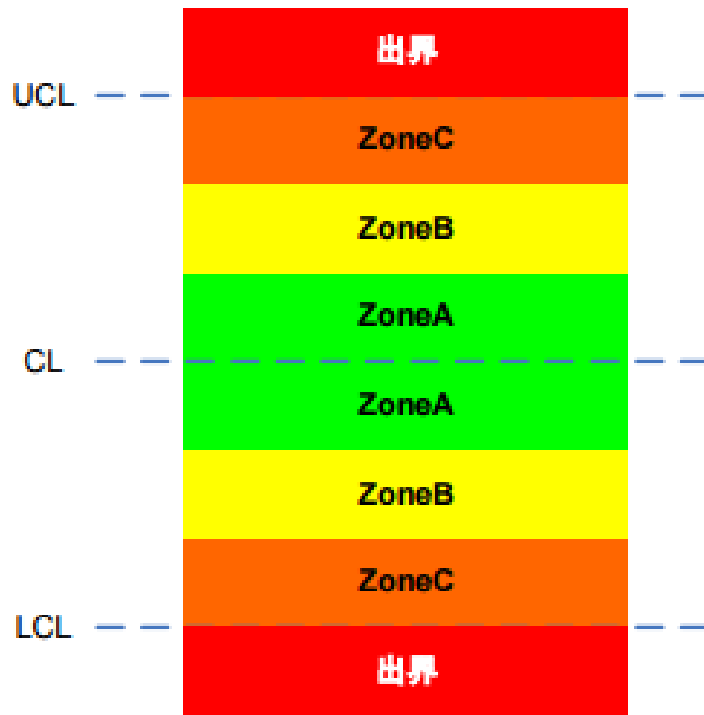
Out-of-control signals

- A single point outside the control limits. Point 16 is above the UCL (upper control limit).
- Two out of three successive points are on the same side of the centerline and farther than 2σ from it. Point 4 sends that signal.
- Four out of five successive points are on the same side of the centerline and farther than 1σ from it. Point 11 sends that signal.
- A run of eight in a row are on the same side of the centerline. Or 10 out of 11, 12 out of 14 or 16 out of 20. Point 21 is eighth in a row above the centerline.
- Obvious consistent or persistent patterns that suggest something unusual about your data and your process.

Assuring the quality of testing results



Assuring the quality of testing results



Out of control

1. One point outside the control limits
2. Continuous chain appears, means, more than 7 consecutive points located in one side of the central line;
3. Intermittent chain appears, means, most of the points located in the same side of the central line;
4. Tendency appears, means, 6 consecutive points located as a trend of increasing or decreasing;
5. Periodicity appears, means, the ups and downs are staggered
6. These phenomena are events with a probability less than 0.27%, and a small probability event occurs, indicating that the process is abnormal.

Assuring the quality of testing results

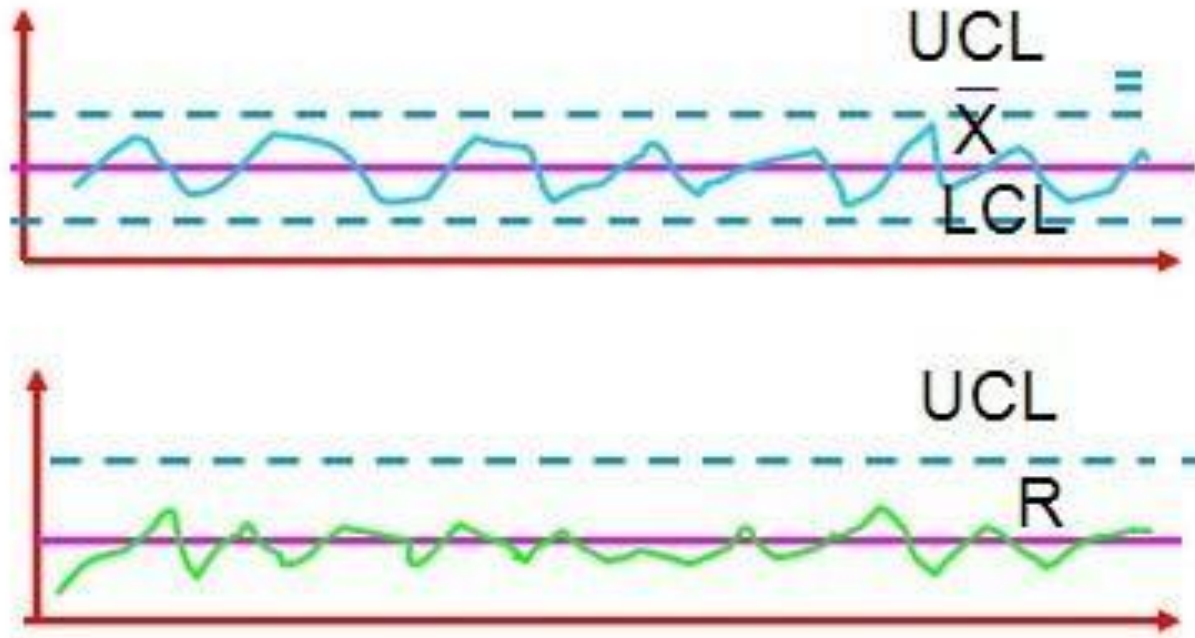
- Xbar-R Control Chart
- Xbar-s Control Chart

\bar{X} -R control chart

- Xbar-R control chart is the basic but widely used control chart
- Used for small sample size (normally no more than 9)
- Xbar chart is used for controlling the mean (average) value
- R (Range) chart is used for controlling the dispersion

\bar{X} -R control chart

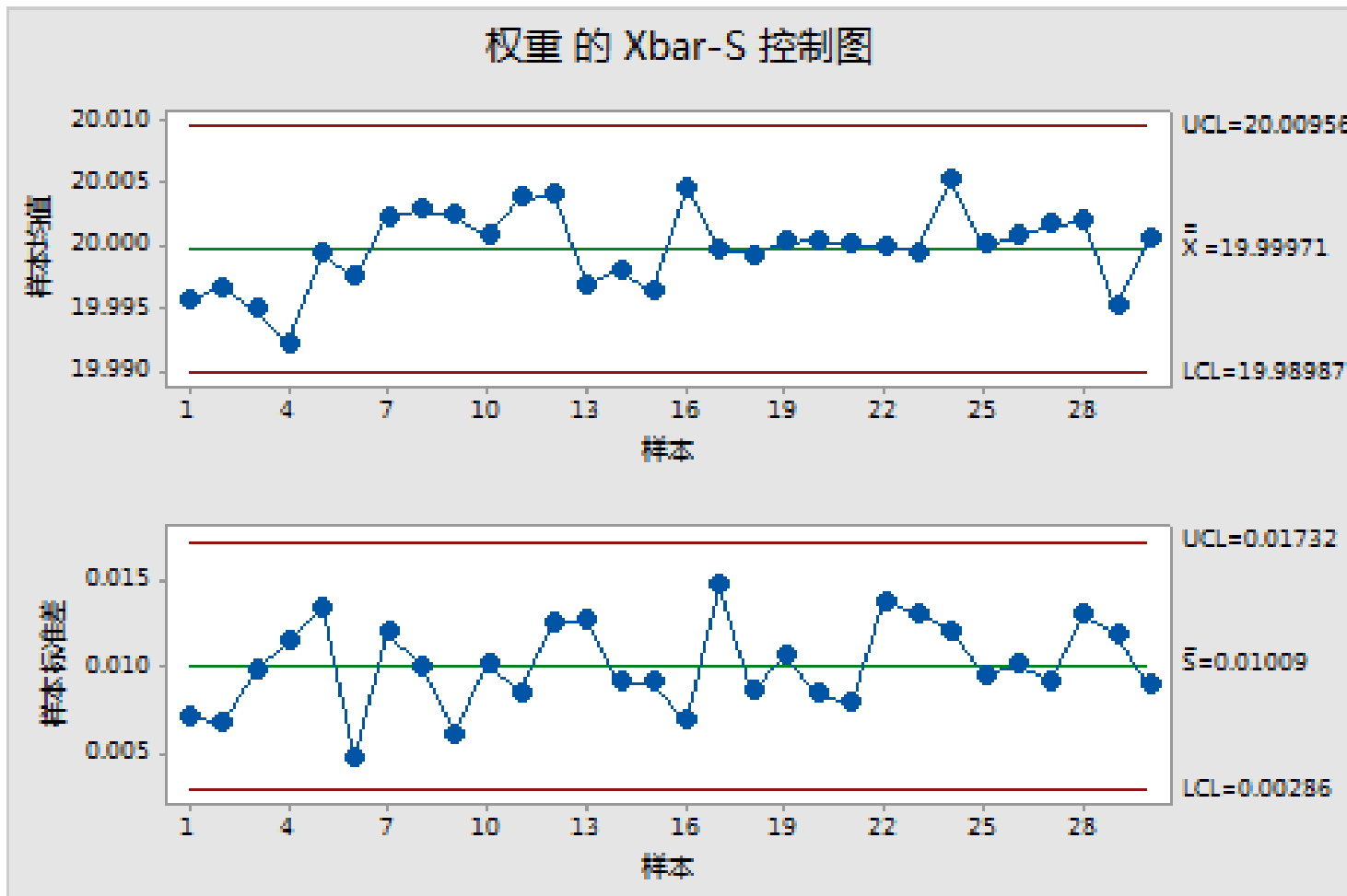
An example



\bar{X} -s control chart

- Similar like Xbar-R Chart, while use s (standard deviation) instead of R
- Sample size (normally no less than 9)
- Xbar chart is used for controlling the mean (average) value
- s chart is used for controlling the dispersion

\bar{X} -s control chart



Assuring the quality of testing results

- 2. Participating PT

Proficiency testing determines the performance of individual laboratories for specific tests or measurements and is used to monitor laboratories' continuing performance.

The results of PT is one of the most important inputs

Assuring the quality of testing results

- Evaluation of PT results

The z-score is calculated for all testing results, and is determined by:

$$z = \frac{x - X}{\hat{\sigma}}$$

is Standard Deviation for Proficiency Assessment (SDPA value), determined as nIQR (normalized interquartile range),

$$nIQR(x) = 0.7413 \times (Q_3(x) - Q_1(x))$$

Q1(x): the 25th percentile of xi (i=1,2, ...p);

Q3(x): the 75th percentile of xi (i=1,2, ...p);

$|z| \leq 2.0$ satisfactory;

$2.0 < |z\text{-score}| < 3.0$ questionable;

$|z\text{-score}| \geq 3.0$ unsatisfactory

Assuring the quality of testing results

3. Inter-laboratory comparison test

- Ensure the capacity of specific testing and monitor laboratories' continuing performance
- Identify the potential problem and conduce the corrective actions, for example the operation of personnel, or calibrations
- Validate the test method
- Increase the confidence of the consumer
-

Assuring the quality of testing results

- The differences between Proficiency testing and inter-laboratory comparison test
 - The purpose is different
 - The organizer is different
 - Evaluation method
 - Confidential consideration

Assuring the quality of testing results

4. Repetitive testing

- Using same method
- Using different methods

Assuring the quality of testing results

- Using same method

$$\frac{|x_1 - x_2|}{\sqrt{U_1^2 + U_2^2}} = \frac{|x_1 - x_2|}{\sqrt{2U}} \leq 1$$

Assuring the quality of testing results

- Using different methods

$$\frac{|x_1 - x_2|}{\sqrt{U_1^2 + U_2^2}} \leq 1$$

Assuring the quality of testing results

4. Re-test on the retained sample

$$\frac{|x_1 - x_2|}{\sqrt{U_1^2 + U_2^2}} = \frac{|x_1 - x_2|}{\sqrt{2U}} \leq 1$$

Thank you!





The Climate Technology Centre and Network (CTCN) fosters technology transfer and deployment at the request of developing countries through three core services: technical assistance, capacity building and scaling up international collaboration. The Centre is the operational arm of the UNFCCC Technology Mechanism, it is hosted and managed by the United Nations Environment and the United Nations Industrial Development Organization (UNIDO), and supported by more than 300 network partners around the world.

CTCN contact details:

Climate Technology Centre and Network

UN City, Marmorvej 51

DK-2100 Copenhagen, Denmark

+45 4533 5372

www.ctc-n.org

ctcn@unep.org