Setting control limits based on demand on measurement quality

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Setting the control limits – warning and action limits

The control limits can be set:

1) Based on method performance characteristics
i.e. standard deviation of QC sample results
- ❑ irrespectively of the requirement on analytical quality

Statistical control limits

2) Based on customer's requirement
- ❑ if the standard deviation is technically possible – compare with the method performance

Target control limits

Target control charts*

The bounds for this type of control charts are given by external prescribed and independent quality criterions.

A target control chart (for the mean. the true value. the blank value. the recovery rate. the range) is appropriate if

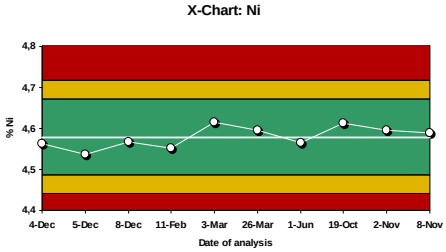
– there is no normal distribution of the values from the control sample (i.e. blank values);

– there are not enough data available for the statistical evaluation of the bounds;

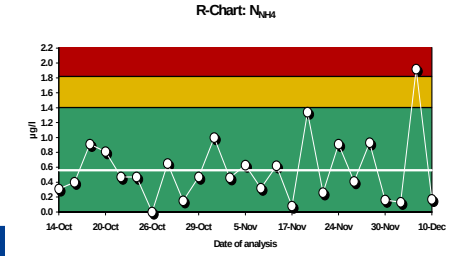
– there are external and internal prescribed bounds which should be applied to ensure the quality of analytical values.

*ISO/TS 13530:2009 Water quality -- Guidance on analytical quality control for chemical and physicochemical water analysis

Input to target control charts



For X-chart we need the within laboratory **target** standard deviation – $s_{Rw\ (target)}$



For R-chart we need the repeatability **target** standard deviation - $s_{r\ (target)}$

Setting target control limits

The standard deviation needed for the X-chart with control samples ***similar to test samples***, $s_{Rw\ (target)}$ is estimated from the requirement on s_{Rw} (the **w**ithin laboratory **R**eproducibility)

Warning limits will be ± 2 $s_{Rw\ (target)}$ around central line

Action limits will be ± 3 $s_{Rw\ (target)}$ around central line

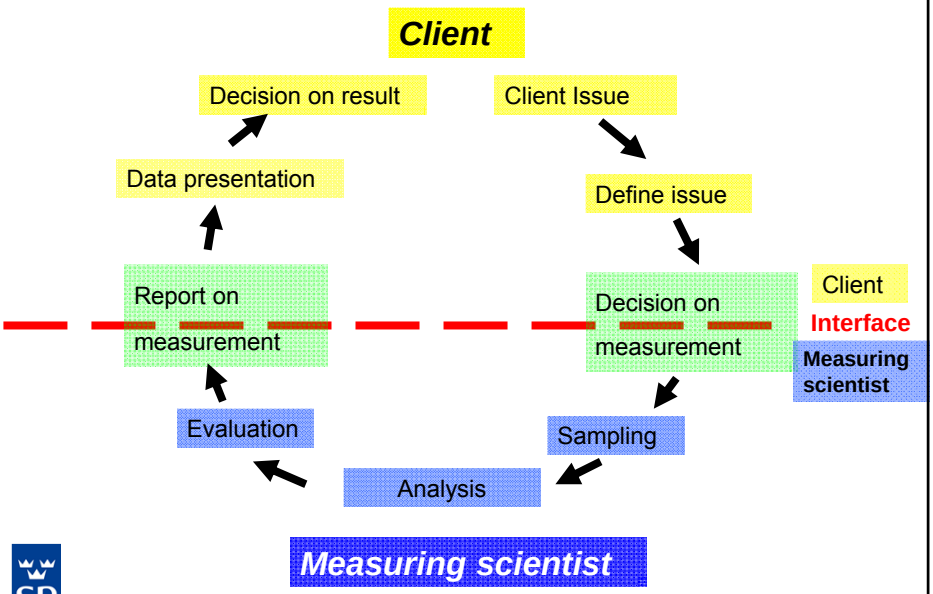
The standard deviation needed for the R-chart, $s_{r\ (target)}$ is estimated the from requirement on s_r (the **r**epeatability)*

Warning limit is + 2.8 $s_{r\ (target)}$

Action limit is + 3.7 $s_{r\ (target)}$

*s_r *can calculated* from duplicates - mean range/1.128 (n=2).

Measurement cycle – how to estimate client's requirememt



From client's requirement to target s_{Rw} and s_r

In most cases it is difficult to obtain the client's requirements.

There are many different approaches. Here some examples on setting up QC starting with requirements will be presented.

- ❑ Measurement Uncertainty (MU) requirements

Using guidance from the Nordtest Trollbook

- ❑ s_{Rw} requirements

Using mandatory regulations for environmental laboratories from the Danish Ministry of the Environment

- ❑ Requirements for an analytical balance

From MU requirements to target standard deviation for X-charts

An expanded uncertainty. U is equivalent for a coverage factor of 2 to a combined standard u_c of U/2. The combined standard uncertainty is estimated from uncertainty contribution due to withinlaboratory imprecision (s_{Rw}) and due to systematic effects (u_{bias}).

$$U = 2u_c = 2\sqrt{s_{Rw}^{\,2} + \left(u(bias)\right)^2}$$

If $s_{Rw} \approx u_{bias}$

$$s_{Rw} = s_{target} \approx \frac{U}{3}$$

Nordtest TR 569 (www.nordtst.info) is conservative and recommends U/4

s_{Rw} *requirements from* Danish Ministry of the Environment

Regarding Quality requirements for environmental measurements

(*The Danish Ministry of the Environment. document nr 900. 19 august 2011. document drafted by Ulla Lund. Eurofins Miljö A-S*)

The requirements are set on **LOD and uncertainty**. Recommended maximum s_{Rw} and CV_{Rw} are given which can be used for setting target control limits.

Example of requirements for ground water analysis

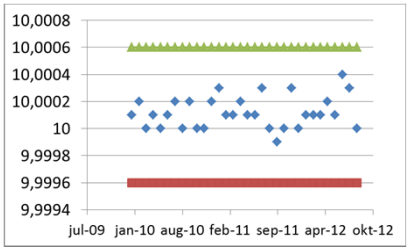
Parameter	Unit	s_{Rw}	CV_{Rw}	LOD	U	U_{rel}
Conductivity	mS/m	**1.5**	**3 %**	1.5	5	15 %
Total P	mg/L	**0.003**	**5 %**	0.005	0.01	15 %
Cadmium	mg/L	**0.002**	**5 %**	0.003	0.005	20 %
Pesticides	µg/L	**0.01**	**7 %**	0.01	0.05	30 %

Ratio U/s_{Rw} varies between 2.5 to 5

Target control limits for balances

At SP we will normally use for balances a quality control with only action limits. Test performed monthly.

The action limit is set on the last digits given by the balance, normally to ± 5 digits. The control sample is a weight with a mass appropriate for the normal use



Example: 4 decimal Mettler AX204
Weight with mass 10.0001 g.
Action limits at 10,0006 and 9.9996 g.

Results 2010 - august 2012

Minimum 9.9999 maximum 10.0004

s_{Rw} = 0.118 mg – statistical action limits 0.35 mg.

We use target action limits ± 0.5 mg

No control values outside action limits

Benefits of target control limits

- Control limits fit for purpose
- Possible to start QC chart directly if assigned value is known i.e. the position of the central line

Providing target control limits are wider than statistical control limits

- Less false positives – specially important for multiparameter control charts

- No need for annual review of control limits (still need for annual review of the control chart)

Comparable quality of analysis

If different laboratories work with

- ❑ the same target control limits
- ❑ similar control rules
- ❑ similar control samples

the quality of analyses will be similar

Quality control - fitness for purpose

If our validated method/procedure has the capability so we can set the control limits based on demand on measurement quality and:

- ❑ the control samples are similar to our test samples
- ❑ the control values show that the method is in control

We can report our analytical results and be sure that

the method
is fit for the intended purpose