Construction of control charts for reference materials

Introduction

Control charts are an appropriate tool to document results from analyses of reference materials (RM), and to identify trends and deviating results.

Control charts typically include a laboratory's internal **warning limits** and **action limits**, usually **±2s_{lab}** and **±3s_{lab}**, respectively. They are based on the *internal* standard deviation for the analysis at the individual laboratory (**s_{lab}**).

Notably, the ±2s_{lab} and ±3s_{lab} limits are expected to be smaller than the **acceptance limits** provided in the instructions provided by the Swedish Food Agency.

The instructions provided by the Swedish Food Agency also include the standard deviation (**s_{RM}**) for the **property value** (**x_{RM}**). The standard deviation x_{RM} can be used as an *initial substitute* for s_{lab}, when a laboratory does not yet have a reliable internal measure for s_{lab}.

Acceptance limits

Definition

The acceptance limits provided in the instruction from the Swedish Food Agency are calculated as the **expanded uncertainty** of the property value at a 95 % confidence interval, with $k = 2$:

$$\text{Acceptance limits} = x_{\text{RM}} \pm 2u_{\text{RM}}$$

x_{RM}: Property value, to be used for start-up control chart.

u_{RM}: Standard uncertainty of the property value (includes uncertainty contributions from characterisation, homogeneity, transportation and method differences).

The property values and acceptance limits are calculated from analysis at the Swedish Food Agency, with the methods specified in the individual instructions.

Guidance and recommendations

The acceptance limits $x_{RM} \pm 2u_{RM}$ take in consideration expected differences due to transport, stability, methods and technicians, and can *in most cases* be treated as the *absolute limits* for accepted results for the RM (at a 95 % confidence interval).

The *dispersion* of results within a single laboratory is generally expected to be the *smaller* than the acceptance limits.

It is completely normal – and sometimes even expected – that laboratories may obtain results primarily in the upper or lower part of the acceptance limits.

Construction of control charts

General construction

It is advised that all laboratory staff that regularly performs an analysis take part in analysing the RM. This will limit systematic errors and prevent obtaining too narrow control limits.

- For each RM and analysis, plot the analysis number (or analysis date) on the x axis and the corresponding result on the y axis.
- Calculate the mean value (m_{lab}) and the standard deviation (s_{lab}) for the results in the respective analyses.
- Calculate the $m_{lab} \pm 2s_{lab}$ and $m_{lab} \pm 3s_{lab}$ warning and action limits and mark them in the chart.

  Upper action limit: $m_{lab} + 3s_{lab}$
  Upper warning limit: $m_{lab} + 2s_{lab}$
  Lower warning limit: $m_{lab} - 2s_{lab}$
  Lower action limit: $m_{lab} - 3s_{lab}$

- Mark the acceptance limits (from the RM instructions) in the chart.

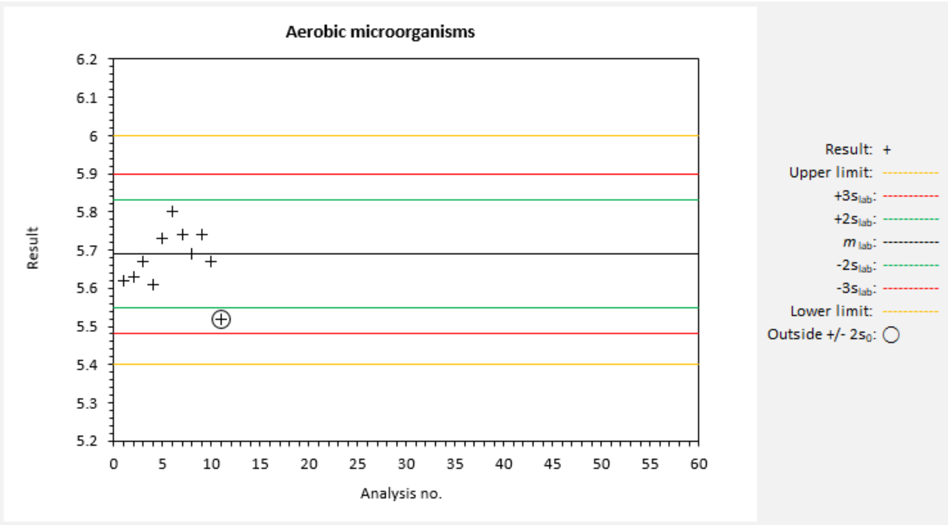

Figure 1. Example of a control chart.

Initial control chart

When starting a new control chart it may be appropriate to initially perform analyses more frequently than usual, in order to rapidly obtain an appropriate estimate of s_{lab}.

For a completely new control chart, the property value (x_{RM}) – possible adjusted according to below – should be used the start-up mean value in the control chart. When a laboratory does not yet have a reliable internal value for s_{lab}, the standard deviation s_{RM} can be used as an initial substitute for s_{lab}.

Updating the control chart

When required, recalculate and update m_{lab}, s_{lab} and the corresponding $m_{lab} \pm 2s_{lab}$ and $m_{lab} \pm 3s_{lab}$ warning and action limits. How often this is done will vary depending on the internal routines at the individual laboratory. A general recommendation is to do this at least after the initial 10 analyses, and when noticing trends with increasingly lower or higher results.

Occasionally, very deviating individual results may be omitted when (re)calculating s_{lab}, to avoid overestimating the internal variation for the analysis.

New control chart using a new RM

When changing to a new RM batch, a new control chart should also be started. This is since the property value (x_{RM}) for an analysis normally differs somewhat between different production batches of the same RM. However, the variation *within a laboratory* is assumed to be constant, and the established s_{lab} can therefore be transferred and used in the new control chart:

1. Calculate the ratio (r) between the mean value obtained for the previous RM ($m_{lab,old}$), and the property value for the old RM ($x_{RM,old}$)

$$r = \frac{m_{lab,old}}{x_{RM,old}}$$

2. Multiply the new property value ($x_{RM,new}$) with the adjustment factor (r) to obtain the *initial mean value* ($m_{lab,initial}$) for the new control chart:

$$m_{lab,new} = r * x_{RM,new}$$

3. Mark the *initial mean value* ($m_{lab,initial}$) in the new control chart.

4. Calculate the initial warning and action limits ($m_{lab,initial} \pm 2s_{lab}$ and $m_{lab,initial} \pm 3s_{lab}$) from the adjusted mean value, and the internal standard deviation from the previous production batch.

Example – control chart for food analyses

A laboratory obtains the individual results (x_{lab}) shown in table 1.

Table 1. Example data (log_{10} cfu/ml) from a laboratory.

Example: Analysis of aerobic microorganisms	
Analysis no.	**x_{lab}**
1	6.62
2	6.63
3	6.67
4	6.61
5	6.73
6	6.80
7	6.74
8	6.69
9	6.74
10	6.67

From the data:

$m_{lab} = 6.690$
$s_{lab} = 0.0618$

Therefore:

Upper action limit: $m_{lab} + 3s_{lab} = 6.690 + 3 * 0.0618 = 6.875$
Upper warning limit: $m_{lab} + 2s_{lab} = 6.690 + 2 * 0.0618 = 6.814$
Lower warning limit: $m_{lab} - 2s_{lab} = 6.690 - 2 * 0.0618 = 6.566$
Lower action limit: $m_{lab} - 3s_{lab} = 6.690 - 3 * 0.0618 = 6.505$

Example – control chart for drinking water analyses

Cfu values

A laboratory obtains the individual results (x_{lab}) shown in table 2.

Table 2. Example data (cfu/100 ml) from a laboratory.

Example: Analysis of *E. coli*	
Analysis no.	x_{lab}
1	45
2	52
3	36
4	41
5	39
6	41
7	39
8	52
9	44
10	40

From the data:

$m_{lab} = 42.900$
$s_{lab} = 5.425$

Therefore:

Upper action limit: $m_{lab} + 3s_{lab} = 42.900 + 3 * 5.425 = 59.176$
Upper warning limit: $m_{lab} + 2s_{lab} = 42.900 + 2 * 5.425 = 53.750$
Lower warning limit: $m_{lab} - 2s_{lab} = 42.900 - 2 * 5.425 = 32.050$
Lower action limit: $m_{lab} - 3s_{lab} = 42.900 - 3 * 5.425 = 26.624$

Square-root transformed values

It may sometimes be beneficial to use *square-root transformed* results when constructing control charts for drinking water analyses. This is since square-root transformation may render a better normal distribution of the results, with a more uniform variance. With this approach, using the same dataset as previously, the procedure would be:

Notably, the acceptance limits for drinking water analyses Swedish Food Agency's RM are calculated from square root transformed results.

Table 3. Example data (cfu/100 ml) from a laboratory.

Example: Analysis of *E. coli*		
Analysis no.	x_{lab}	$\sqrt{x_{lab}}$
1	45	6.708
2	52	7.211
3	36	6.000
4	41	6.403
5	39	6.245
6	41	6.403
7	39	6.245
8	52	7.211
9	44	6.633
10	40	6.325

From the data:

$m_{lab\surd} = 6.538$
$s_{lab\surd} = 0.407$

Therefore:

Upper action limit: $m_{lab} + 3s_{lab} =$ 6.538 + 3 * 0.407 = 7.758
Upper warning limit: $m_{lab} + 2s_{lab} =$ 6.538 + 2 * 0.407 = 7.351
Lower warning limit: $m_{lab} - 2s_{lab} =$ 6.538 – 2 * 0.407 = 5.725
Lower action limit: $m_{lab} - 3s_{lab} =$ 6.538 – 3 * 0.407 = 5.319

Finally, these limits are transformed back to the normal cfu scale, and can be plotted in the control chart:

Upper action limit: $7.758^2 = 60.186$
Upper warning limit: $7.351^2 = 54.044$
Lower warning limit: $5.725^2 = 32.780$
Lower action limit: $5.319^2 = 28.291$

Notably, this approach will give *different values* compared to the previous approach, as summarised below in table 4.

Table 4. Warning and action limits calculated from normal and square root transformed results.

Aerobic microorganisms		
Limit	***cfu***	***√cfu***
Upper action limit	59.176	60.186
Upper warning limit	53.750	54.044
Lower warning limit	32.050	32.780
Lower action limit	26.624	28.291