

16 October 2019

 Science Division
 Department of Biology

Control charts for RM – Food

Control charts are an appropriate tool to document results from analyses of reference materials. Directly after an analysis, the results are plotted in a graph where limits of accepted values are represented. Deviating results are in this way detected immediately, facilitating the detection of sources of error and problems with the analysis.

In the instructions for reference materials from the Swedish Food Agency, *initial control limits* are provided for each analysis. They can be used as *provisional intervals* until a laboratory has determined its own control limits.

The initial control limits take in consideration variation when the reference materials are analysed at different laboratories, with different methods, and by different technicians. Consequently, the initial control limits are rather wide. The dispersion of results within a single laboratory is therefore expected to be the smaller than the initial control limits that are provided in the instructions for the reference material.

It is also expected that some laboratories may obtain results primarily in the upper part of the control limits, whereas other laboratories may obtain results primarily in the lower part of the control limits.

It is advised that all staff that regularly perform an analysis take part in analysing the reference material. This is to avoid systematic errors or obtaining too narrow control limits.

Construction of control charts

Preliminary control chart after obtaining 5-10 results

- Make a chart for each reference material and analysis, by plotting the analysis no. (date) on the x-axis and the corresponding result (\log_{10} cfu ml⁻¹) on the y-axis.
- Calculate the mean value (m) and the standard deviation (s) for the logarithmic results in the respective analyses.

$$m = \sum x / n \quad s = \sqrt{\sum (x - m)^2 / (n - 1)}$$

where x is the analysis result and n the number of analyses performed

- Calculate the warning and action limits.
 - Warning limits: $m \pm 2s$
 - Action limits: $m \pm 3s$
- Mark the mean value, and the warning and action limits in the control chart.

16 October 2019

Update of the control chart after obtaining 10-20 results

- Calculate new mean values and standard deviations.
- Calculate new warning and action limits.
- Adjust the mean value, warning limits and action limits in the control chart.

Update of the control chart after analysing a new batch of the same reference material

The mean value for an analysis normally differs somewhat between different production batches of the same reference material. The variation within a laboratory is however assumed to be constant between batches. When starting to analyse a new production batch of a reference material, the following procedure is recommended:

- Calculate the ratio between the mean value obtained for the previous batch, and the mean value provided in the instructions for the “new” reference material. Use the ratio as an adjustment factor.
- Multiply the mean value provided in the instructions for the new batch with the adjustment factor. Mark the adjusted mean value in the control chart.
- Calculate warning and action limits from the adjusted mean value, and the internal standard deviation from the previous production batch. Adjust the limits in the control chart accordingly.
- Update the control chart after performing 5-10 analyses of the new reference material, as described above.

16 October 2019

Example of construction of a control chart

Analysis of aerobic microorganisms

Analysis no.	x	$(x-m)^2$
1	6.62	0.0049
2	6.63	0.0036
3	6.67	0.0040
4	6.61	0.0064
5	6.73	0.0016
6	6.80	0.0121
7	6.74	0.0025
8	6.69	0.0000
9	6.74	0.0025
10	6.67	0.0004

The results (x) are expressed in \log_{10} cfu ml⁻¹.

$$n = 10 \quad \sum x = 66.90 \quad m = \frac{66.90}{10} = 6.69$$

$$s = \frac{\sqrt{\sum(x-m)^2}}{n-1} = \frac{\sqrt{0.03440}}{9} = 0.06184$$

The warning and action limits are based on the mean value and the standard deviation.

Upper and lower warning limits: $m \pm 2s = 6.69 \pm 0.12$

Upper and lower action limits: $m \pm 3s = 6.69 \pm 0.19$

