# The Use of CRMs in Quality Control

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October 2016

Application Note: 7

# 1. Using a CRM in Quality Control

The recommend procedure for the use of this CRM as a control standard in laboratory quality control is to develop a Shewhart chart. A Shewhart chart is a plot of sequential assay results obtained from quality control material such as an AMIS CRM The warning and control limits are set based on the standard deviation obtained from the mean of the replicates of the CRM (Ellison, *et al.,* 2009; Thompson, 2010). The procedure in preparing a Shewhart chart is as follows:

1. Analyse 10 to15 replicates or more of an AMIS CRM;
2. Determine the mean and standard deviation of the replicates;
3. Calculate ±2s and ±3s, where *s* is the standard deviation calculated from:

$$s = \sqrt{\frac{\Sigma(x_i - \bar{x})^2}{n - 1}} \qquad [1]$$

where, $x_i$ is the individual measurements in the data set, $\bar{x}$ is the mean of the data set at *n-1* degrees of freedom (*df*) and n is the number of replicates.

4. Construct the control chart around the mean value;
5. Use ±2s as the warning limits
6. Use ±3s as the control limits
7. Set the "Warning Limits' at ±2s. It is recommended that if 2 to 3 points are outside warning limits, analyse another sample.  If it is then within warning limits, continue.  If it is outside the warning limits, stop and troubleshoot.
8. Set "Control Limits" at ±3s. It is recommended that if any point is outside control limits, analyse another sample.  If it is within control limits, continue.  If it is outside control limits, stop and troubleshoot.
9. The Shewhart chart is continually updated by the addition of the CRM assay values determined as part of daily quality control.
10. The accuracy is validated on a regular basis by the use of the following equation:

$$t_{calc} = \frac{|\bar{x} - \mu|}{\sqrt{(u_\mu)^2 + \frac{s^2}{n}}}$$
[2]

Where, $t_{calc}$ is the calculated t-statistic, $\bar{x}$ the mean of $n$ replicates with a standard deviation of $s$ for a CRM of μ certified value.  The standard uncertainty $u$ is the stated expanded uncertainty divided by the coverage factor (k) as stated on the certificate of analysis.  Note that the | | bars indicate that the absolute value between the mean and the certified value is to be used, *i.e.* ignore the sign.

**How to cite this article:**

Fraser A.W. (2016). The use of CRMs in quality control.  www.allanfraserandassociates.co.za. Add the date that the article was accessed.