Setting control limits based on demand on measurement quality

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How to properly set up and use a control chart is more complex than usually acknowledged, and one of the critical issues is the determination of robust and fit for purpose control limits.

Control limits may be set according to the performance of the analytical method used irrespective of the requirement on analytical quality – *statistical control limits*. This is the most common method to set the limits. An alternative is to start with the analytical requirements or intended use of the results. From the requirement *within-laboratory reproducibility* is estimated and then the control limits are set – *target control limits*.

The target control chart is defined in ISO 13530¹ as a control chart operating without statistically evaluated control limits. The bounds for this type of control chart are given by external prescribed and independent criteriafor the demand on measurement quality. The chart may be constructed with only an upper and lower control limit (action limits) or with both warning and action limits. The quality criteriacan be given by

- Requirements from legislation
- Standards of analytical methods or requirements for internal quality control (IQC)
- The (at least) laboratory-specific precision and trueness of the analytical value, which had to be ensured
- The evaluation of within laboratory data for the same sample type

The benefits and drawbacks with target control charts with examples of control charts from different sectors will be presented.

1. ISO/TS 13530:2009. *Water quality - Guide on analytical quality control for water analysis*. Geneva: International Organization for Standardization; 2005.