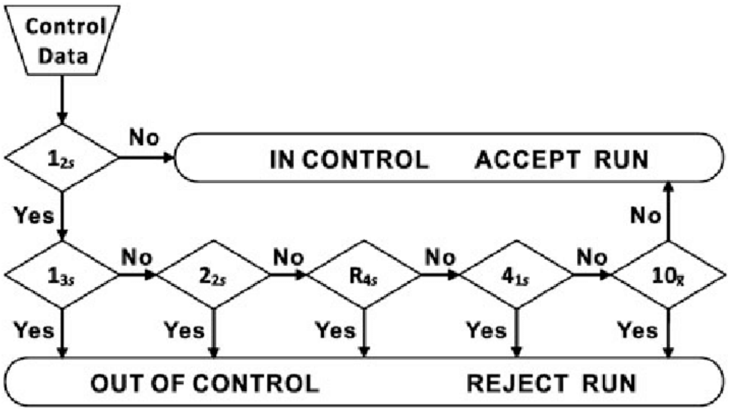
CALIBRATION AND CONTROL GUIDE (III): THE WESTGARD RULES



We call "errors" in an analysis to the difference between the value obtained for a sample and the actual value of the analyte in it. Some of these errors are random and therefore unavoidable. They are the consequence of the random dispersion around a mean value (the real value) and will present positive and negative differences with respect to it represented by the statistical parameter called standard deviation. These types of errors cannot be eliminated, but they can be minimized. Other errors are systematic deviations caused by our measurement process. Those can be corrected by different procedures depending on the nature of the error (for example, by recalibrating the method).

Quality protocols are the tools used to determine both the intensity of a random error (and determine when the established tolerance limits are exceeded) and to identify the existence of systematic errors that must be corrected. It is the use of these protocols that ultimately determines the reliability of the result.

The usual way of evaluating the quality of a series of measures is the use of control material; that is, a sample whose composition is known for the parameters that we want to control and that we include along with other unknown samples. If we obtain the expected value for the control sample, then it is assumed that the test samples are giving correct results (which is called series validation); otherwise (the control does not give the expected value), we would reject the series since the results would be compromised by an indeterminate error. However, the concept 'expected value' needs some additional clarification, since the control measure itself is subject to errors.

The first step is to focus on the random error that, under the usual measurement conditions, is represented by a **normal distribution function** of the results (the so-called Gaussian Bell). This function allows you to calculate the probability that a result is more or less far from the real value; thus, at a distance of 1 standard deviation above or below, we will have 68.2% of the results; at a distance of 2 standard deviations, 95.4% and at a distance of 3 standard deviations, 99.7%. Therefore, the first element to determine in order to know if our control result is acceptable or not is to know the **standard deviation** associated with our method through measurements made specifically for that purpose (for example, n replicates of the control material); or simply set it based on the **maximum tolerable error** that we will accept for this determination. That is, the maximum value of error that won't change the decisions to be made based on that specific test. In the first case, we will focus on the specific characteristics of the measurement method, while in the second on the general needs of the process.

Through this procedure, we do not have any information about the systematic error, since the information we have is strictly punctual in time. In addition, the measure itself is subject to error, thus we will always have a non-zero risk both of not detecting a possible error and of accepting a false rejection. By looking at the **data set obtained over time** we obtain additional information to estimate the existence of non-random errors (and therefore repeated over time if they are not corrected) as well as minimize the probability of false rejections or to accept errors out of tolerance.

The most used of all are the so-called Westgard Rules in which some of the most frequent control rules are combined:

- 1_{2s}: If the value obtained is outside ± 2 standard deviations, we proceed to check
- 1_{3s}: if it is outside ± 3 standard deviations, we reject it; if not, we check
- 2_{2s}: if we have two results in a row outside ± 2 standard deviations, we reject; but,
- R_{4s}: if there are more than 4 standard deviations between the two results, we reject; but,
- 4_{1s}: if we have 4 results in a row outside 1 standard deviation with the same sign, we reject; but,
- 10?: if we have 10 results on the same side of the expected value, we reject; otherwise, we accept the series.

Each of these rules points to a different error detection mechanism. Thus, using only a 1_{2s} rule, we would find that 4.6% of the series would be wrongly rejected (since statistically it corresponds to the probability of the tails that are outside 2s), while a 1_{3s} rule would possibly be too permissive and we could end up accepting some intolerable error (for example, a systematic error that took the results beyond 3 standard deviations, would still give 50% "acceptable" and 50% "unacceptable" results). By combining them, we strengthen the ability to detect both increases in imprecision (random error) and the appearance of systematic errors. By entering several consecutive data, as in 2_{2s} and R_{4s}, the ability to detect relevant deviations from the expected value or imprecision is strengthened.

Not all rules must be applied systematically, but it is the laboratory that decides which rules to apply taking into account the number of controls available, the cost of the analysis procedure, the frequency with which it is performed, the risk of false rejection or the probability of detecting intolerable errors. It is common to consider the breach of the 1_{2s} rule as a warning (it does not generate rejection of the series) and to gradually incorporate additional rules such as 2_{2s} and R_{4s} until reaching the appropriate level of error detection and limitation of false rejections.

The use of controls during the measurement process and their correct interpretation in the context of laboratory work is one of the most powerful tools available to the laboratory manager to assess the quality of the results provided. Sinatech has multiparametric control material to help in this task and help the oenological laboratory to provide reliable and precise results and its Dionysos system incorporates tools for the automatic application of different control rules and graphics that support their correct interpretation.

For more than 10 years, Sinatech's commitment to the winemaker has been to work side by side to provide the most appropriate analytical solutions to control and monitor the wine-making process. Automated methods easily adaptable to any work routine, with a personalized consulting team to help you a quick and smooth implementation.

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References:

https://www.westgard.com/. **Official webpage**