Validation of analytical methods of a chemistry automated in a medical analysis laboratory

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Introduction

In order to obtain the ISO 15189 accreditation, the medical analysis laboratory of Val de Saône, has to validate its analytical methods to make sure of the efficiency of the laboratory.
The evaluation of the measurement uncertainties was one of the points which were evaluated.
Each measurement is associated with an error and the study of this error will allow comparing two values.
The experimental value can be compared to a reference one and therefore can contribute to the establishment of a medical diagnosis.
The goal of the study is to determine the measurement uncertainties of a sample whatever its concentration.

Experimental methods

To evaluate the measurement uncertainties, I back up with an evaluation method described by the Cofrac. This method is a coupling of two methods using internals quality controls (CQI) and external quality controls (EEQ) which will be two components of measurement uncertainties. To determine the measurement uncertainties of a sample whatever its concentration, models of each component of the total error (error of CQI and error of EEQ) as function of the concentration were established.
The mathematical formula to calculate the uncertainties is given by the following relation:

$$u(C) = \sqrt{(ucqi2 + ueeq2)}$$

The two components of the uncertainties ucqi2 and ueeq2 will be replaced by equations in this relation to determine the uncertainties

Results

To illustrate these models, the evaluation of the measurement uncertainty for the determination of potassium in the automated DXC 800 was performed . Those models are described in the figure 1.

Concerning the error of the internal quality control, there were 3 levels of concentration and a polynomial trend line could be used to solve the equation. Concerning the error of the external quality control, it was more difficult because I only had one point.
Indeed, the outliers should be excluded beforehand that is why we have only one point.
Therefore it was impossible to draw a line which represented reality.

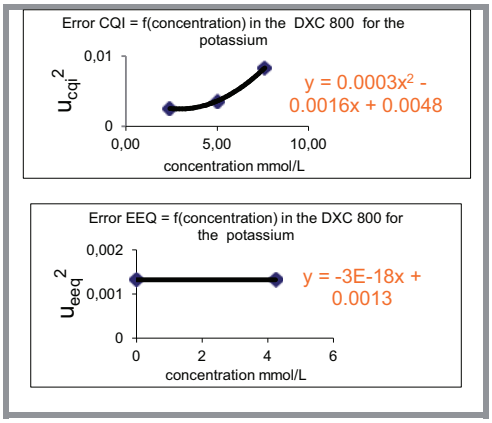

Figure 1 : *Models of the error CQi and the error EEQ as function of the concentration for the potassium in the DXC 800.*

Conclusion

To conclude, there were issues with drawing models and as a consequence determining the measurement uncertainties of a sample whatever its concentration was difficult too.
To solve this problem, solutions were found and protocols established with the usage of software tools.
One of these solutions was to undertake the external quality controls several times in order to collect a greater data set and process it in excel in order to determine the measurement uncertainties of a sample whatever its concentration.

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