

# NEQAS + (IQC)<sup>n</sup> = √UQ (the root of Ultimate Quality)

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## Introduction

The above formula looks authentic by virtue of the fact that it uses mathematical notation – no such formula exists so maybe it's time it should. Internal Quality Control (IQC) is the mainstay of knowing that your performance is within or outside specified limits for a test or assay system. Control material is a formulated matrix, designed to suit the test or assay system. and processing of this material is used to determine if analysis of samples can proceed or not. Then, approximately once a month External Quality Assessment (EQA) samples (sometimes the same matrix material as your IQC) arrive, are tested, and the results are submitted for evaluation. What could be simpler? I hear you ask, results come back and are reviewed: all O.K. (phew!) no problem, all NOT O.K. – problem; *Why if my IQC is within tolerance, is my EQA performance out of limits?*

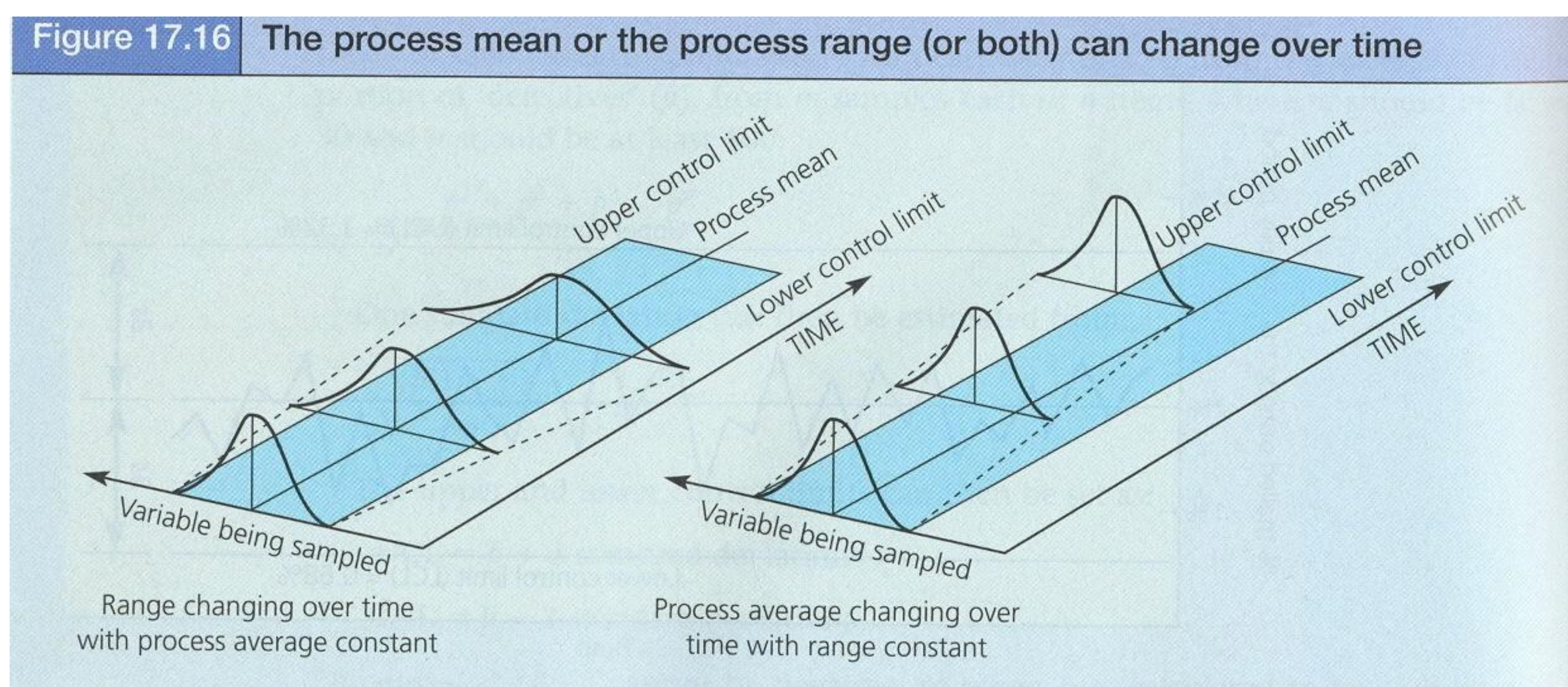
*How can I correct a problem (EQA out of limits) that I cannot see on my IQC? Is there something else wrong that I don't know about?*

When we scrutinize the EQA report, solutions to the problem are not immediately obvious and are merely highlighted by participation in an EQA programme. NEQAS do not ask for IQC performance data from participants and I am unaware of how participants correlate their IQC with EQA performance

This presentation will outline methods used in Statistical Process Control [SPC] and suggest solutions whereby participation in EQA should be an endorsement of what we already know.

## Method and Results

Most laboratories use statistical process control (SPC) in the form of Levey-Jennings plots and indeed this is facilitated by PC technology used to drive instrumentation, which includes software for Quality Control. The presentation of results on a Schewart Chart is visually uncomplicated, but lacks an element of precision and accuracy, or more correctly can you identify 'trueness' and 'uncertainty' from the data presented for the test system?<sup>1</sup> (see Figure 17.16 below)

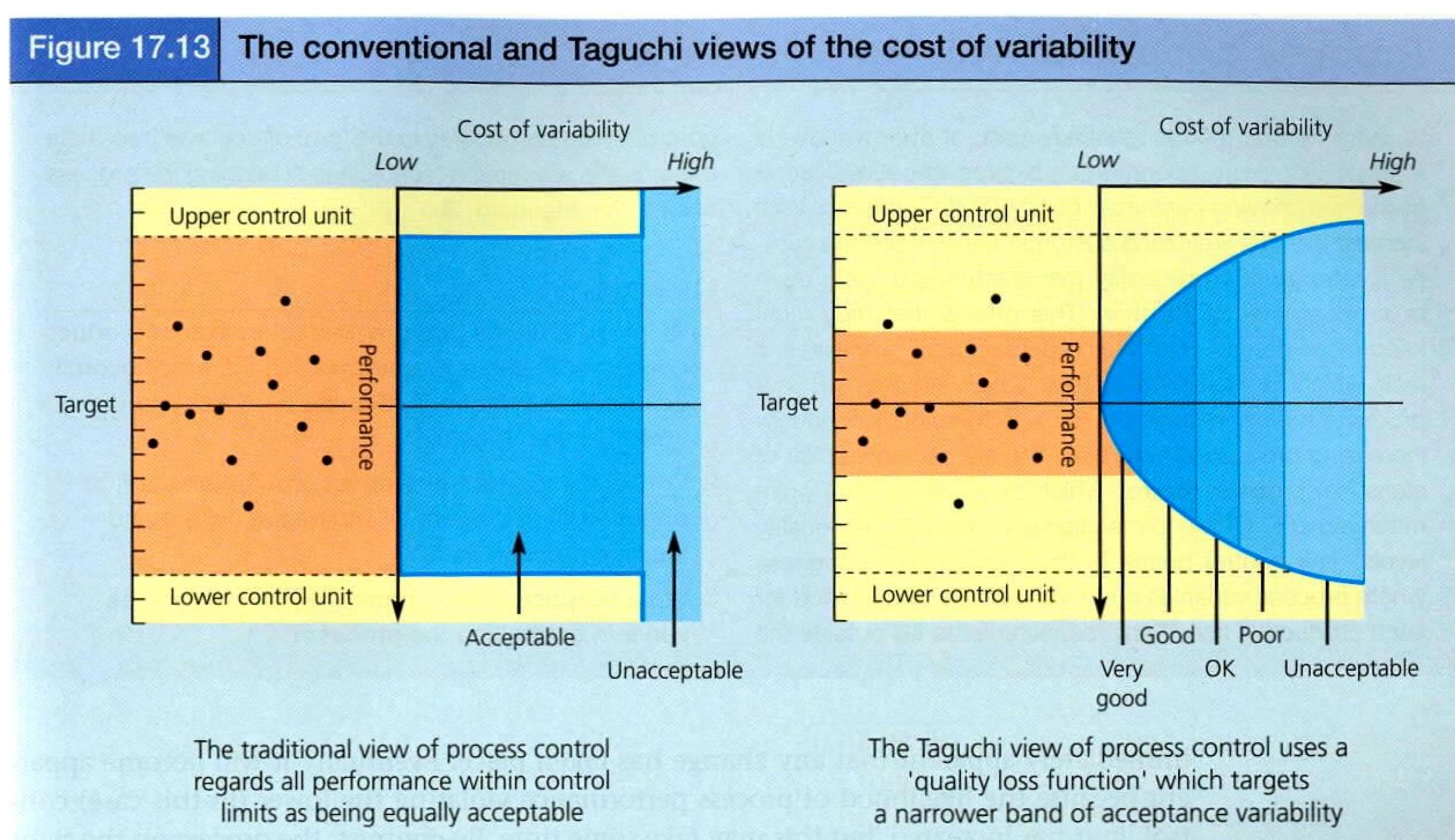


When Internal Quality Control (IQC) begins to go 'off target', do we wait for our performance in an EQA scheme to flag this situation? By adopting the method proposed by Taguchi, known as Quality Loss Function (QLF)<sup>2</sup> and expressed mathematically as:

$$L = D^2C$$

(L is total loss to society costs e.g. wastage, repairs, etc., C is a constant and D<sup>2</sup> is the deviation from the target performance, which could be the Deviance Index value or the Analytical Performance Score)

In practice Figure 17.13 below, should take the guess work out of data interpretation.



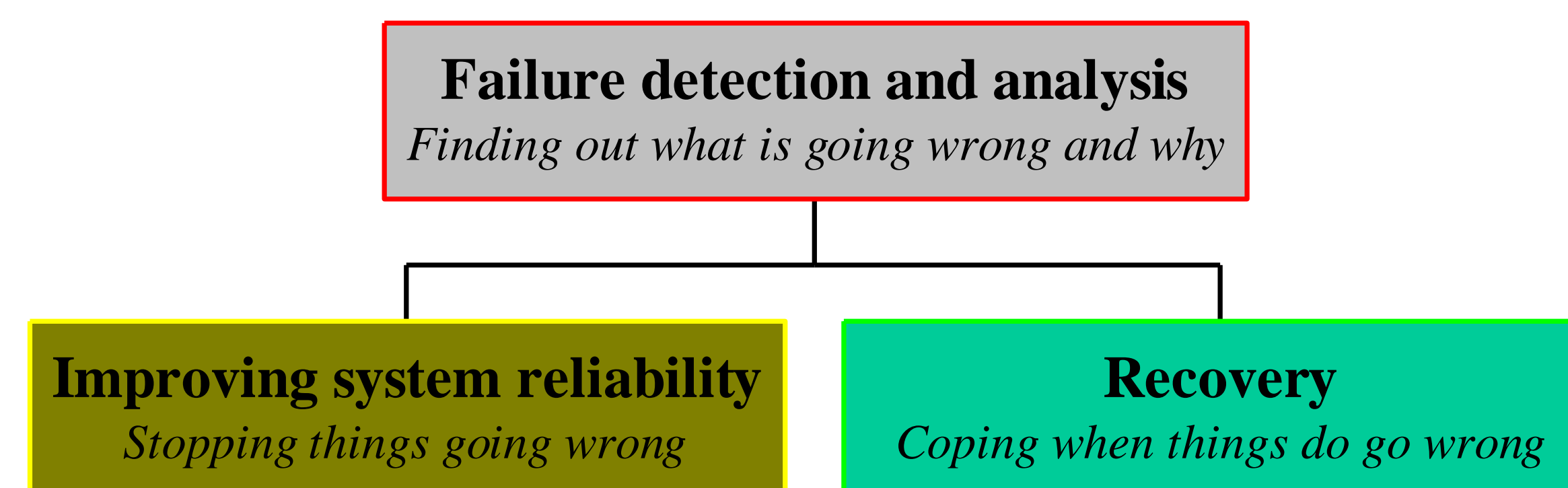
## Discussion

Currently Deviance Index is main performance parameter that laboratories use however Analytical Performance Score [APS] is also provided and how many of us use this to monitor quality? Have we ever altered our IQC strategy based on NEQAS performance? Maybe the time has come for us to utilise the Analytical Performance Score in the QLF formula, e.g. D<sup>2</sup> = APS.

Other information provided in the NEQAS report includes the Coefficient of Variation (CV) as a percentage value for measured parameters in automated systems. How does this value vary for each parameter from trial to trial? How does the CV value compare with the CV obtained in individual laboratory's IQC .

Recently NEQAS Haematology have introduced evaluation of the Erythrocyte Sedimentation Rate and reports contain a mean value, standard deviation, and coefficient of variation, and also shows a breakdown of the number of participants, but no Deviance Index or Analytical Performance Score so how do we evaluate performance of this test?

## Failure Prevention and Recovery (FPR)



One aspect of EQA no matter which scheme is involved is the lack of data on 'failure'. So what constitutes a failure in performance, as one eminent haematologist who has devoted a lifetime to quality in haematology once said, 'performance in EQA is like a snapshot from your holidays' – it just captures that moment in time and sometimes poor performance merely reflects a random failure.' Each laboratory will have failures from time to time, so a policy of failure prevention and recovery (FPR)<sup>2</sup> should easily identify failure rates such as mean time between failure (MTBF) and its causes, and also mean time to repair (MTTR). If laboratories were to pilot a system (yet to be devised) of marrying the DI or APS with MTBF, a real situation regarding 'performance' in EQA might be achieved.

## Conclusions

The question now arises as to whether laboratories are getting satisfaction from participation in EQA? Is the data sensitive enough to highlight minor as well as major problems? If not what can NEQAS do to improve this situation? or more importantly, What can we as participants do to improve?

This is an open invitation to all to explore any of the ideas above and who knows the 'formula' above may well prove that NEQAS plus its participants, is the solution to ultimate quality.

## References

1. Is GUM injurious – Or just superfluous? (see <http://www.westgard.com/guest24.htm> - Per Hyltoft Petersen)
2. Operations Management (4th Edition 2004) Slack, N et al.