Critical systematic error supports use of varied QC rules in routine chemistry.
AACC 2000

Authors:
Z. Brooks, Q.I.K. Quality Is Key Ltd.;
D. Plaut, Dade-Behring;
Conrad Begin, Aline Letourneau, Cochrane Region Laboratory Program

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Objective: We studied critical systematic error (ΔSEc) on monthly QC summary data to evaluate the range of ΔSEc values observed and the efficacy of modifying QC rules based on ΔSEc and method stability.

Relevance: International authorities recommend selecting quality control rules to match the varying performance of each analytical method.

ΔSEc relates method accuracy and precision to the performance requirement (target value and total error allowed (TEa)) of each control.

ΔSEc provides a numerical measure of the number of SD's a control mean may shift before more than 5% of results will exceed specified error limits.

Previous posters and publications claim improved efficiency in QC by selecting QC rules based on ΔSEc and method stability.

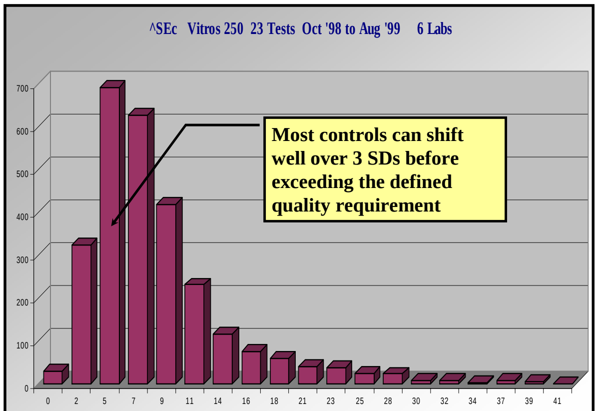
Methodology: We analyzed output from Quality Advisor software, © Q.I.K. Quality Is Key Ltd., from 6 Vitros 250 analyzers (Ortho Clinical Diagnostics) in 6 hospital laboratories from October 1998 to August 1999.

Target values and TEa limits were specified for each level of each control for each test on each instrument. Target values were based on peer comparison data. TEa limits were specified by the laboratory director to meet clinical requirements.

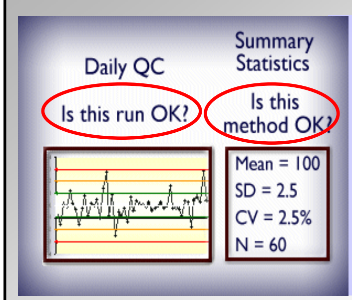
Mean and SD values, generated each month from routine daily QC data, were entered in real time into Quality Advisor. Quality Advisor calculated ΔSEc as ([(TEa - |Bias|)/SD] – 1.65) and recommended QC rules based on ΔSEc and method stability.

Validation: This study examined ΔSEc values and QC rule recommendations on 2712 quality control summary results from 23 routine chemistry tests in six hospital laboratories over 11 months. Data were exported from Quality Advisor to Microsoft Excel and SPSS to create summary graphs.

Conclusion: Over 75% of monthly control results for these 23 routine chemistry methods showed SEc values above 3.0. It is appropriate to select QC rules to match ΔSEc and method stability.



Indroducing "Performance Driven Quality Control"

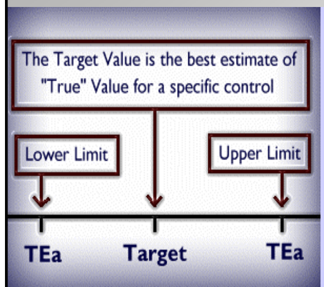


1. Most laboratories use an internally-defined mean and SD to decide each day if each QC data point is "OK"
2. "Performance-Driven Quality Control" selects a QC strategy to maintain current actual method performance within a defined quality requirement

Indroducing "Performance Driven Quality Control"

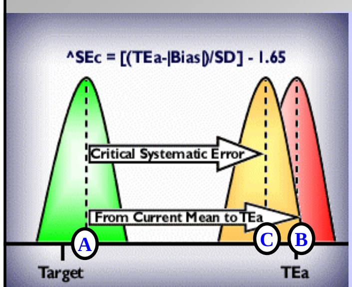
1. Calculate method performance as ΔSEc, (maximum acceptable shift in the mean)
2. Categorize method stability based on historical information for each test
3. Select rules to maintain method performance within defined quality requirements

Performance Driven Quality Control



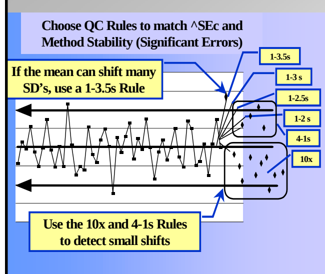
1. Specify the "Target" for each control
2. Set a maximum acceptable variation from that target: allowable Total Error limit (TEa) to maintain clinical and proficiency requirements for your institution
3. Calculate a valid mean and SD

ΔSEc = # of SDs the mean can shift before >5% of data will exceed TEa



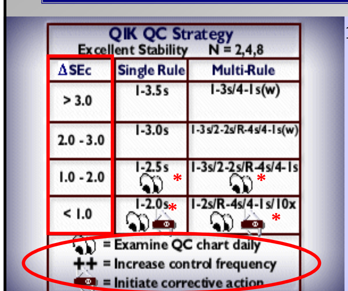
1. If the mean shifts from its current bias (A) all the way to the TEa limit (B), half the data will exceed the quality requirement
2. Normal distribution assumes 90% of data fall within +/- 1.65 SD of the mean. We subtract 1.65 SD (C) so <5% of data exceed the upper (or lower) TEa limit

Select appropriate QC rules based on ΔSEc to detect shifts in the mean



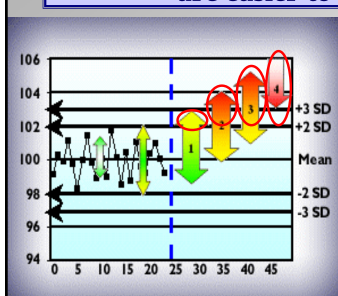
QC Rule	Shift Detected	False Positives
1-2s	Small	Many
1-2.5s	Moderate	Moderate
1-3s	Large	Few
1-3.5s	Large	Rare
4-1s	Small	Mod/many
10x	Small	Many

QC Strategy Tables simplify rule selection



1. Select the single rule or multi-rule combination based on the calculated ΔSEc for each test/control/ level
2. When indicated, apply additional QC strategies to increase error detection

Larger shifts in the mean are easier to detect



1. The graphic shows mean shifts of 1, 2, 3 and 4 SD
2. Note the proportion of data above the 2SD and 3SD limits on the QC chart with each shift in the mean
3. Larger shifts will generate more QC flags

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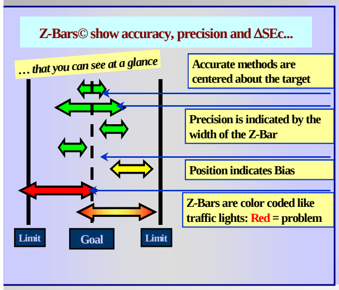
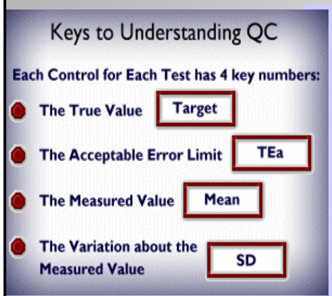
Method performance is shown graphically



1. Z-Bars© (©) show method accuracy and precision relative to the defined target and TEa limit for each control
2. Z-Bars© vary with the data distribution (mean and SD); Tests/controls with low ΔSEc are close to the TEa limit

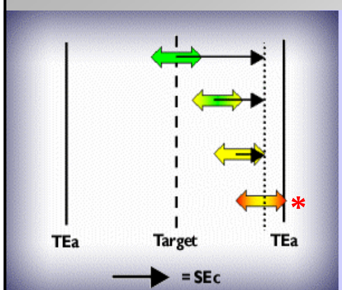
Four key numbers indicate method performance



1. The **target** may be the historical average or peer mean
2. The **TEa** may be the CLIA limit or a clinically acceptable variation
3. The **mean** is a current calculated value
4. The **SD** must represent actual method performance

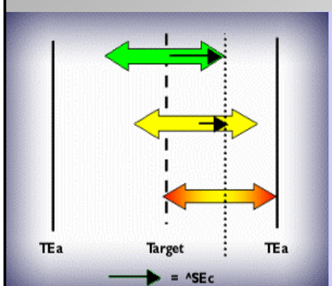
SD's assigned from other sources are misleading

ΔSEc is the maximum mean shift before the method exceeds TEa



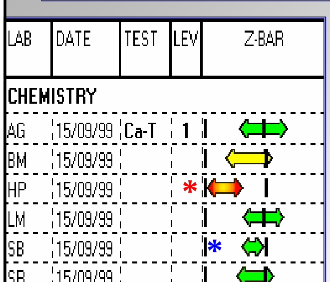
1. The top Z-Bar© shows a method with an ΔSEc of approximately 8. A shift of this magnitude would easily be detected with a 1-3.5s QC rule
2. The other controls can shift 4, 2 and zero SDs. These require closer monitoring with a 1-3s, 1-2.5s, 1-2s or multi-rules; 1(*) needs corrective action.

ΔSEc and Z-Bars© vary with method accuracy and precision



1. The top Z-Bar© has the same bias as the top Z-Bar© in the previous example, but a higher SD. The ΔSEc in this example is only 2, instead of 8 when the SD was lower.
2. ΔSEc = [(TEa-|Bias|)/SD]-1.65
3. ΔSEc combines the 4 key numbers

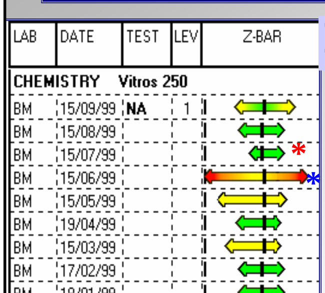
ΔSEc varies from lab-to-lab, using the same controls and instruments



Target for all labs is 2.95
TEa for all labs is 0.2

Lab	Mean	SD	ΔSEc
AG	2.95	.036	3.88
BM	2.88	.031	2.61
HP	2.81*	.027	0.39 *
LM	2.96	.024	6.43
SB	2.90	.020 *	5.98 *
SR	2.90	.029	3.56

ΔSEc varies from time-to-time within the same laboratory



Target for all months is 142.3
TEa for all months is 5.0

Date	Mean	SD	ΔSEc
Sept	142.0	1.07	2.75
Aug	142.1	0.87	3.83
July	143.2 *	0.68	4.43 *
June	141.0 *	2.02 *	0.18 *
May	140.9	1.40	0.91
April	141.5	0.87	3.17

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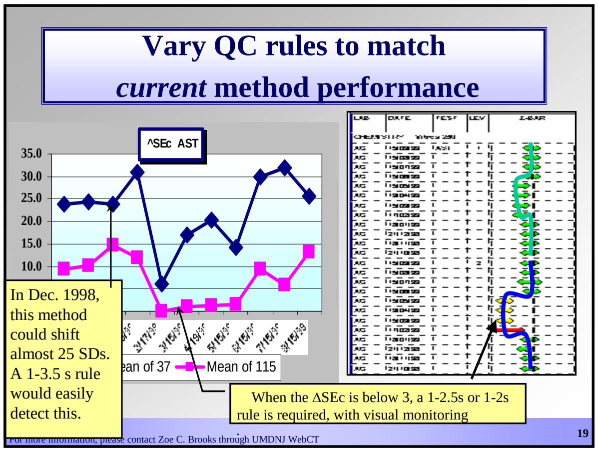

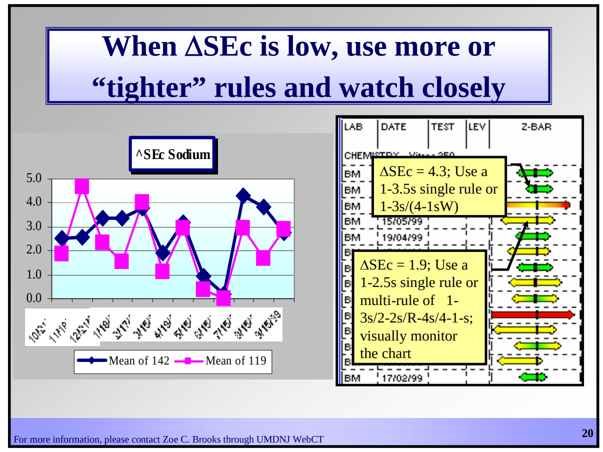

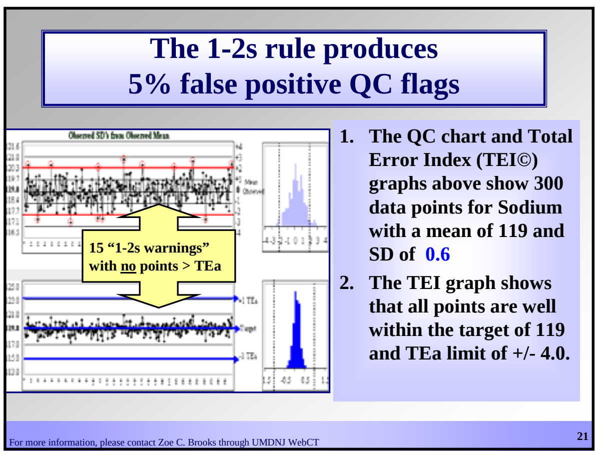

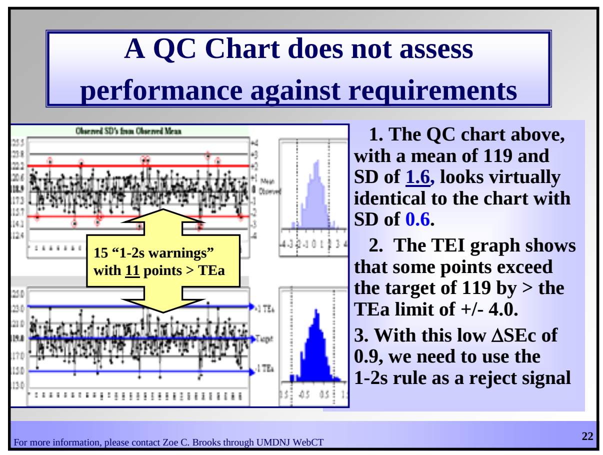

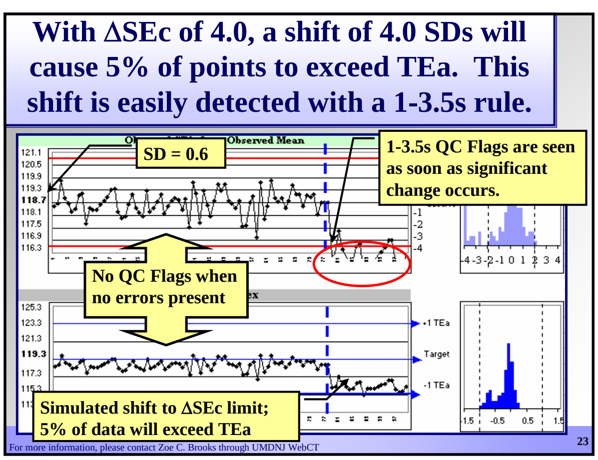

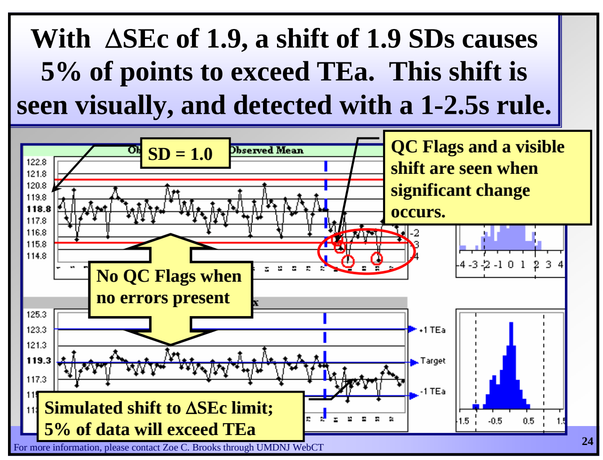

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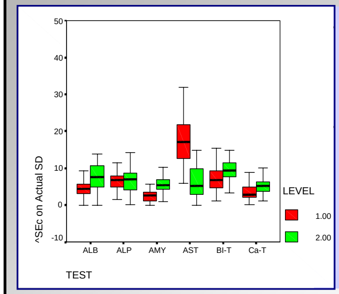
ΔSEc varies over time for all tests in all labs



1. Most tests average ΔSEc above 3.0, and can be controlled with a 1-3.5s rule
2. Most tests occasionally approach ΔSEc of zero – at the TEa limit - requiring tighter QC rules, increased visual monitoring and corrective action.

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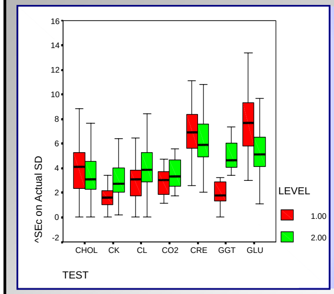
ΔSEc varies between control levels



1. TEa limits and method performance (accuracy/ precision) vary between control levels.
2. If one control level is closer to the TEa limit, use tighter QC rules to "watch it more closely".

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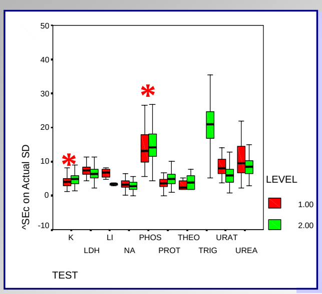
Variations in ΔSEc require changes in QC strategy



Some controls on some tests (e.g. Phosphate) can shift over 20 or 30 SDs before exceeding TEa limits.

Other tests (e.g. Potassium) usually have a low ΔSEc and require close monitoring to meet clinical and proficiency requirements

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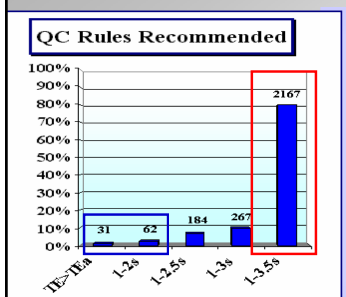
80% of routine chemistry tests could use a 1-3.5s QC rule



1. Of the 2711 controls monitored in 12 months in 6 labs, 2167 had ΔSEc above 3.0 and could use a 1-3.5s QC rule.
2. Only 93 tests required a 1-2s rule and performance improvement.
3. Use of a 1-2.5s, 1-3s and 1-3.5s QC rule reduces false positive QC flags.

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Good QC strategy reduces false positives and false negatives

1. False positive QC flags are reduced by selecting QC rules such as 1-2.5s, 1-3s and 1-3.5s when ΔSEc is high.
2. False negative QC flags are reduced (error detection is increased) by using the 1-2s rule as a reject and visually monitoring charts when ΔSEc is low.

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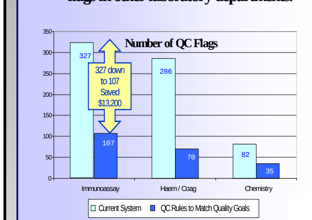
QC rules selected by ΔSEc save money in laboratories

Previous studies by Q.I.K. show reduced QC flags in other laboratory departments.



1. In our study, 2618 controls did not require a 1-2s rule.
2. At 30 runs per month, these controls represent 78,540 QC data points.
3. A 5% false positive rate from the 1-2s rule would have produced 3,927 flags.
4. At $10 per repeat/QC investigation, this represents $39, 270.00

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