MaxE(Nuf) QC model

حسن بیات
دانش آموخته علوم آزمایشگاهی

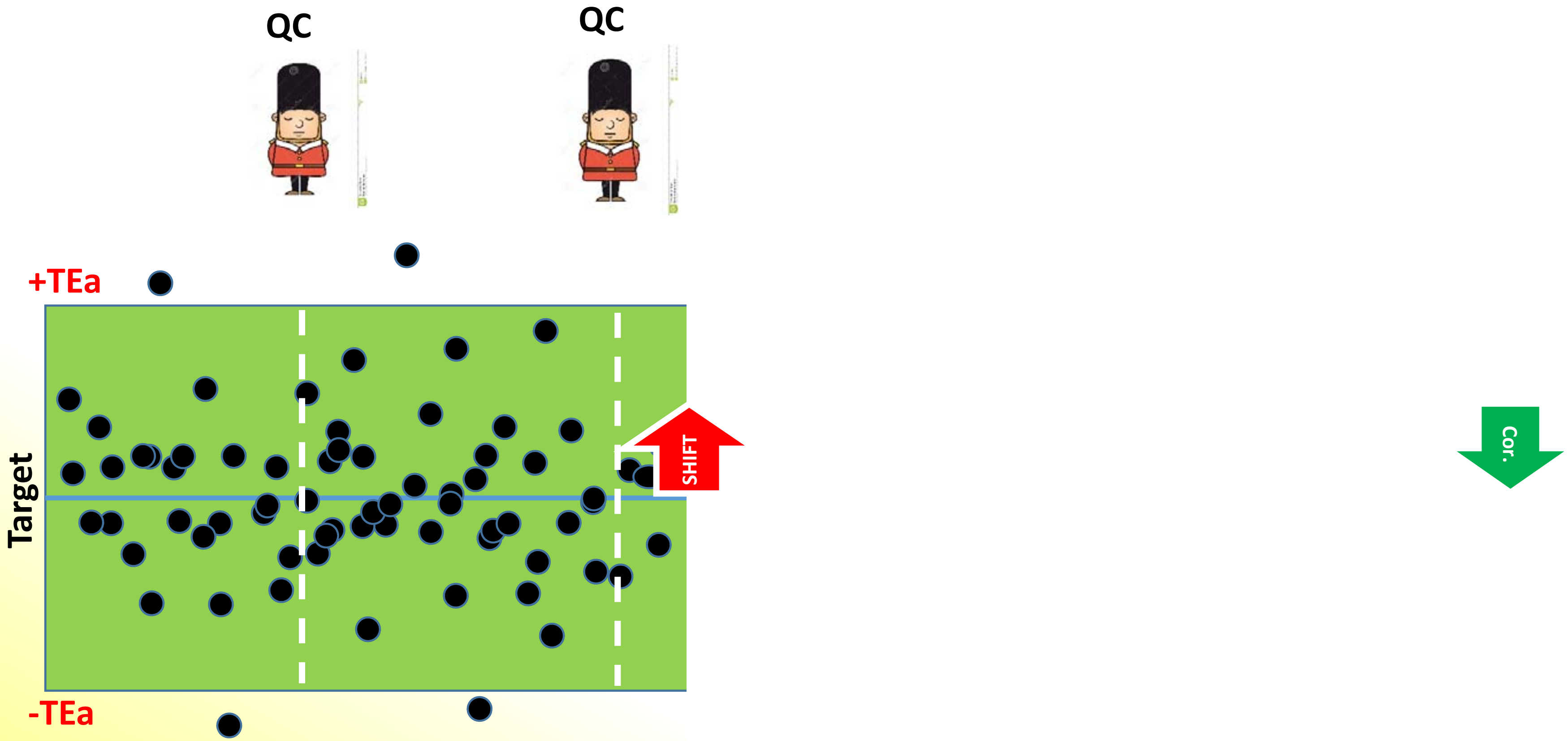
Background

- **Conventional QC Planning:**
  - Performance Specification (TEa)
  - Performance Characteristics (Bias & CV)
  - SQC Characteristics (P_{ed} & P_{fr})

What was lacking? **Frequency** or **Run size**

Max E(Nuf) SQC Model

- Developed by Dr. C. Parvin
- CLSI C24-Ed 4 (2016)

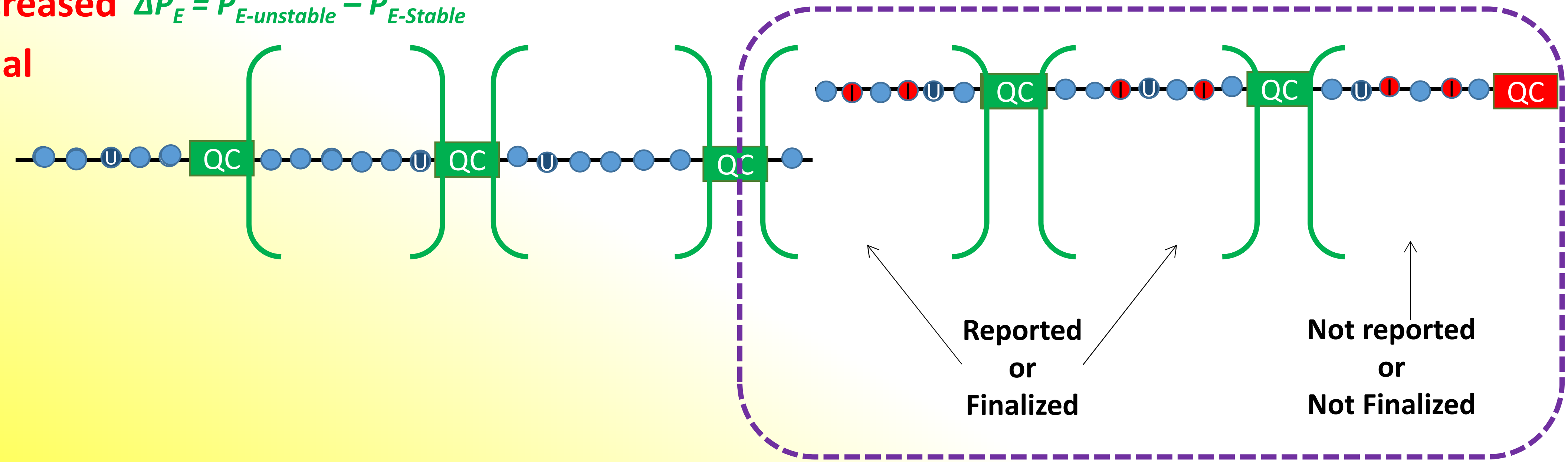


Schematic view of Max E(Nuf) model

- ***How many increased errors are produced?***
- ***Of the them, how many are reported?***

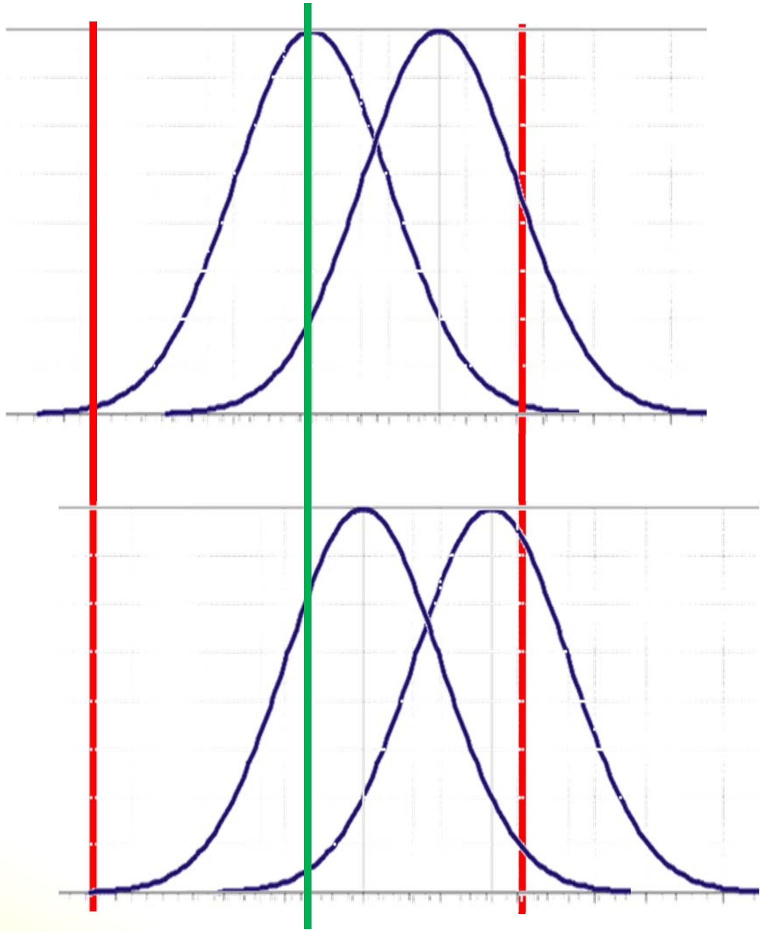
E(Nuf): *Expected Number of Increased Unreliable Final Results*

- TE-based model; **Unreliable**: Results that differ from the reference value more than TEa (pTE)
- Sigma Metric; **SM = (TEa – Bias)/SD** or **SM = (%TEa - %Bias)/CV**
- Bracketed QC for Continuous Performance
- **Increased** $\Delta P_E = P_{E\text{-}unstable} - P_{E\text{-}Stable}$
- **Final**



Factors contributing to E(Nuf)

- **Increase in the probability of producing error; ΔP_E**
  - **Shift size;** The larger is shift, the higher is ΔP_E
  - **Bias**



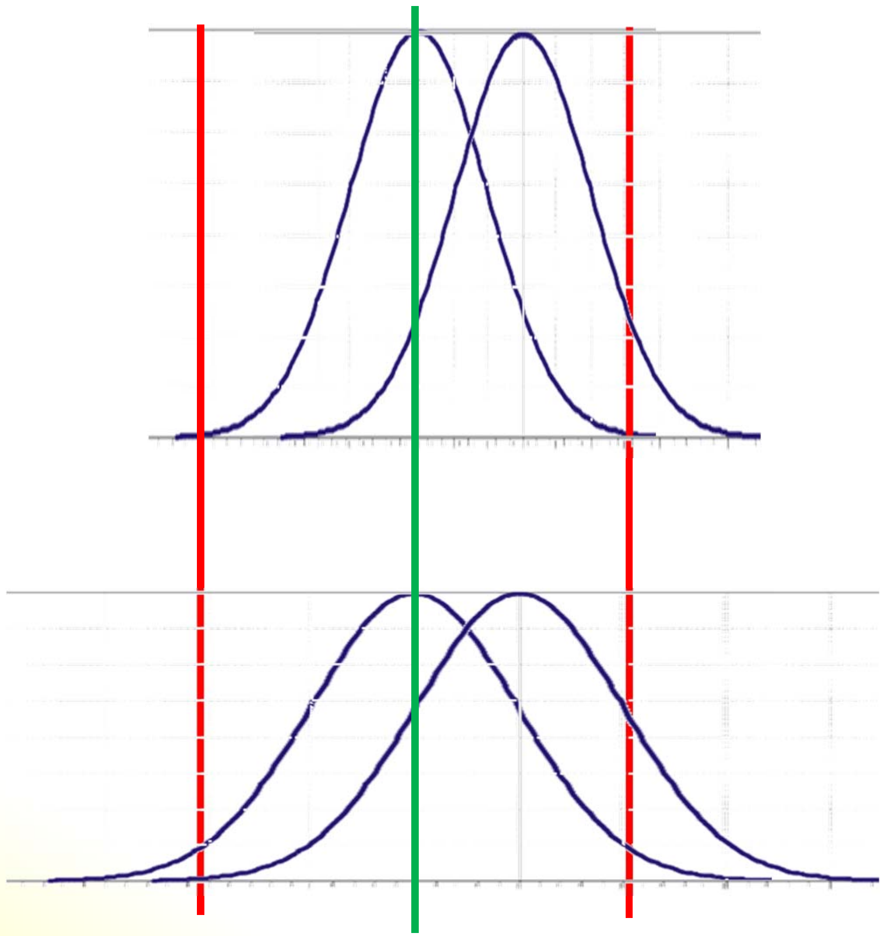
Factors contributing to E(Nuf)

- **Increase in the probability of producing error; ΔP_E**

  - **Shift size;** The larger is shift, the higher is ΔP_E
  - **Bias**
  - **Imprecision**

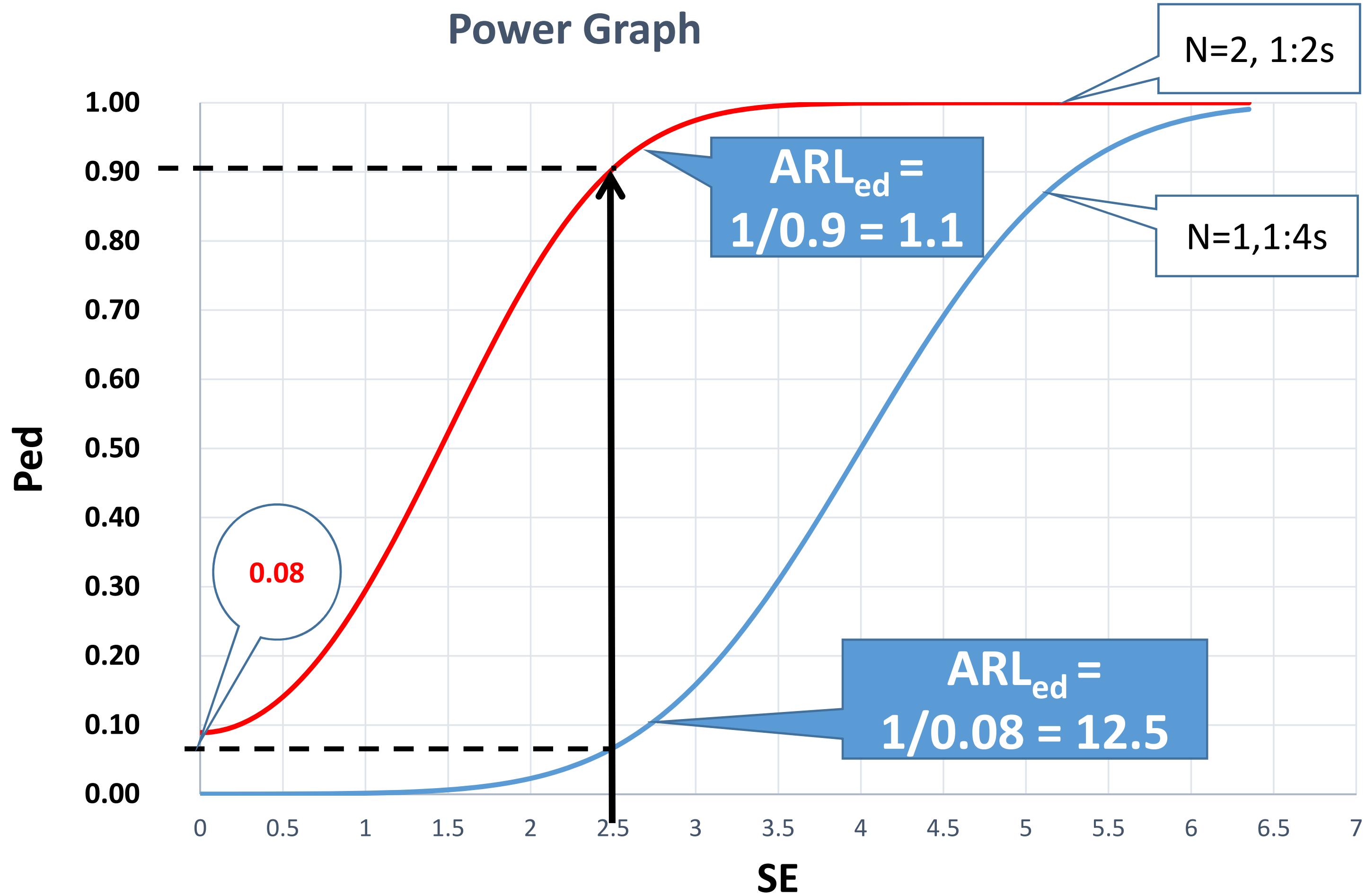
SM = (TEa – B) / SD

The higher is Sigma, the lower ΔP_E



Factors contributing to E(Nuf)

- ΔP_E
- ARL_{ed}

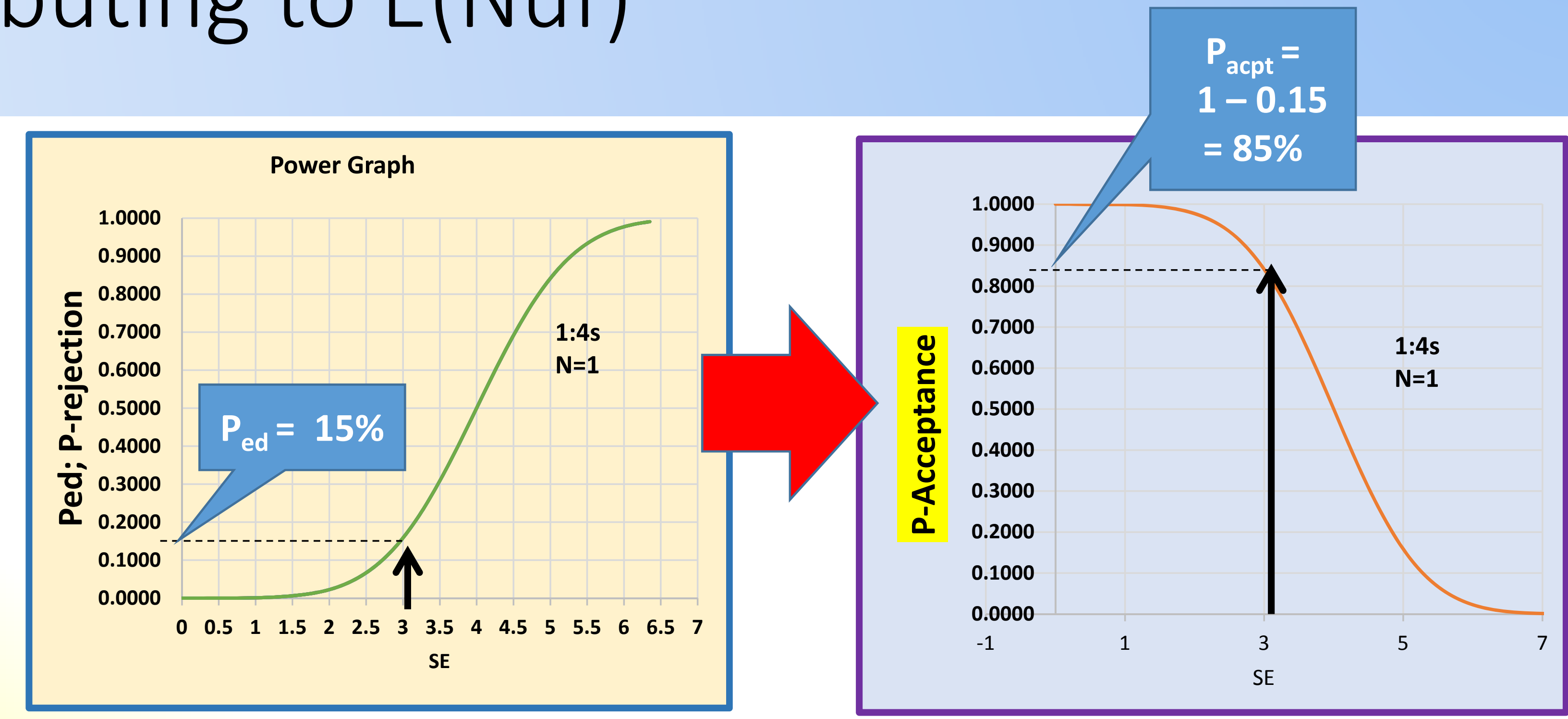


ARL_{ed}: Average Run Length

P_{ed}: Probability of Error Detection

Factors contributing to E(Nuf)

- ΔP_E
- ARL_{ed}



$P_{Accept} = 1 - P_{ed}$

ARL_{ed}: Average Run Length

P_{ed}: Probability of Error Detection

Factors contributing to E(Nuf)

- ΔP_E
- ARL_{ed}
- Run Length; M

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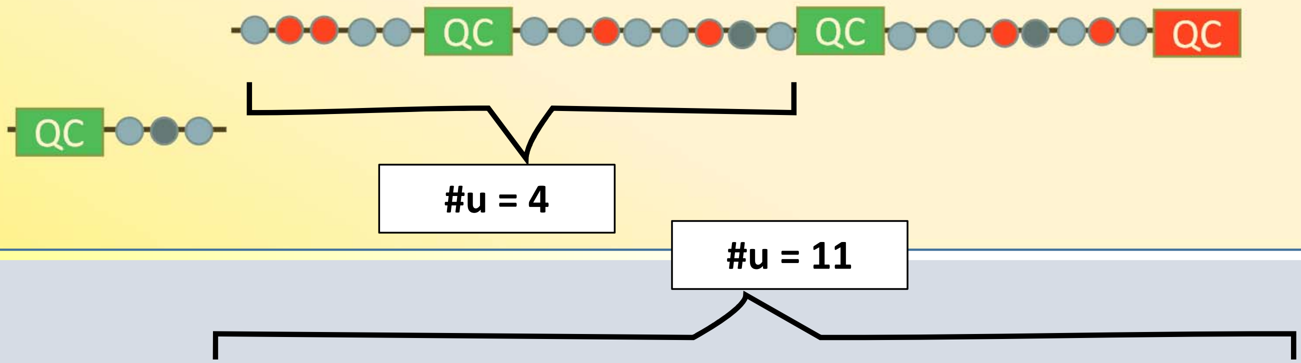
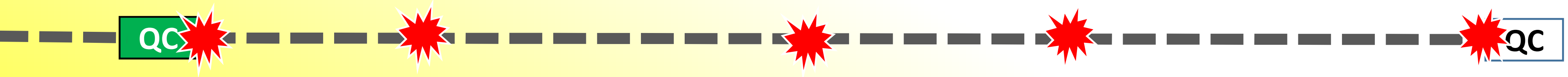


Factors contributing to E(Nuf)

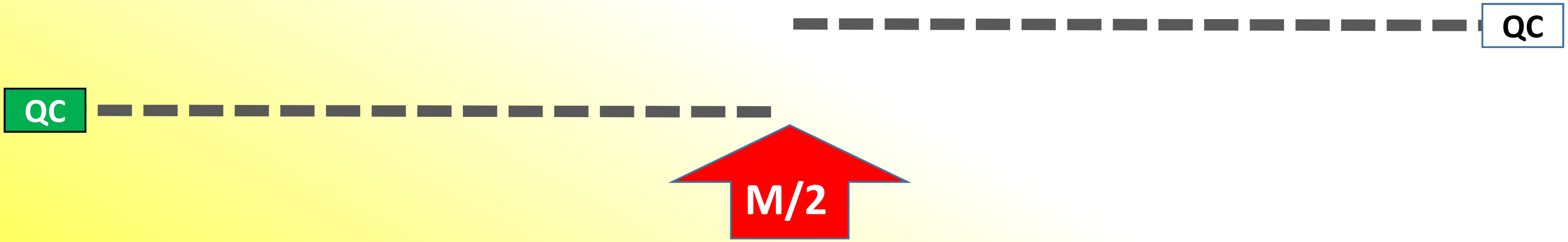
- ΔP_E
- ARL_{ed}
- Run Length; M
- Shift point

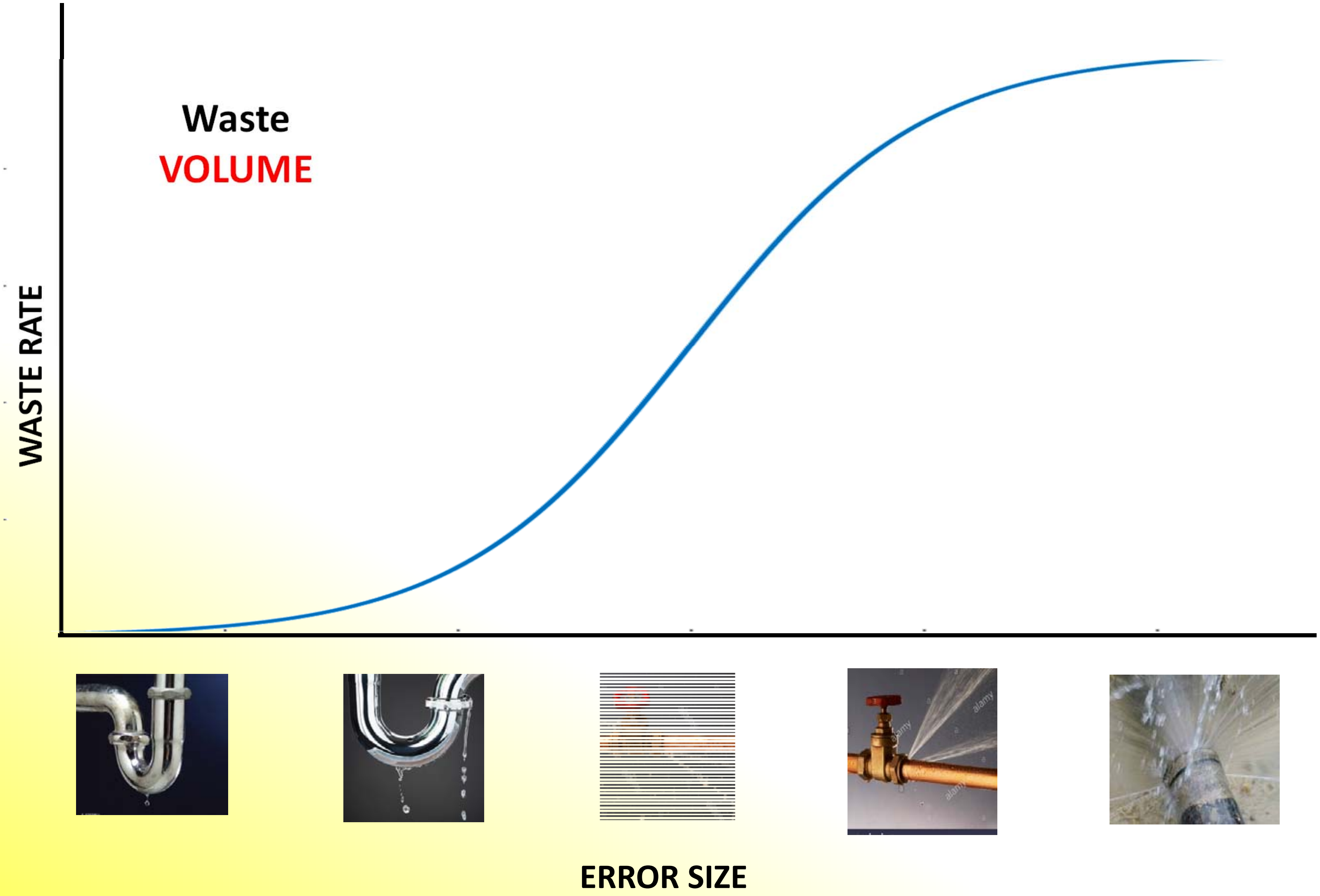


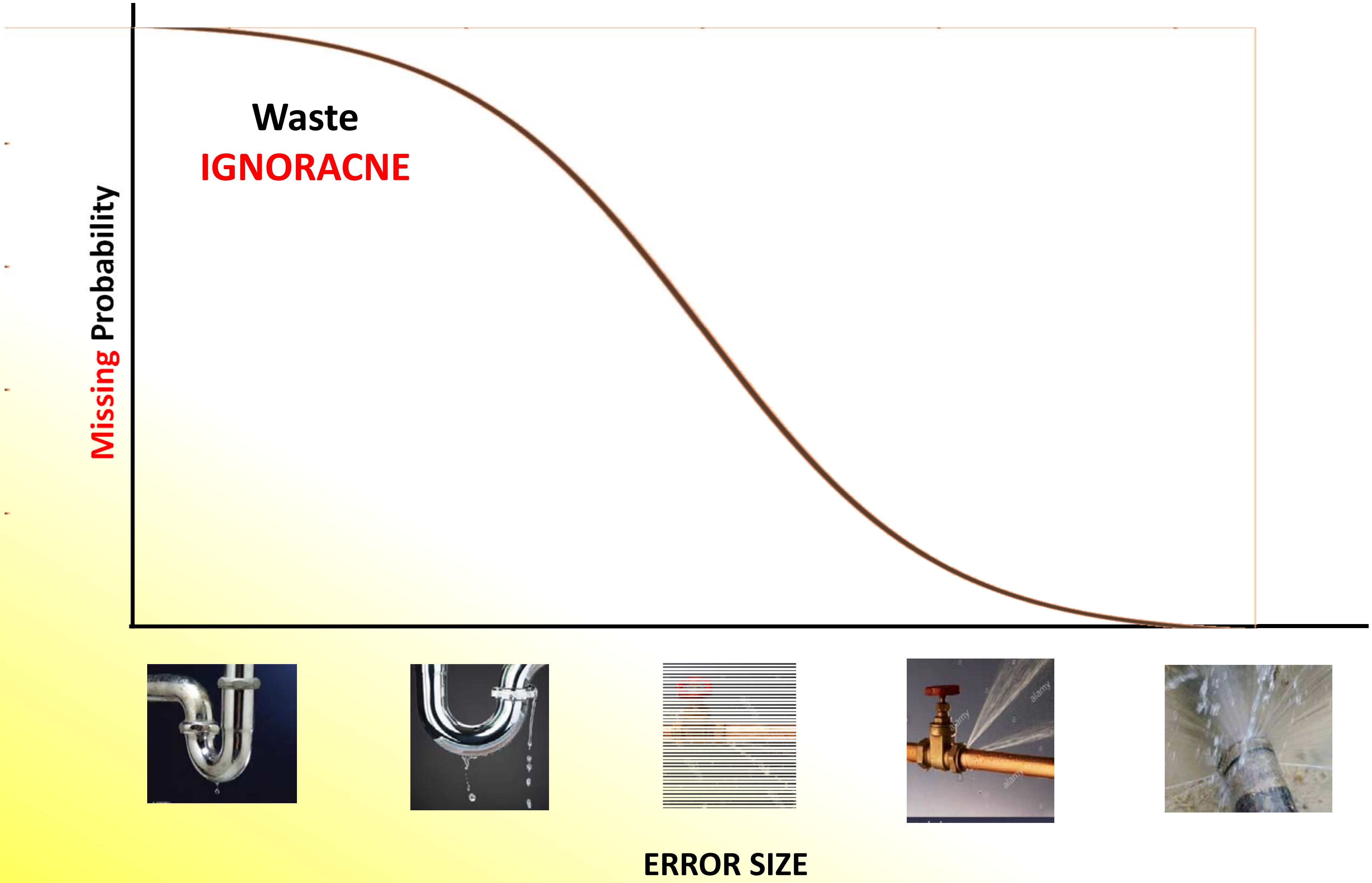
Factors contributing to E(Nuf)

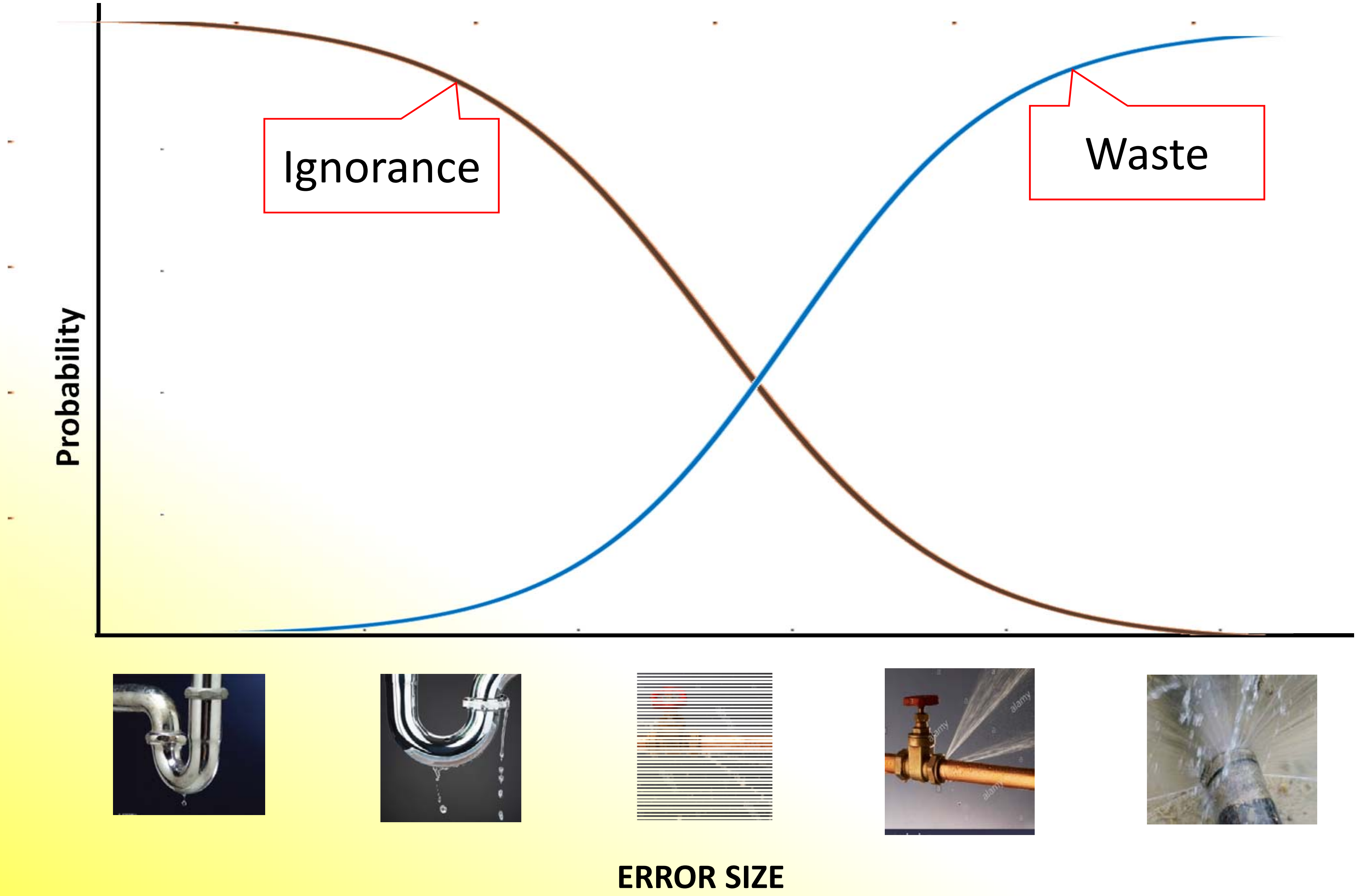
- ΔP_E
- ARL_{ed}
- Run Length; M
- Shift point

$$E(N_{uf}) = \Delta P_E[M(ARL_{ed} - 1) - (1 - 1/ARL_{ed})(M/2)]$$




Waste
VOLUME
WASTE RATE
ERROR SIZE


Waste
IGNORACNE
Missing Probability
ERROR SIZE



Ignorance
Waste
Probability
ERROR SIZE

Example:

Sigma = 5 QC: 1:3s, N = 1, M = 200

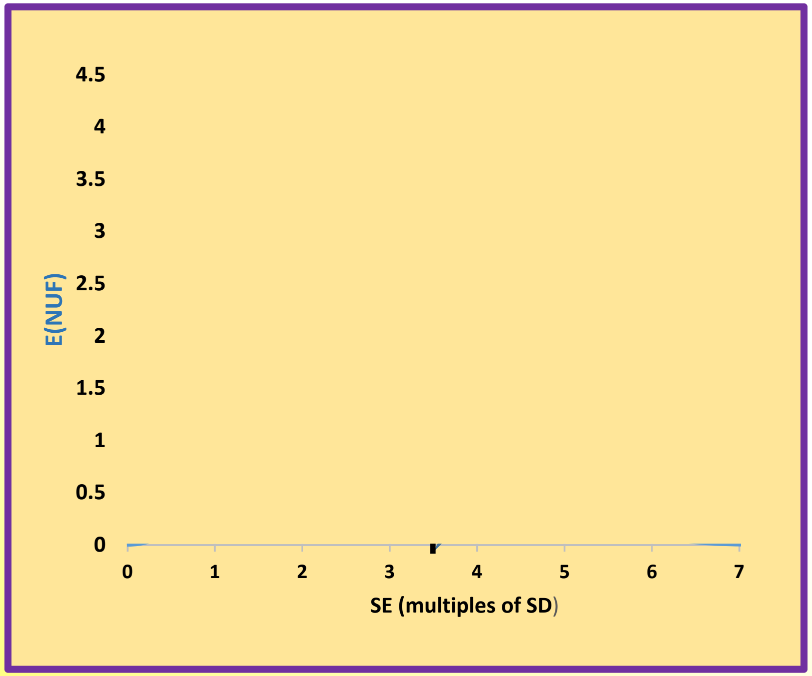
$P_{E\text{-}Stable} = 0.00006\%$

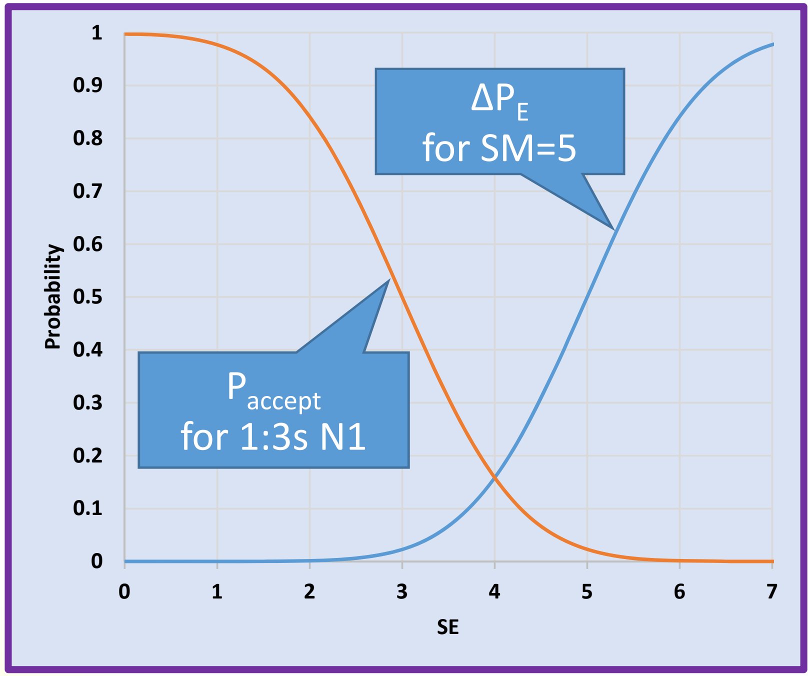
Example:

Sigma = 5 **QC: 1:3s, N = 1, M = 200**

SE (x SD)	ΔP_E	ARL_{ed}	MaxE(Nuf)
3.5	6.77%	1.4	3.9

Max Patient Risk





Smaller MaxE(Nuf) or Lower Patient RISK ?

- **Smaller Run Size**
- **Smaller ARL_{ed} (Tougher QC)**

ISO 15189: QC frequency should be "based on…the risk of harm to the patient from an erroneous result"

QC	Run Size	MaxE(Nuf)
1:3s, N1	200	3.9

(2/3.9) x 200 = 102

Caveat!

Stable error rate shouldn't be neglected!

Example:

Utilization of Assay Performance Characteristics to Estimate Hemoglobin A1c Result Reliability

Woodworth et al. Clin Chem (2014) http://hwmaint.clinchem.org/cgi/doi/10.1373/clinchem.2013.220772

Sigmas (TEa=6%):	**3.9**	**2.84**	**2.36**	**2.29**	**1.57**	**1.43**	**0.36**
Stable Error rate:	**0.001%**	**0.5 %**	**1.8 %**	**2.2%**	**11%**	**15%**	**72%**

QC: 1:2s, 3 levels, 3 time/day

Run-size≈33 ***P_{fr} = 14% (30% per day!)***

Via Making QC More Demanding, We Can't Get More from a Weak Method!

It's important to note that QC plans - at best - can help when performance is stable. The more robust the QC strategy, the more its ability to keep performance stable. In no way can a QC strategy, regardless of how stringent it is, compensate for the bad quality of a method. For example, if we purchase a 0.85 sigma method, this means that if there is no shift in the calibration and/or no increase of imprecision at all, this method in its most stable performance produces 40% erroneous results. If there was

Hassan Bayat, CLS, Sina Lab (Qaemshahr)
January 2015

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CLSI C24-Ed4 (2016)

5.4.2.

Quality Control Performance Goals Cannot Alter Measurement Performance

Tools for applying MaxE(Nuf) model

Acceptable MaxE(Nuf) or *Patient Risk Factor*

Depends on:

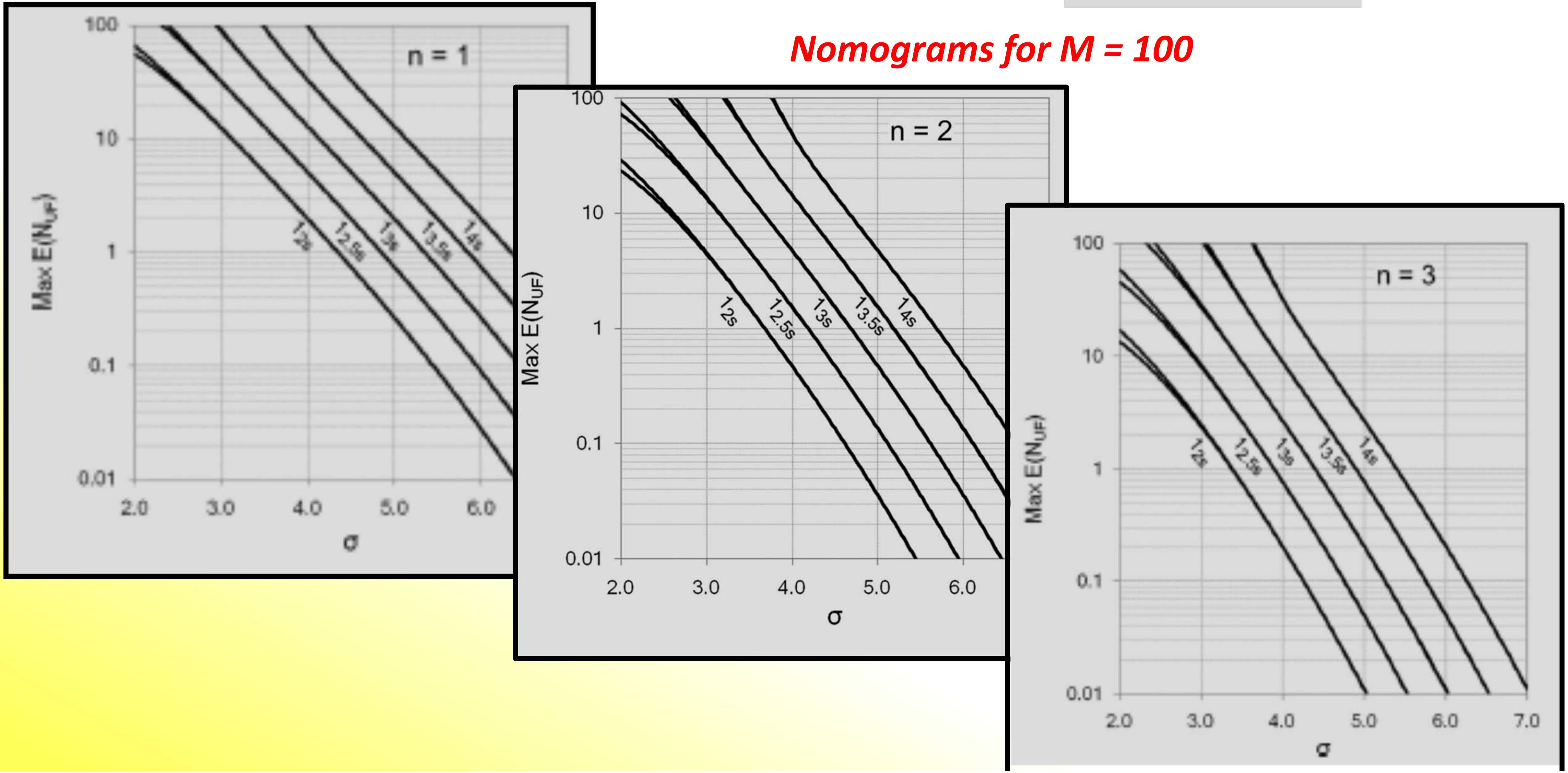
- **Probability of acting upon an erroneous result**
- **Probability of hazard to patient from an erroneous result**
- **The stability of the system**
- **SM**

- **NOTE:** CLSI C24-Ed4 (2016) is "only a road-map."

Selecting Statistical Procedures for Quality Control Planning Based on Risk Management

Yago M, Alcover S.
Clin Chem62:7; 2016

Nomograms for M = 100



Hassan Bayat*

Selecting multi-rule quality control procedures based on patient risk

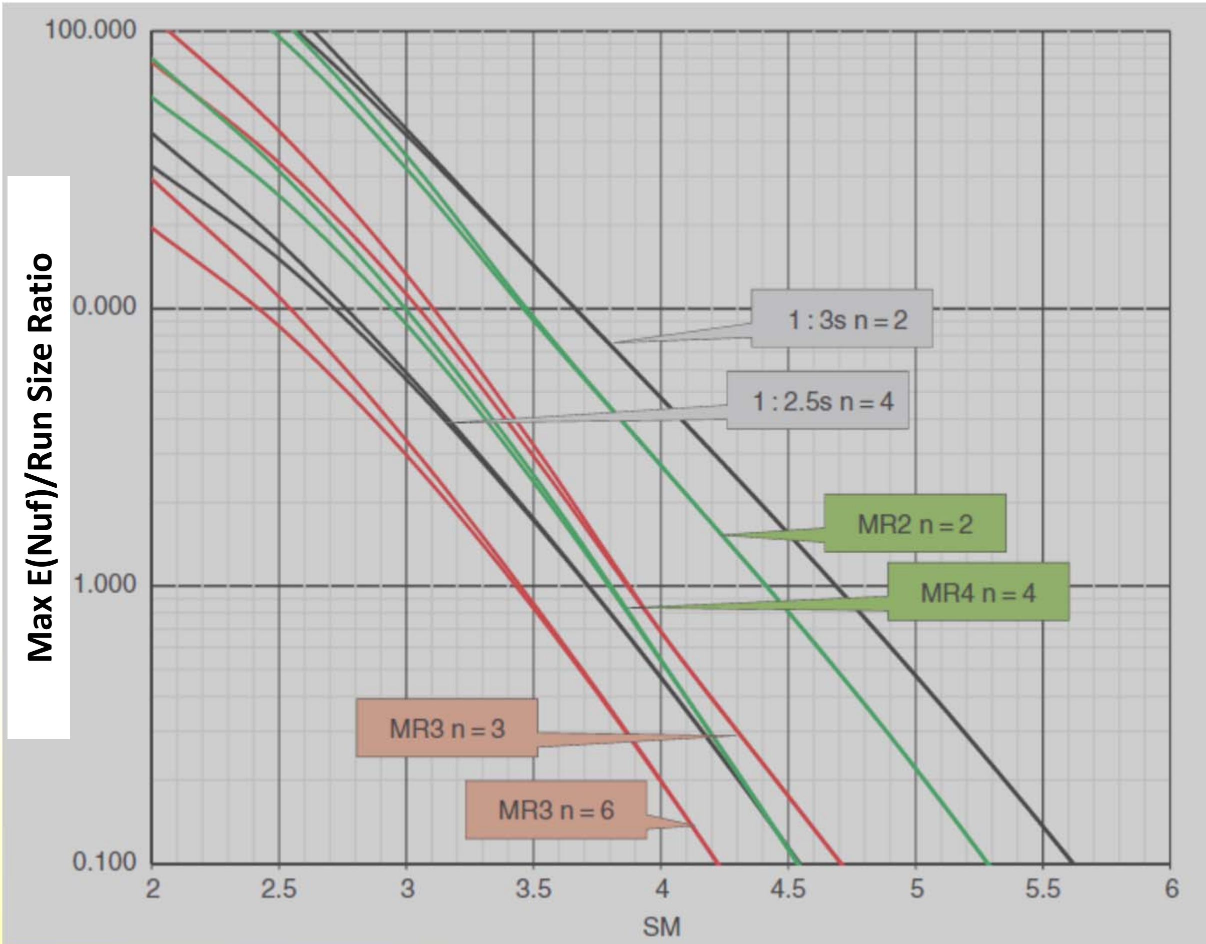
CCLM; 55(11), 2017

MR3 N3: $1_{3s}/2of3_{2s}/R_{4s}/3_{1s}$

MR3 N6: $1_{3s}/2of3_{2s}/R_{4s}/3_{1s}/6x$

MR2 N2: $1_{3s}/2_{2s}/R_{4s}$

MR4 N4: $1_{3s}/2_{2s}/R_{4s}/4_{1s}$



Planning Risk-B
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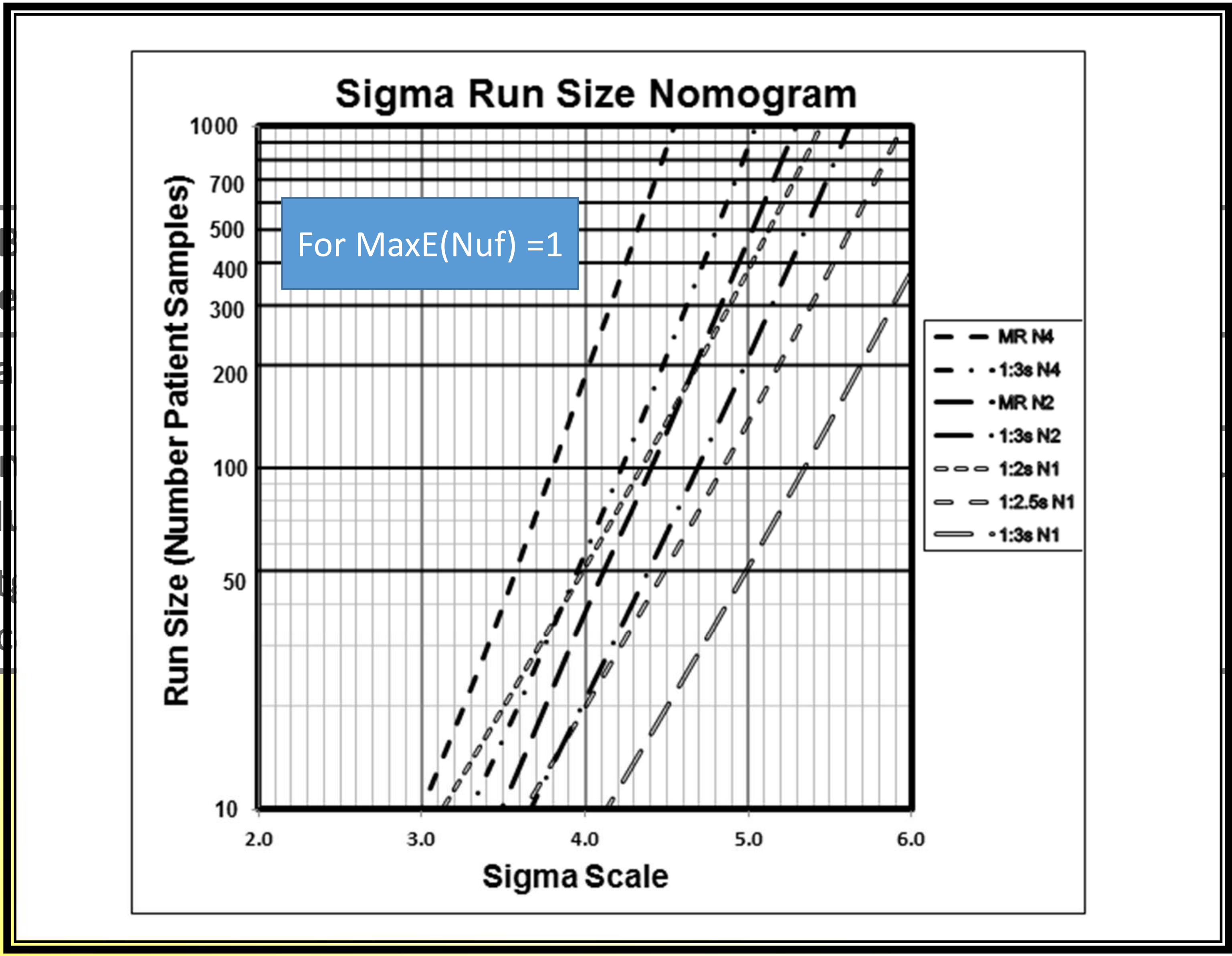
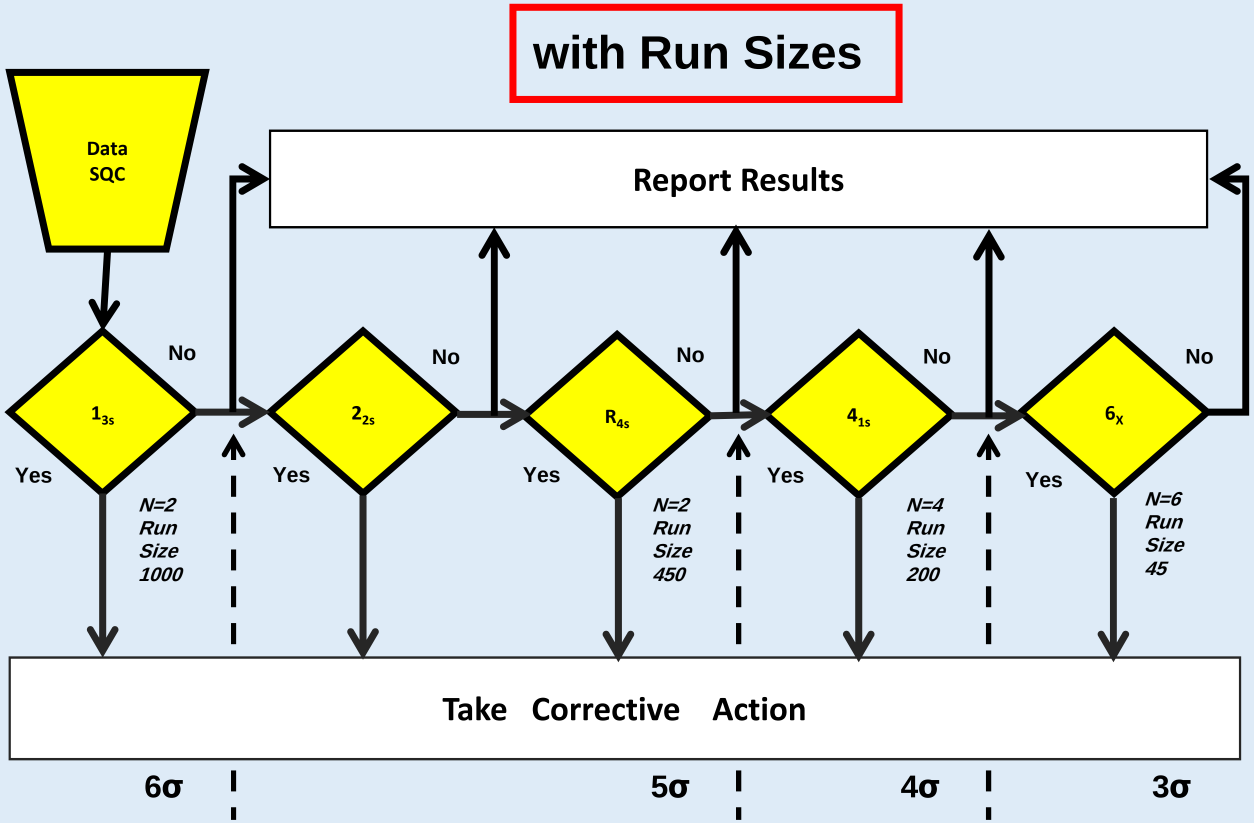


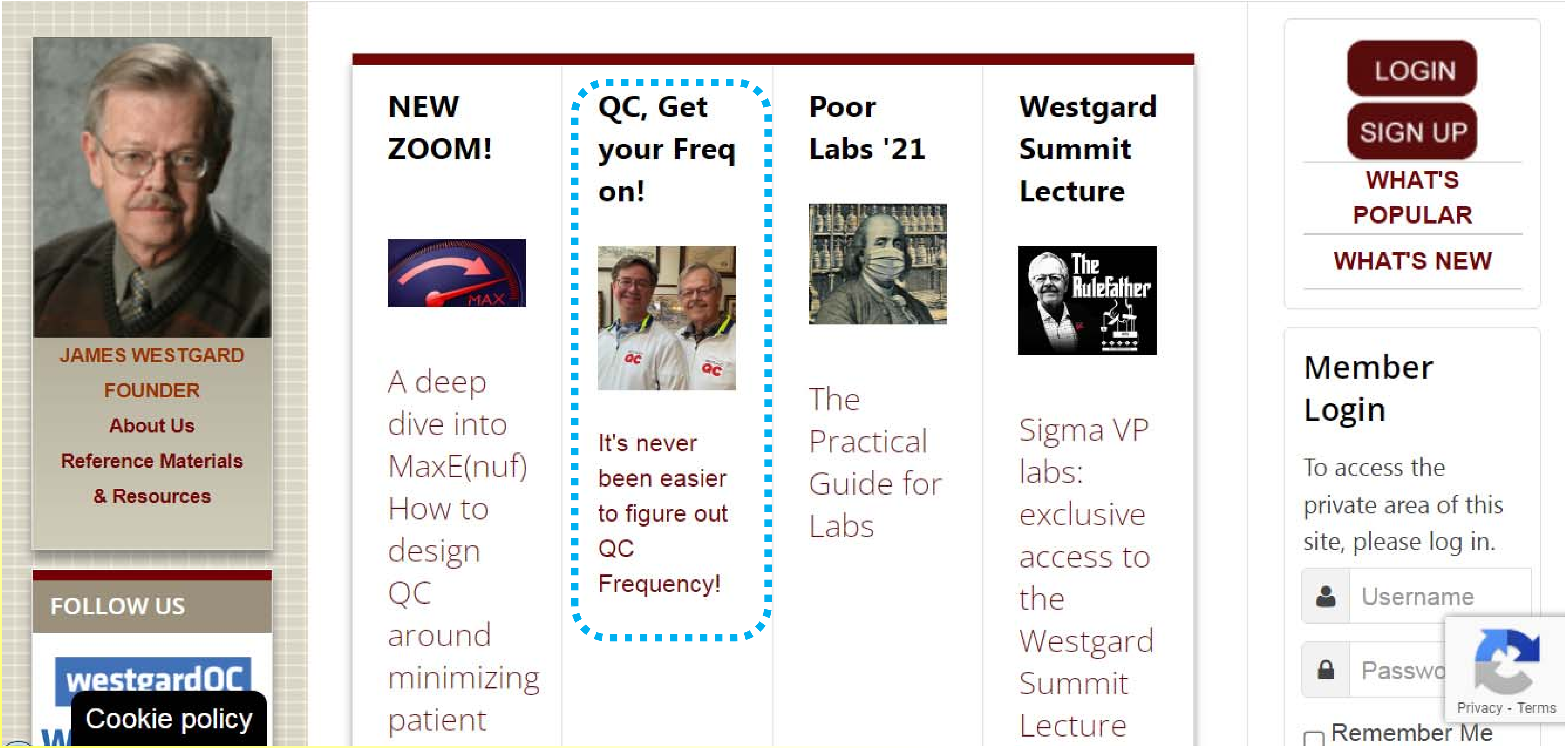
Establishing Evidence-Based Statistical Quality Control Practice

Westgard JO, Westgard SA

Am J Cling Pathol 2018

Westgard Sigma Rules®





https://www.westgard.com/qc-frequency-calculator.htm

QC Frequency Calculator (Run Size)

A new online tool to help you determine your QC Frequency (Run Size)

Online Calculator for QC Frequency or Run Size

James O. Westgard, Hassan Bayat, Paul Schilling, and Sten A. Westgard

July 2021

The CLSI C24-Ed4 document [1] describes a "roadmap" for planning a risk-based SQC strategy, which is defined as the *"number of QC materials to measure, the number of QC results and the QC rule to use at each QC event, and the frequency of QC events."* A QC event is defined as *"the occurrence of one or more QC

QC Frequency Calculator

Number of Levels/Tests:	4			
Analyst				
Date	mm / dd / yyyy			
Analyzer				
Test				
Units				
Critical Decision Level, Xc	0.00	0.00	0.00	0.00
Quality Requirement, TEa	0.00	0.00	0.00	0.00
Bias observed	0.00	0.00	0.00	0.00
Precision observed	0.00	0.00	0.00	0.00
Calculated Sigma-metric	0.00	0.00	0.00	0.00
Patient Risk Sigma	0.00	0.00	0.00	0.00
Patient Risk Factor	1	1	1	1
Maximum Run Size	1000	1000	1000	1000

Calculate Results

Clear Form

Candidate SQC Procedures	Run Size 1	Run Size 2	Run Size 3	Run Size 4
1:3s/2:2s/R:4s/4:1s, N=4 (P_{fr}=0.03)				
1:3s, N=4 (P_{fr}=0.01)				
1:3s/2of3:2s/R:4s/3:1s N=3 (P_{fr}=0.02)				
1:3s N=3 (P_{fr}=0.01)				
1:3s/2:2s/R:4s, N=2 (P_{fr}=0.01)				
1:3s, N=2 (P_{fr}=0.00)				
1:3.5s, N=2 (P_{fr}=0.00)				
1:2s, N=1 (P_{fr}=0.05)				
1:2.5s, N=1 (P_{fr}=0.01)				
1:3s, N=1 (P_{fr}=0.00)				

Number of Levels/Tests:	2	
Analyst		
Date	mm / dd / yyyy	
Analyzer		
Test	A1c	A1c
Units	%Hb	%Hb
Critical Decision Level, Xc	6	9
Quality Requirement, TEa	6	6
Bias observed	0	0
Precision observed	1.1	1.4
Calculated Sigma-metric	5.45	4.29
Patient Risk Sigma	5.45	4.29
Patient Risk Factor	1	1

Candidate SQC Procedures	Run Size 1	Run Size 2
1:3s/2:2s/R:4s/4:1s, N=4 (P_{fr}=0.03)	1000	481
1:3s, N=4 (P_{fr}=0.01)	1000	137
1:3s/2of3:2s/R:4s/3:1s N=3 (P_{fr}=0.02)	1000	310
1:3s N=3 (P_{fr}=0.01)	1000	84
1:3s/2:2s/R:4s, N=2 (P_{fr}=0.01)	1000	77
1:3s, N=2 (P_{fr}=0.00)	795	54
1:3.5s, N=2 (P_{fr}=0.00)	193	13
1:2s, N=1 (P_{fr}=0.05)	987	102
1:2.5s, N=1 (P_{fr}=0.01)	352	36

Sigma: 5.45
Patient Risk: 1

Sigma: 4.29
Patient Risk: 1

Candidate SQC Procedures	Run Size 1	Run Size 2
1:3s/2:2s/R:4s/4:1s, N=4 (P_{fr}=0.03)	1000	1924
1:3s, N=4 (P_{fr}=0.01)	1000	547
1:3s/2of3:2s/R:4s/3:1s N=3 (P_{fr}=0.02)	1000	1241
1:3s N=3 (P_{fr}=0.01)	1000	335
1:3s/2:2s/R:4s, N=2 (P_{fr}=0.01)	1000	306
1:3s, N=2 (P_{fr}=0.00)	795	218
1:3.5s, N=2 (P_{fr}=0.00)	193	52
1:2s, N=1 (P_{fr}=0.05)	987	407
1:2.5s, N=1 (P_{fr}=0.01)	352	146
1:3s, N=1 (P_{fr}=0.00)	127	53

Sigma: 5.45
Patient Risk: 1

Sigma: 4.29
Patient Risk: 4

Analyst	
Date	mm/dd/yyyy
Analyzer	
Test	T4
Units	
Critical Decision Level, Xc	8
Quality Requirement, TEa	20
Bias observed	0.00
Precision observed	4.5
Calculated Sigma-metric	4.44
Patient Risk Sigma	4.44
Patient Risk Factor	1
Maximum Run Size	1000

Candidate SQC Procedures	Run Size 1
1:3s/2:2s/R:4s/4:1s, N=4 (P_{fr}=0.03)	790
1:3s, N=4 (P_{fr}=0.01)	212
1:3s/2of3:2s/R:4s/3:1s N=3 (P_{fr}=0.02)	491
1:3s N=3 (P_{fr}=0.01)	127
1:3s/2:2s/R:4s, N=2 (P_{fr}=0.01)	114
1:3s, N=2 (P_{fr}=0.00)	58
1:3.5s, N=2 (P_{fr}=0.00)	19
1:2s, N=1 (P_{fr}=0.05)	139
1:2.5s, N=1 (P_{fr}=0.01)	50
1:3s, N=1 (P_{fr}=0.00)	18

Candidate SQC Procedures	Run Size 1
1:3s/2:2s/R:4s/4:1s, N=4 (P_{fr}=0.03)	790
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1:3s, N=1 (P_{fr}=0.00)	18

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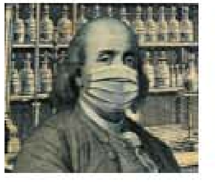
A deep dive into MaxE(nuf) How to design QC around minimizing patient

QC, Get your Freq on!

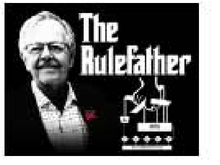
It's never been easier to figure out QC Frequency!

Poor Labs '21



The Practical Guide for Labs

Westgard Summit Lecture



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