Sigma Metric
in Analytical Laboratory Performance

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Objectives

- Review of Normal distribution
- Concept of Sigma Metric
- Characteristics of Sigma Metric
- Applying Sigma Metric
- Short-term/Long-term issue in medical laboratory

Background

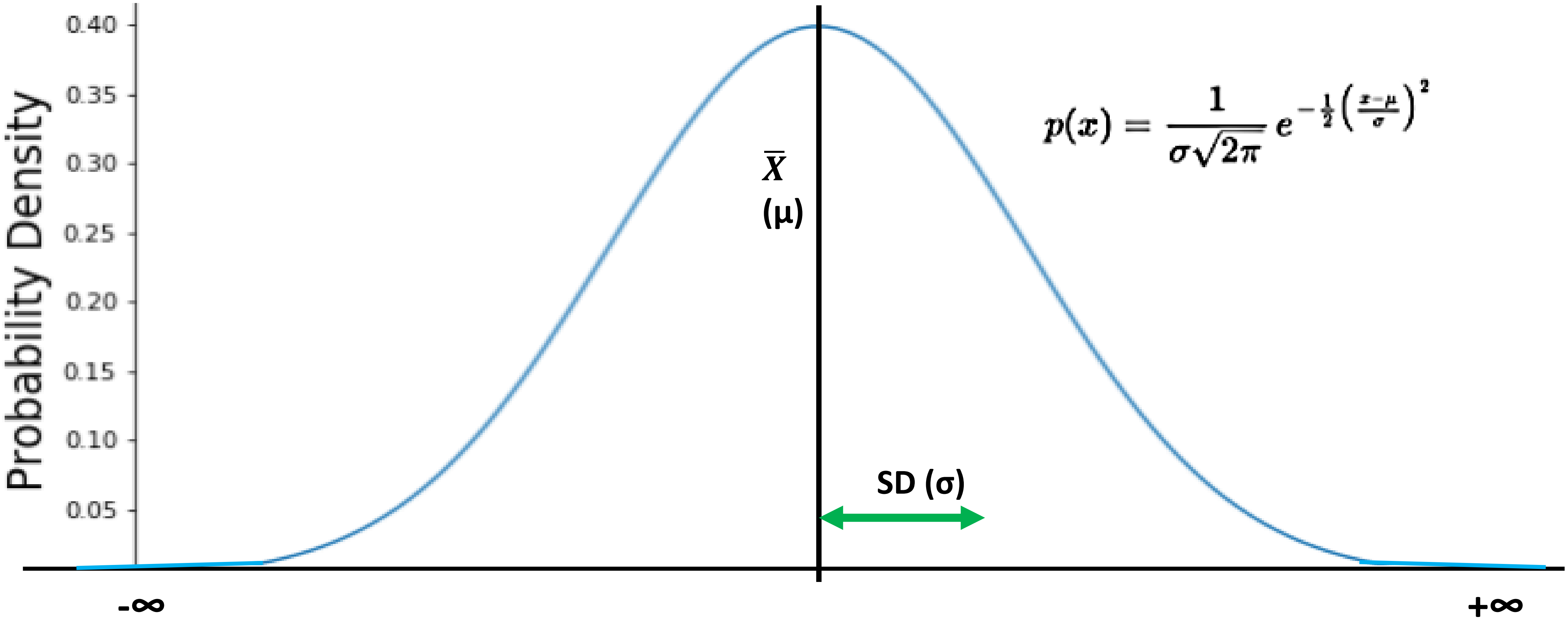
Six Sigma management technology:

- Developed by Motorola in the 1980s
- To systematically improve processes and eliminate defects
- Requiring to fall within plus or minus six sigma from the process mean

Sigma Metric:

- Core concept in Six Sigma Methodology
- Defect Rate; DPM or DPMO
- Based on Gaussian (Normal) distribution

Gaussian Distribution



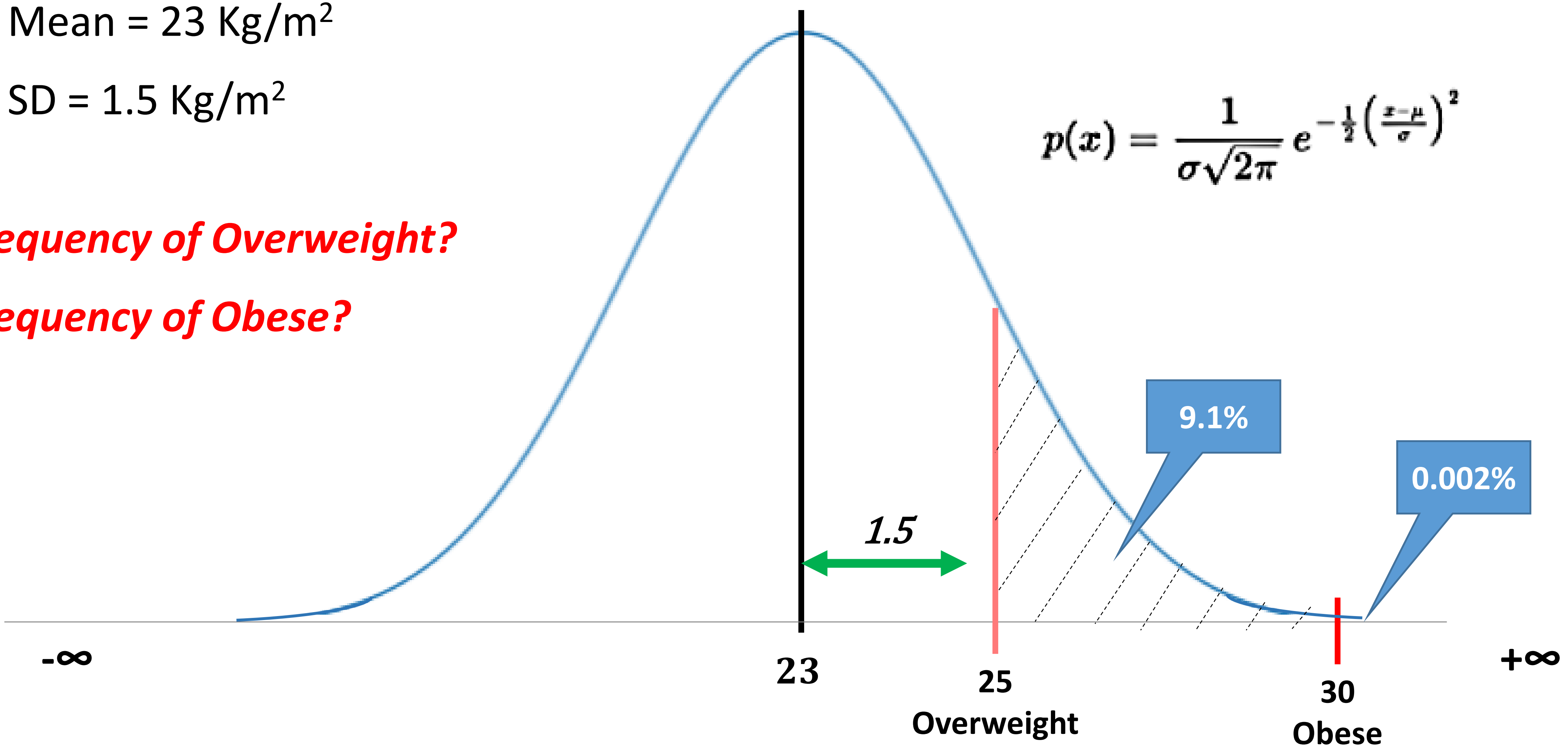
Example

Body Mass Index

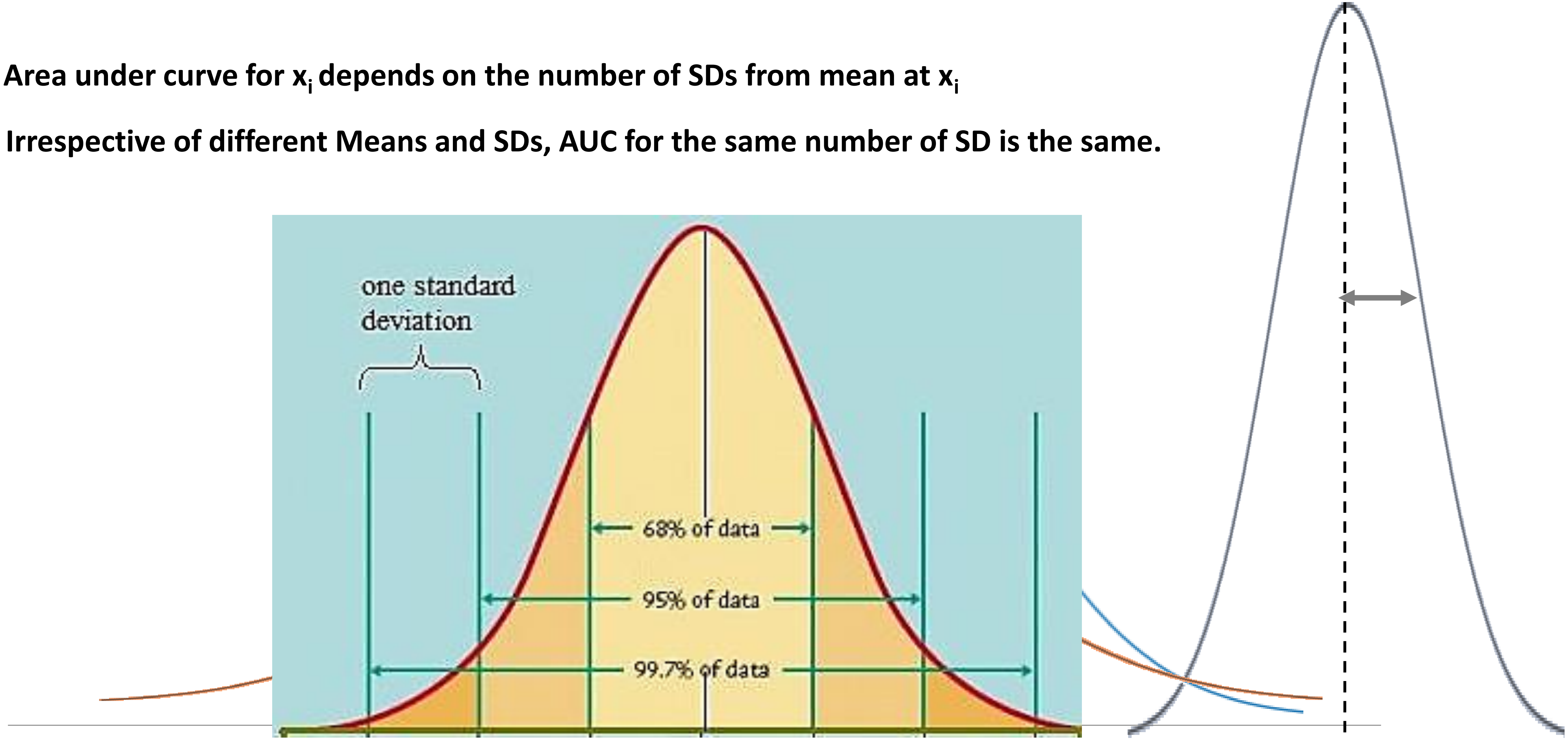
- Mean = 23 Kg/m^2
- SD = 1.5 Kg/m^2

Frequency of Overweight?

Frequency of Obese?

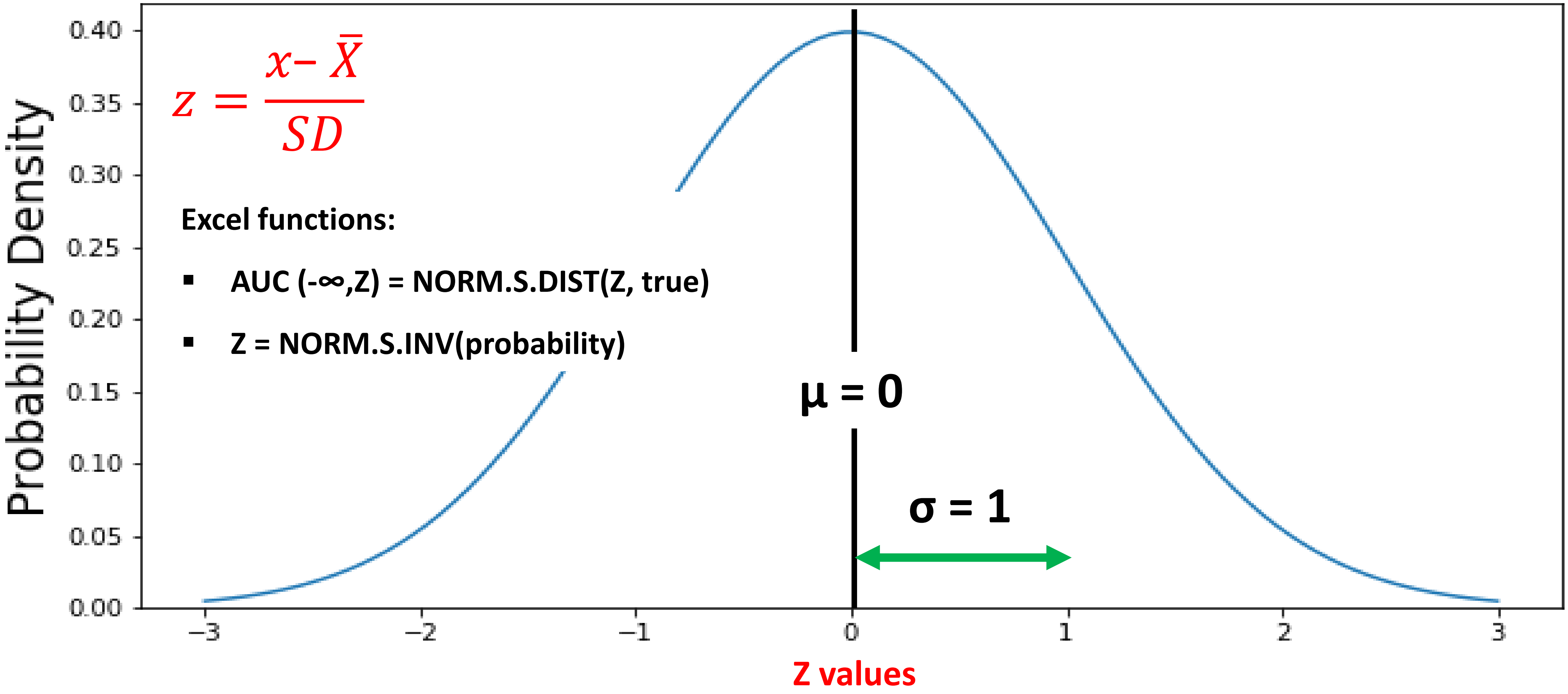


- Area under curve for x_i depends on the number of SDs from mean at x_i
- Irrespective of different Means and SDs, AUC for the same number of SD is the same.



Standard Gaussian Distribution

Z value: **The position of a variable in terms of its distance from the mean when measured in stanDEVard deviation units.**



Example

Steel rod lengths

Mean = 108 cm

SD = 3 cm

Frequency of rods >115?

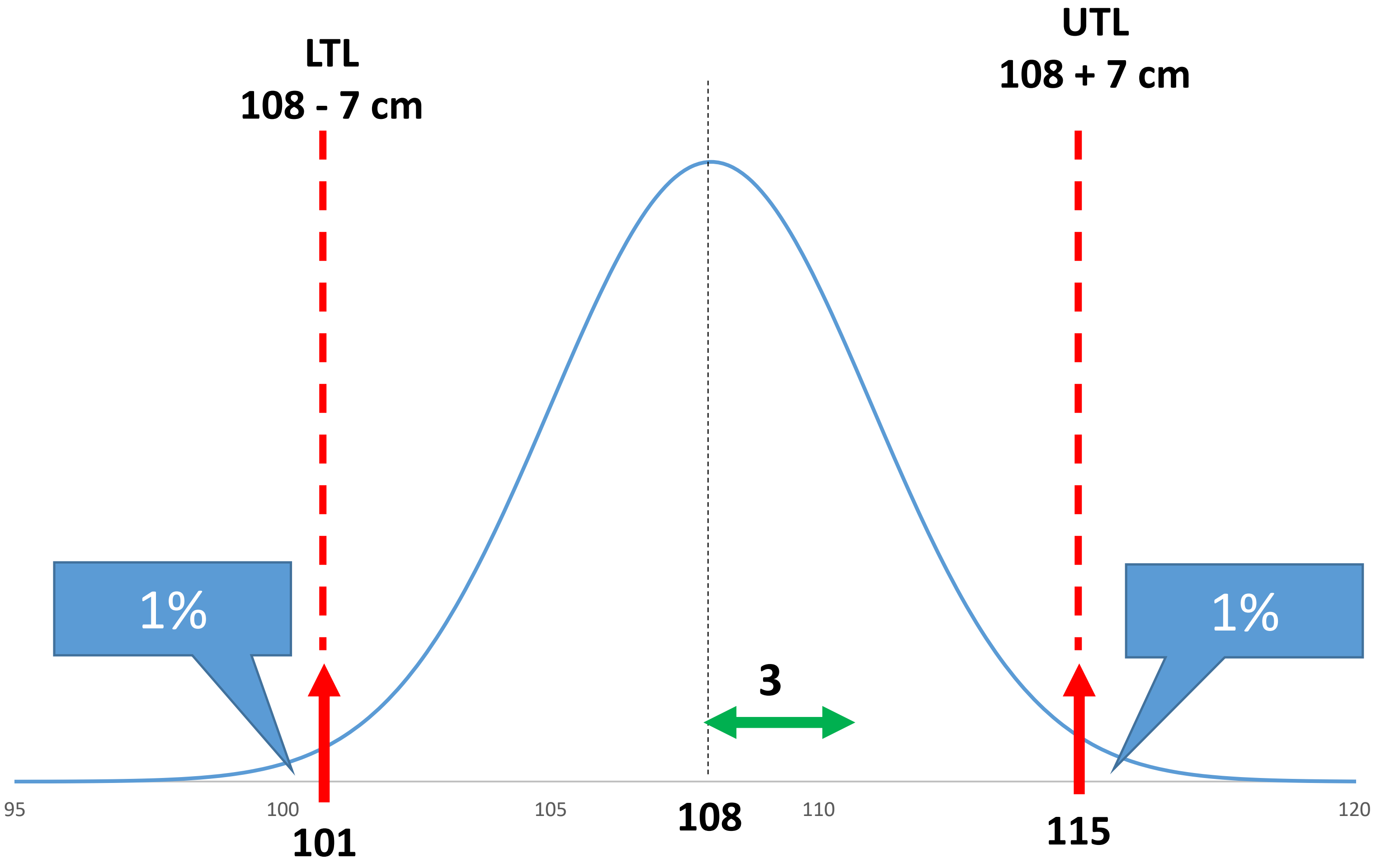
Z = (115-108)/3 = 2.3

AUC (-∞,115) = 0.99 (99%)

Tail = 1 – 0.99 = 0.01 (1%)

P(101<x<115) = 2%

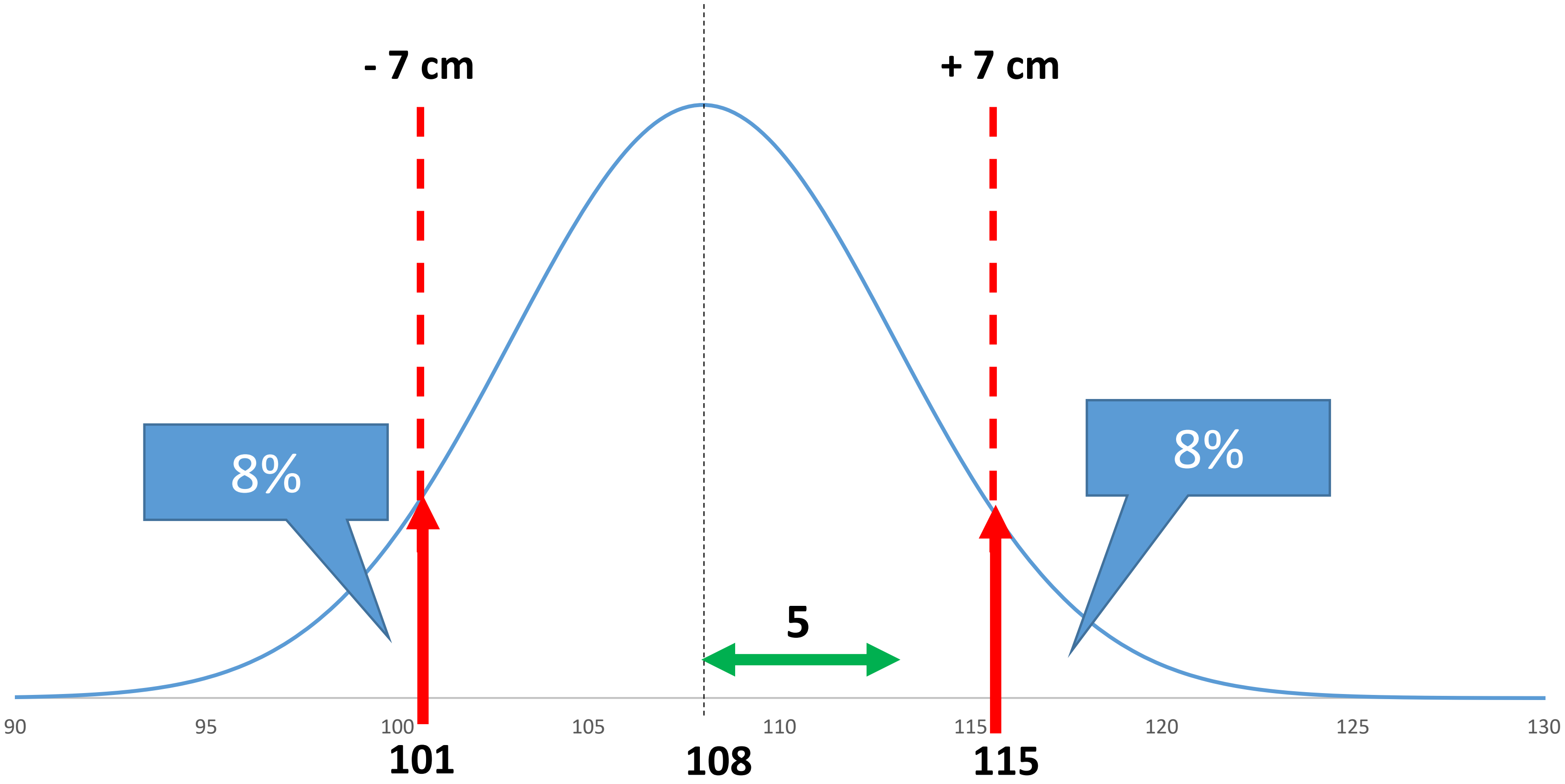
Unacceptable Products



Example

Mean = 108 cm

SD = 5 cm



Z = (116-108)/5 = 1.4

Unacceptable parts = 16%

Sigma Metric

What?

Why?

Where?

Analytical Performance

What & Why of SM?

Main aspects of laboratory analytical practice, i.e.

- Performance Specifications, — **Define Quality; DRa**
- Method Evaluation, and — **Measure Quality; Lab DR?**
- Quality Management, — **QC; Keep Lab DR<DRa**

- ➢ are about Defect Rate, and
- ➢ SM is a measure of Defect Rate

Where SM?

SM is a useful tool:

- Assess the analytical quality of assays; Method Evaluation,
- Planning quality control strategies (IQC),
- Describe assay analytical performance in EQA
- Improve performance

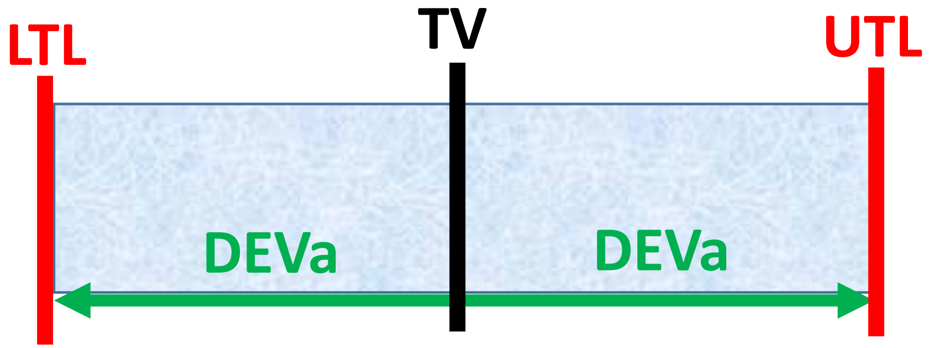
Sigma Metric

What? **A measure of Defects**

Why? **Defect rate is an indicator of Reliability**

Where? **In the all aspects of analytical performance**

SPECIFICATION in Six Sigma



❖ **Target Value; TV**

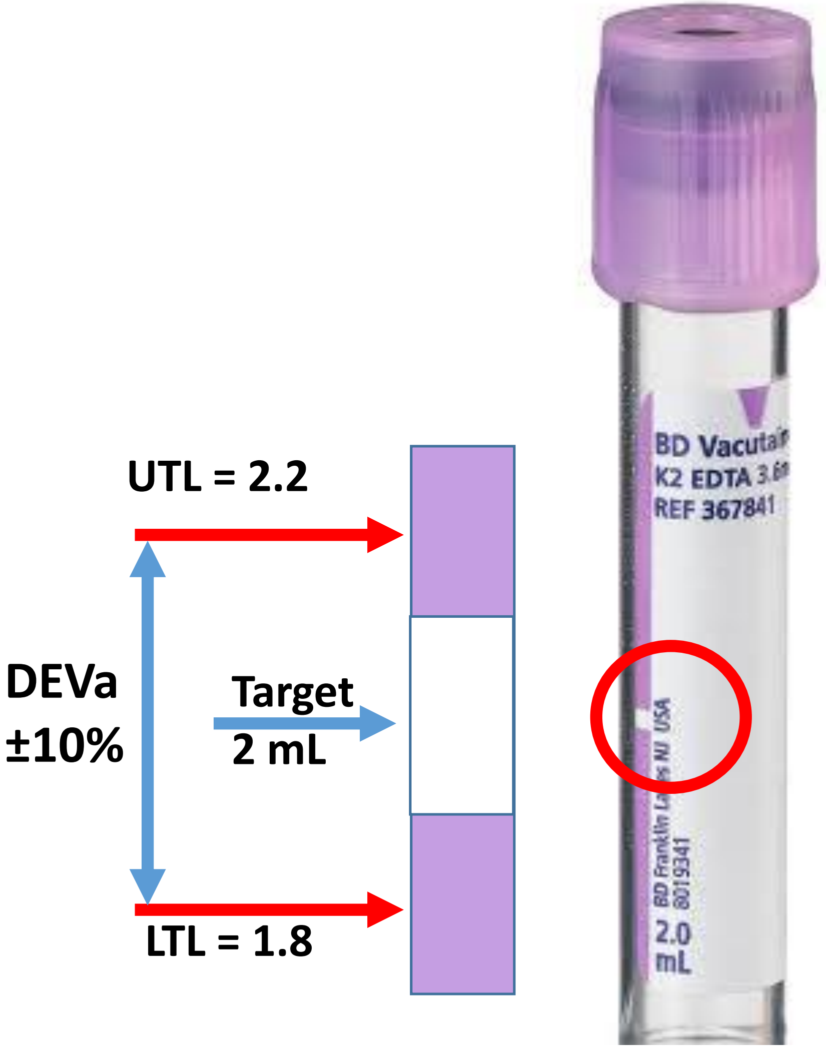
1. **Allowable Deviation; DEVa:**
   How much deviation from TV is acceptable?

   - Tolerance Limit, TL

   - Perfect/Defect

2. **Allowable Defect Rate; DRa:**
   How many defects are acceptable?

DEVa vs DRa



Acceptable Specimen

QI: < 2% Under/Overfilled

DRa = 2%

Acceptable Performance

DEVa vs DRa

1. **DEVa:** Acceptance criterion for a single product/occurrence/opportunity
2. **DRa:** Acceptance criterion for performance — ***Reliability***

Example

Performance Specification; Example from lab:

- TEa = 5 mmol/mol — ***DEVa; Acceptable result***
- At most 5% chance of erroneous result — ***DRa; Acceptable Performance***

Investigation of 2 Models to Set and evaluTEa Quality Targets for Hb A1c: Biological Variation and Sigma-Metrics.
IFCC WG-A1C: Weykamp et al. Clin Chem 61:5 (2015)

Example:

Order: Steel rods = 100 cm

- ❖ **TV = 100**

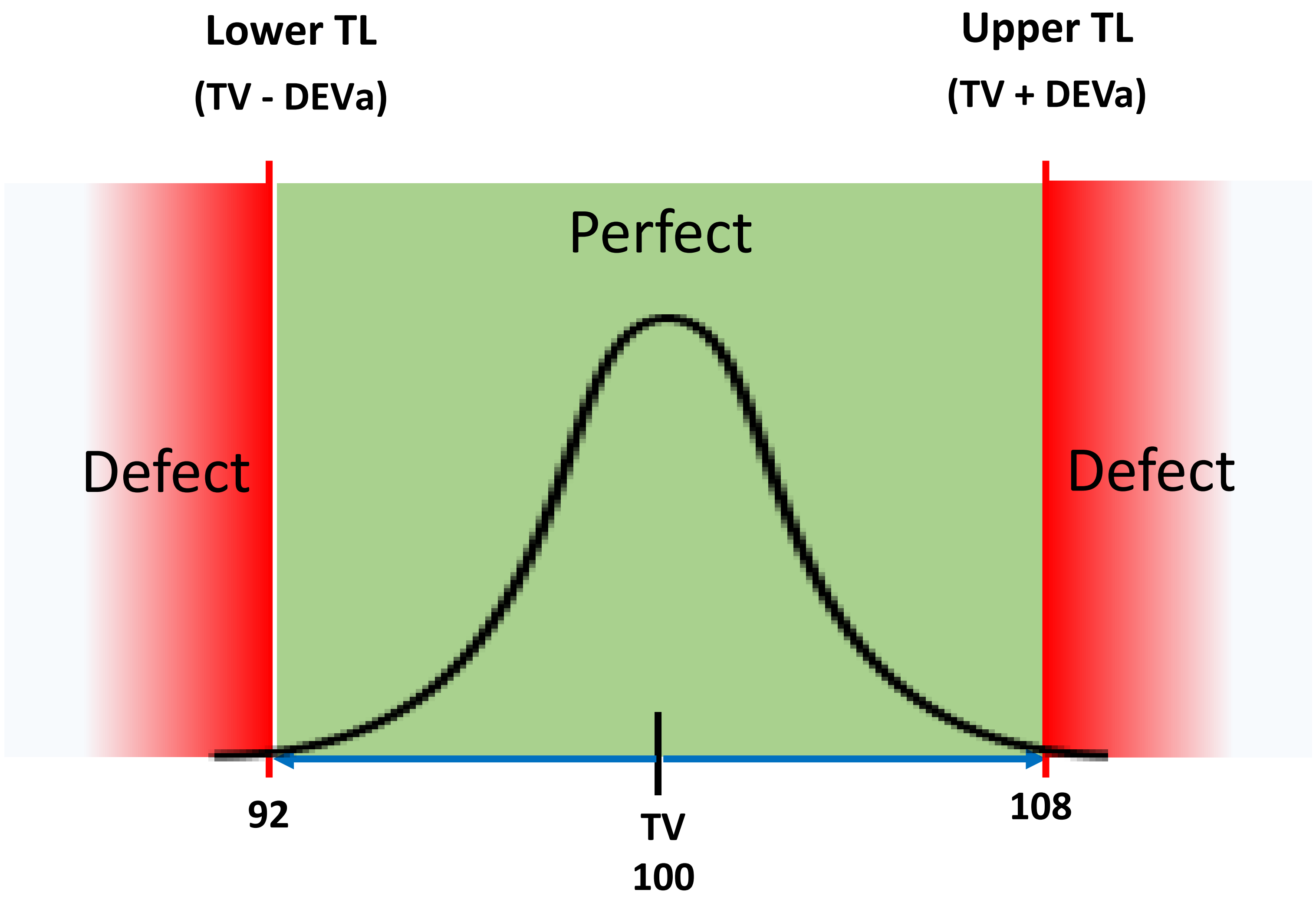
1. DEVa = 8%

TV ± DEVa = TLs

Perfect: 92 to 108

Defect: <92 or >108

2. DRa = 1%



❖ Performance EVALUATION

1. Determine Defect Rate

2. Is Defect Rate ≤ Allowable Defect Rate?

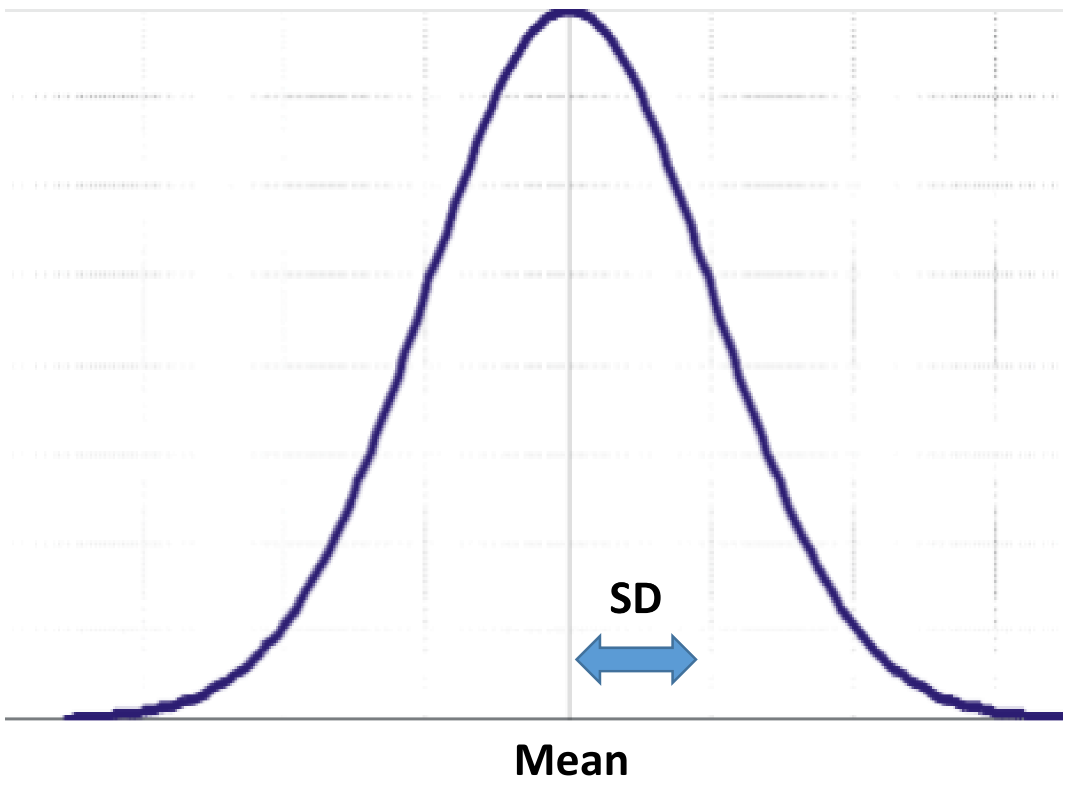
Counting Approach

Probabilistic (Distribution-Based) Approach

Counting methodology

Probabilistic Approach

- Sampling from products
- Mean?
- Centered?
- Imprecision?
- AUC at tails out of TLs?



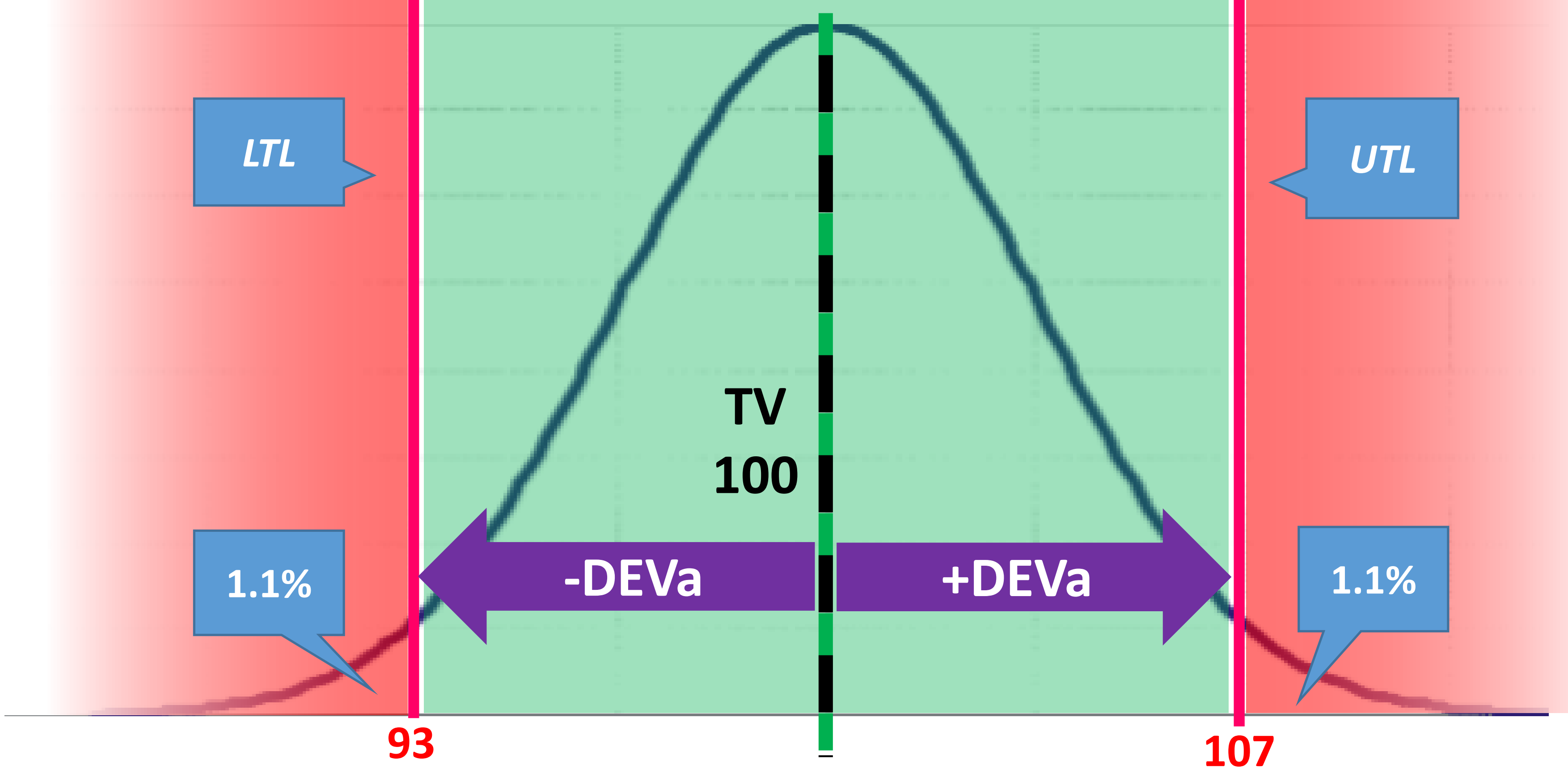
Example

Manufacturing metal balls

Target Dimeter = 100 mm

SPECIFICATION

- **DEVa = 7%**
- **DRa = 5%**



Z = LTL– Mean)/SD

Z = (93-100)/3 = -2.3

NORM.S.DIST(2.3, true) = 1.1%

Mean = 100
SD = 3

Z = UTL– Mean)/SD

Z = (107-100)/3 = +2.3

1-NORM.S.DIST(2.3, true) = 1.1%

EVALUATION

- **Mean = 100 mm**
- **SD = 3 mm**

Performance DR

DRa

Defect Rate = 2.2% < 5%

Calculation: Defect Rate?

Example

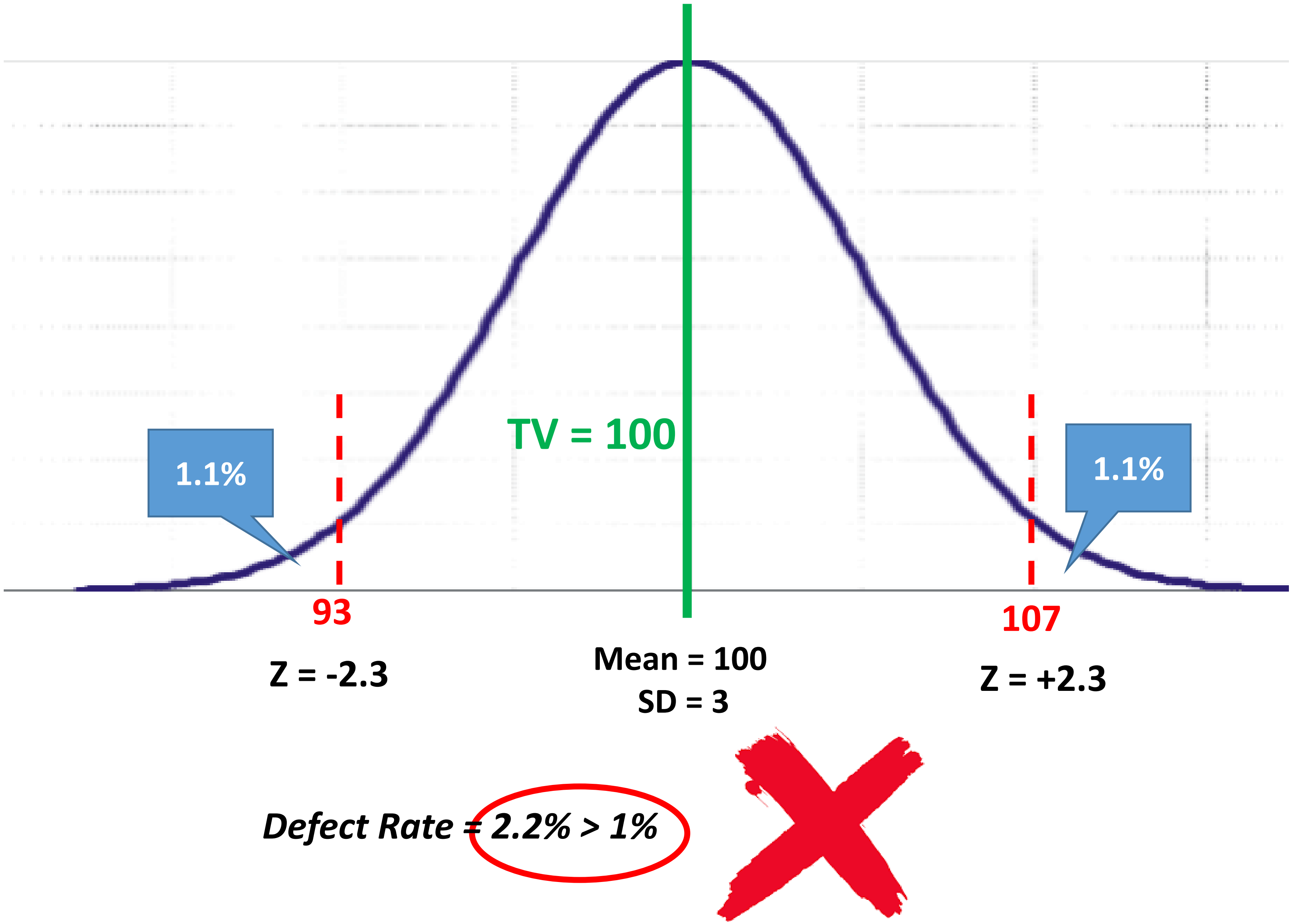
Manufacturing metal balls

Target Value = 100 mm

Mean = 100 mm

SD = 3 mm

- **DEVa = 7%**
- **DRa = 1%**



Example

Manufacturing metal balls

Target Value = 100 mm

Mean = 100 mm

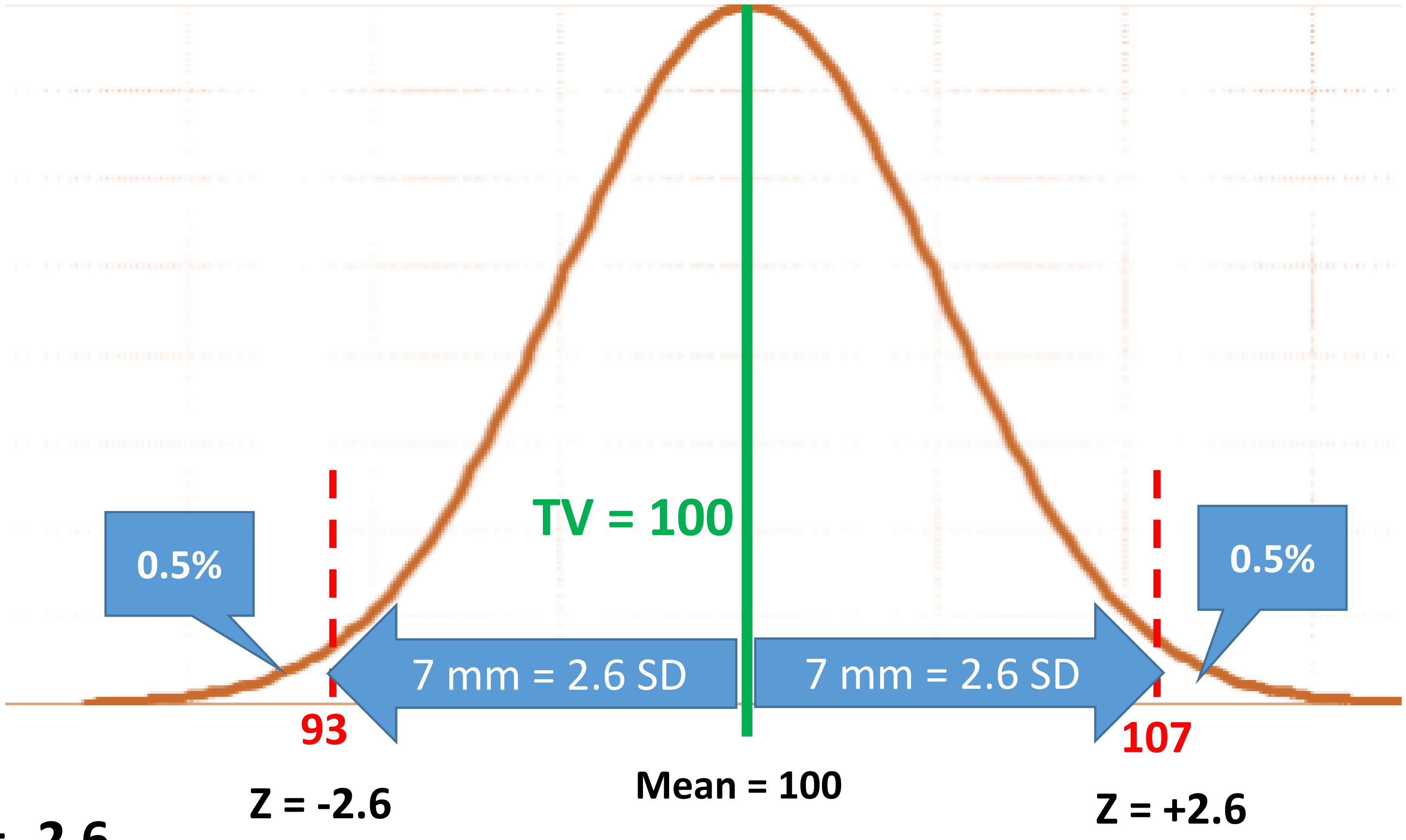
SD = ?

- **DEVa = 7%**
- **DRa = 1%**

Z@LTL = NORM.S.INV(0.005) = -2.6

Z@UTL = NORM.S.INV(1-0.005) = 2.6

$z = \frac{x - \overline{X}}{SD}$ → **SD = 7 mm/2.6 = 2.7 mm**



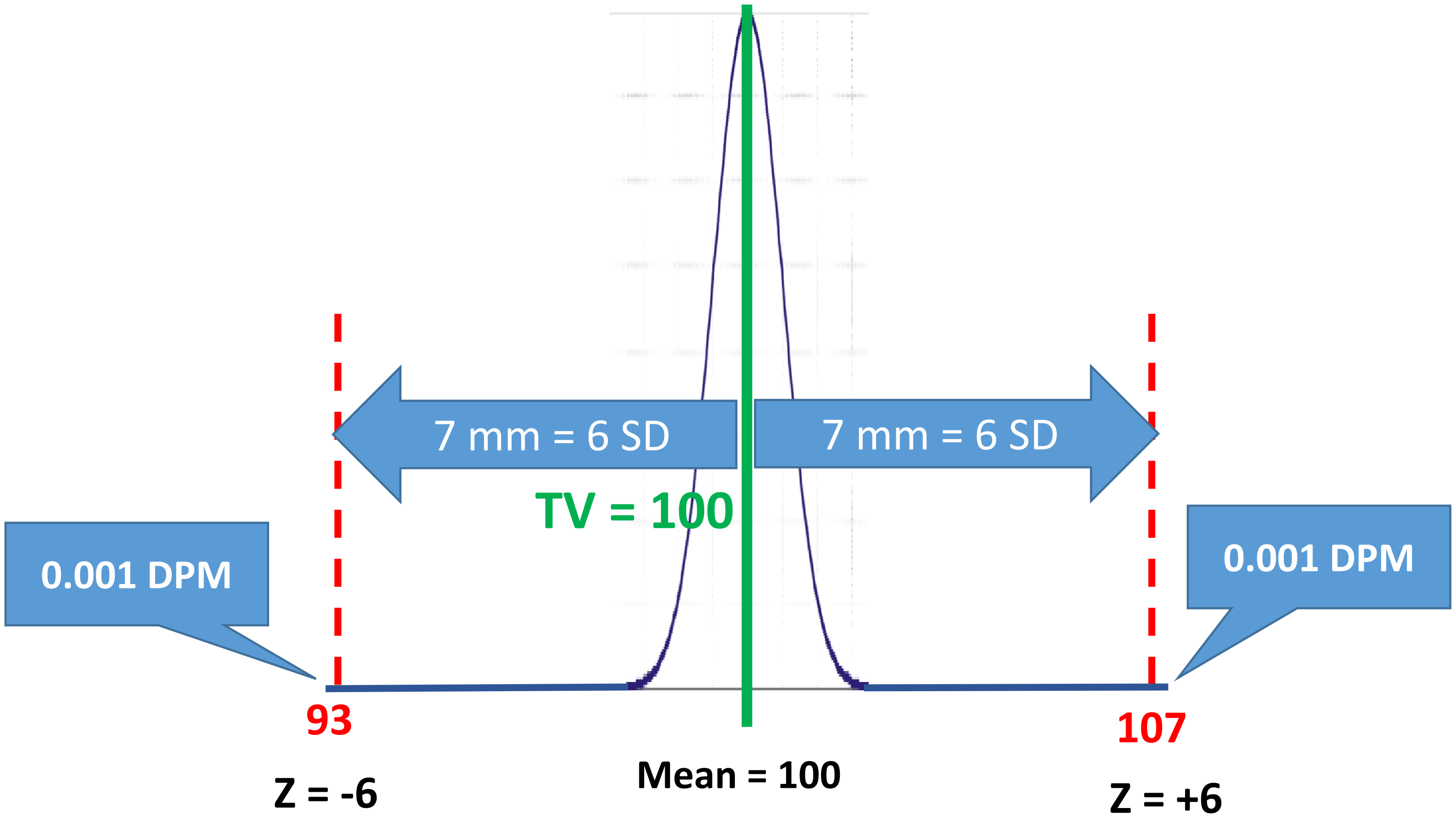
Example

- DEVa = 7%
- **DRa = 0.002 DPM**

Z@LTL = -6

Z@UTL = 6

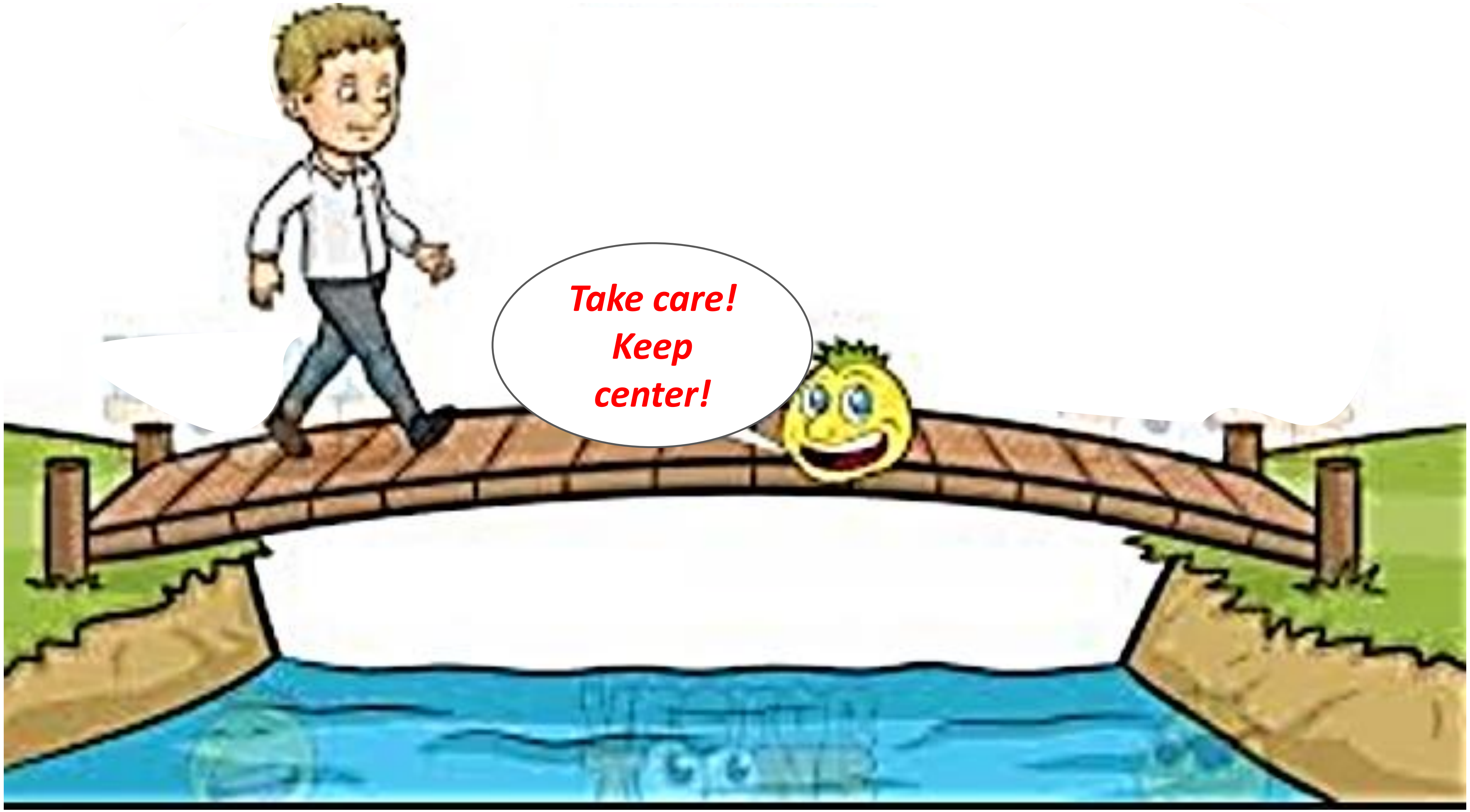
SD = 7 mm/6 = **1.16 mm**

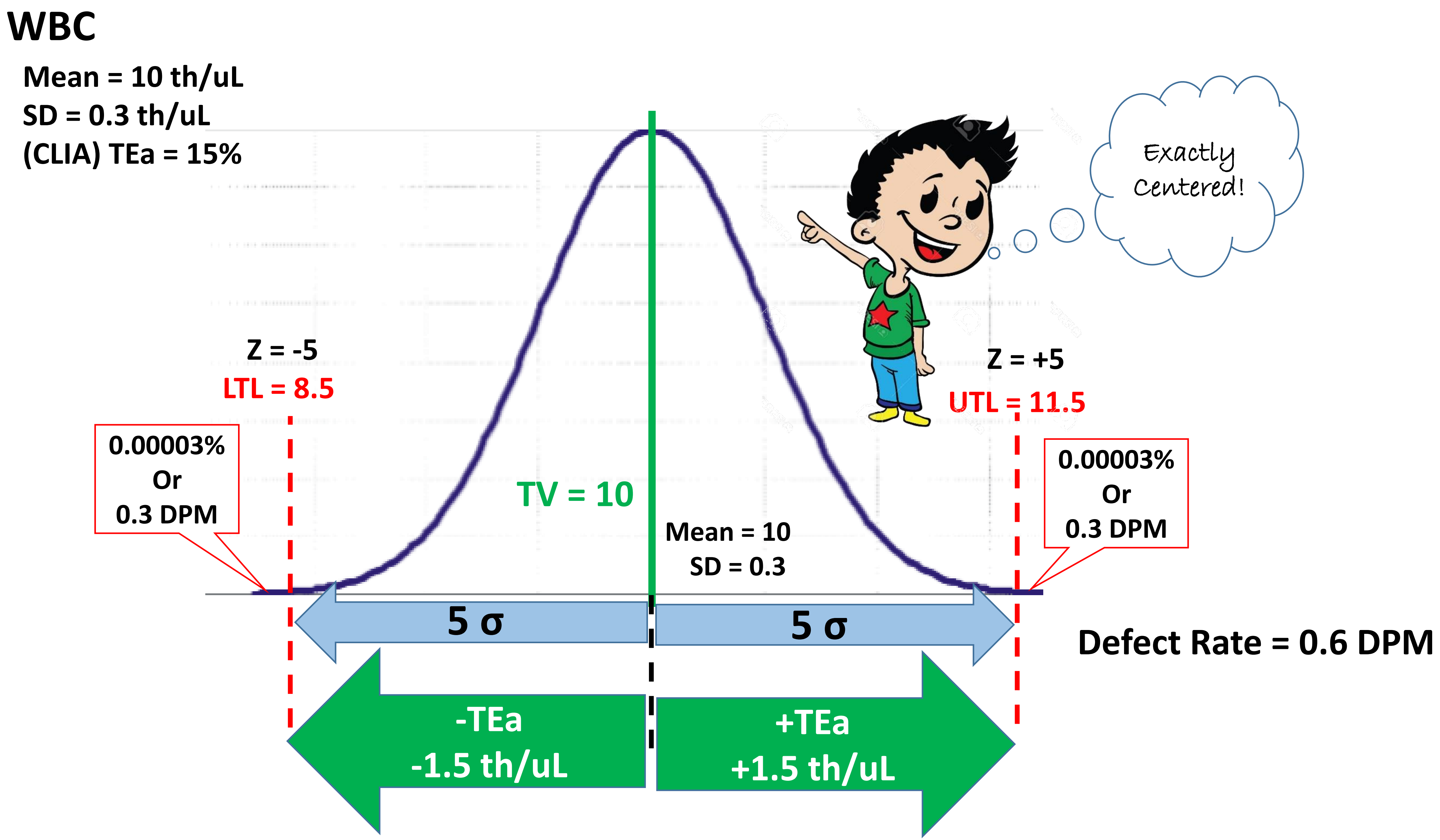


- ➢ Z at TL: Number σs (SDs) between mean and TL

- ➢ **Z value of TLs is a measure of Defect Rate**

  - ✓ The larger is Z at TL, the smaller is the tail beyond TL

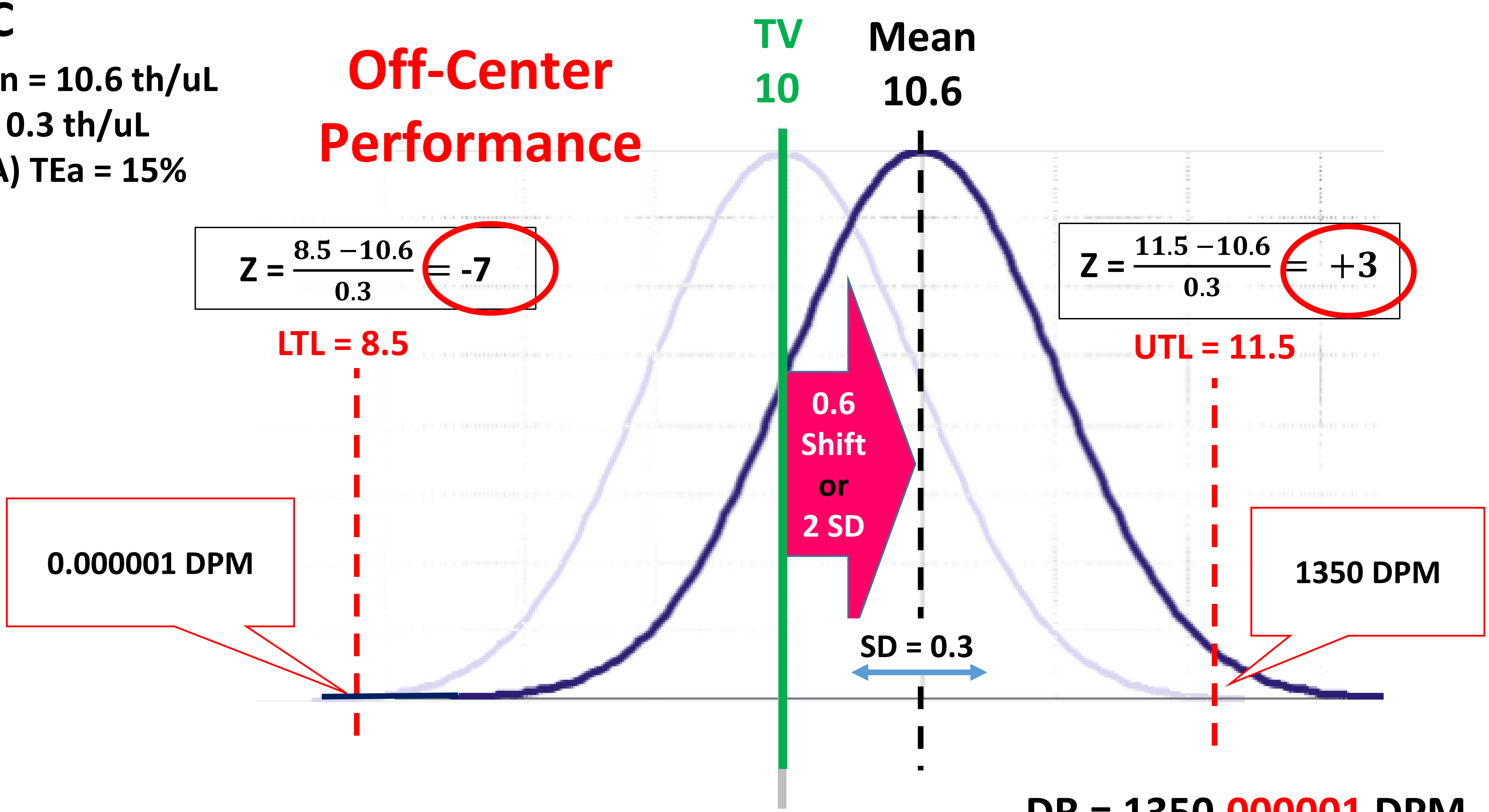

Take care! Keep center!


WBC
Mean = 10 th/uL
SD = 0.3 th/uL
(CLIA) TEa = 15%
Exactly Centered!
Z = -5
LTL = 8.5
Z = +5
UTL = 11.5
0.00003%
Or
0.3 DPM
TV = 10
Mean = 10
SD = 0.3
0.00003%
Or
0.3 DPM
5 σ
5 σ
Defect Rate = 0.6 DPM
-TEa
-1.5 th/uL
+TEa
+1.5 th/uL

WBC

Mean = 10.6 th/uL
SD = 0.3 th/uL
(CLIA) TEa = 15%

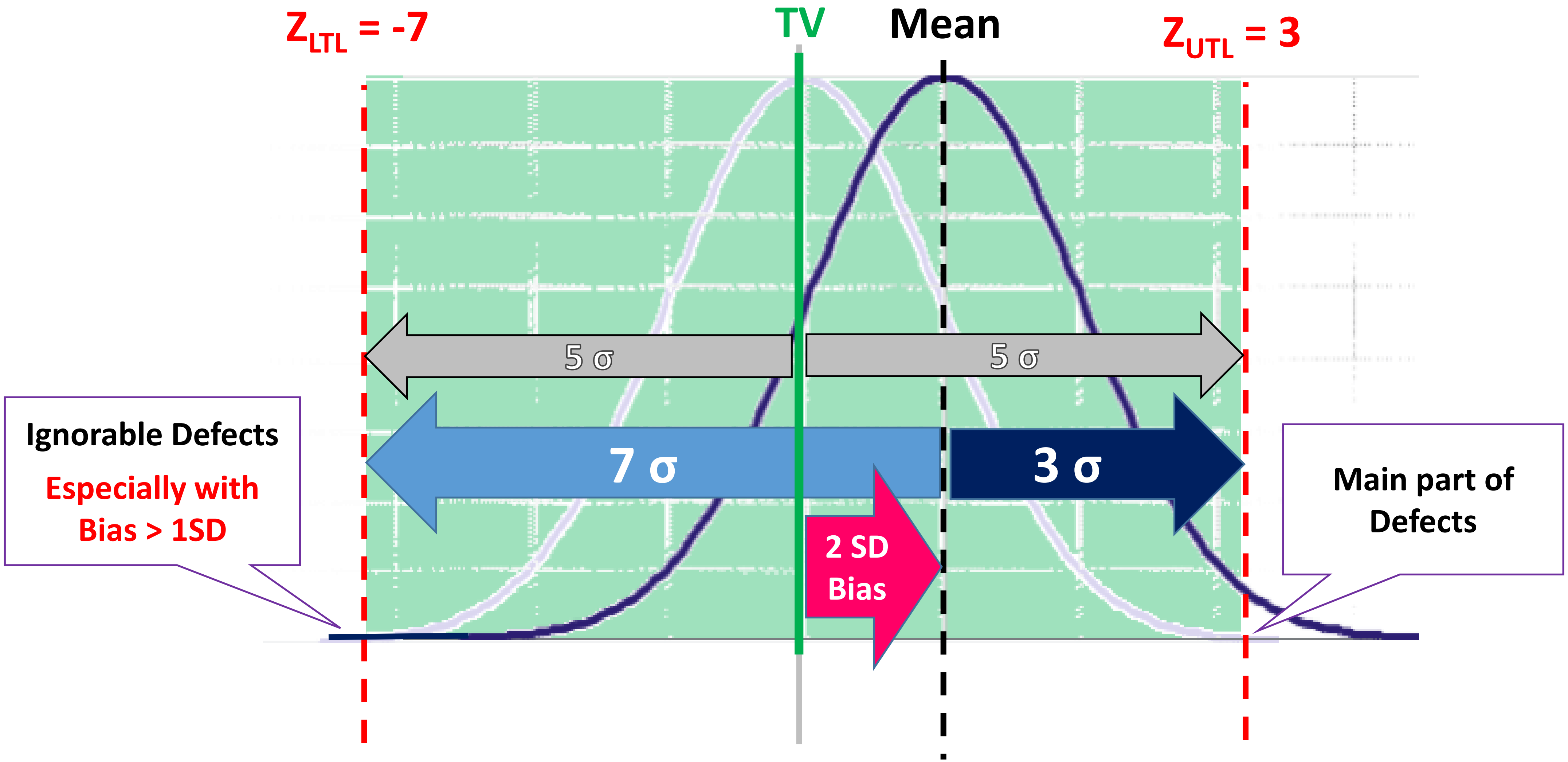
Off-Center Performance

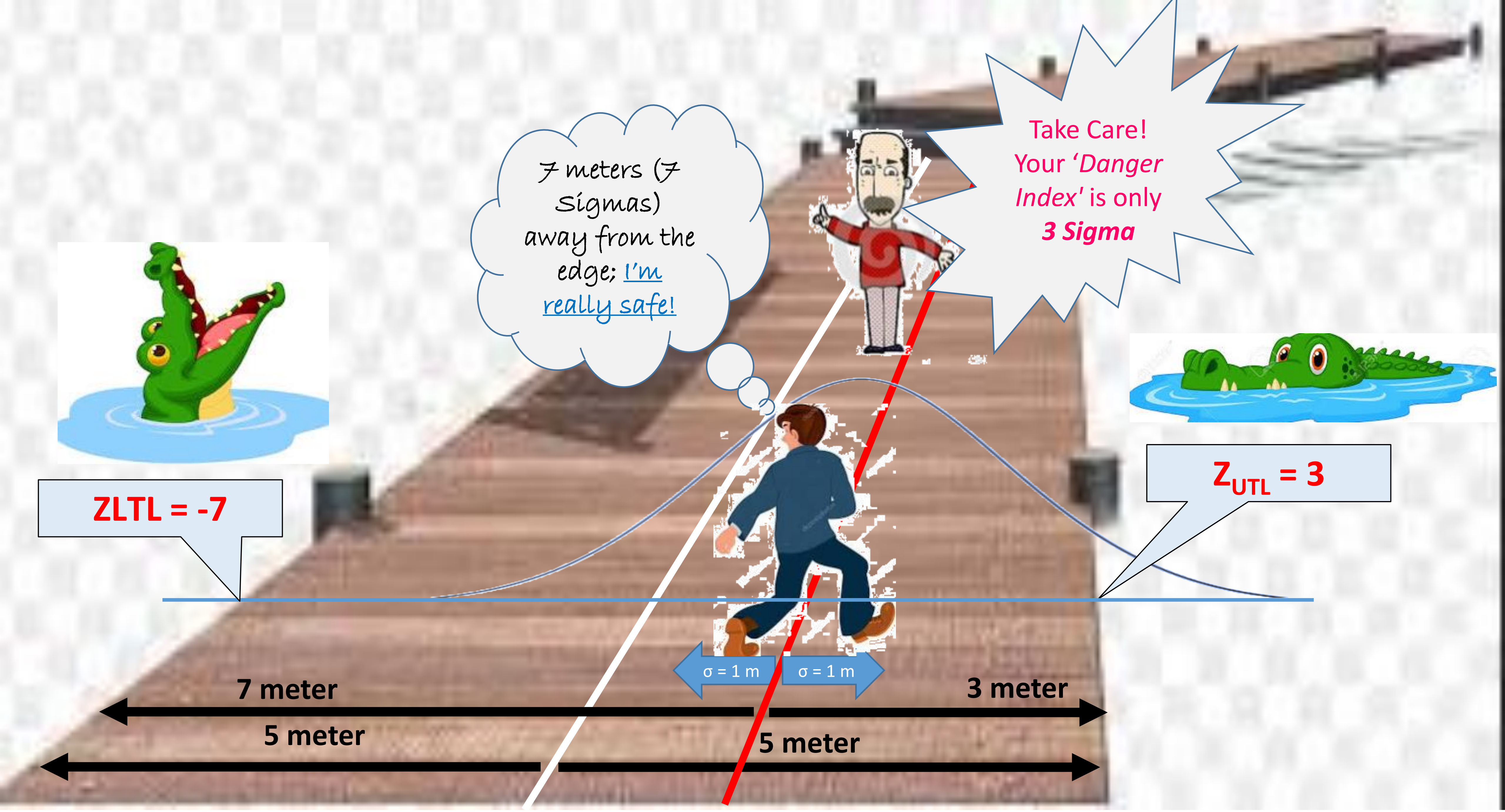


DR = 1350.000001 DPM

DR ≈1350 DPM

Q: If Z of TL is measure of defect rate, Z at which TL is the right indicator of defect rate?

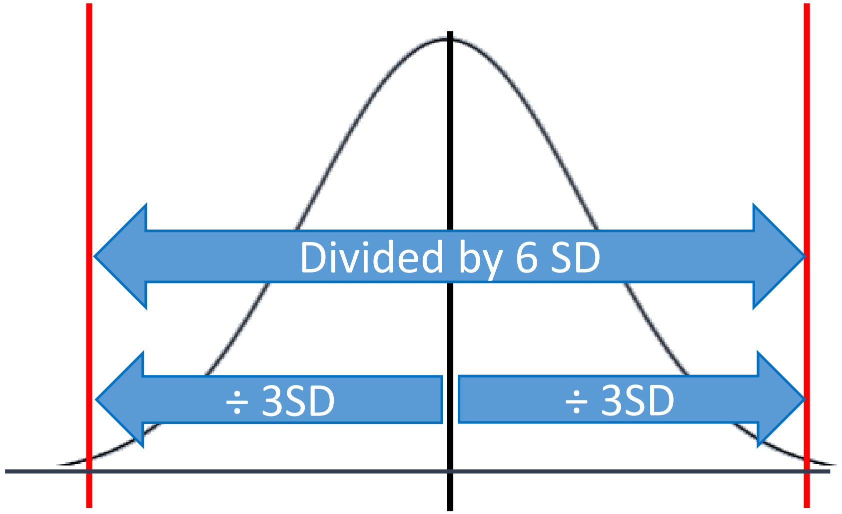



7 meters (7 Sigmas) away from the edge; I'm really safe!
Take Care! Your 'Danger Index' is only 3 Sigma
ZLTL = -7
Z_{UTL} = 3
σ = 1 m
σ = 1 m
7 meter
3 meter
5 meter
5 meter

Centered vs Off-Center; Industrial origin

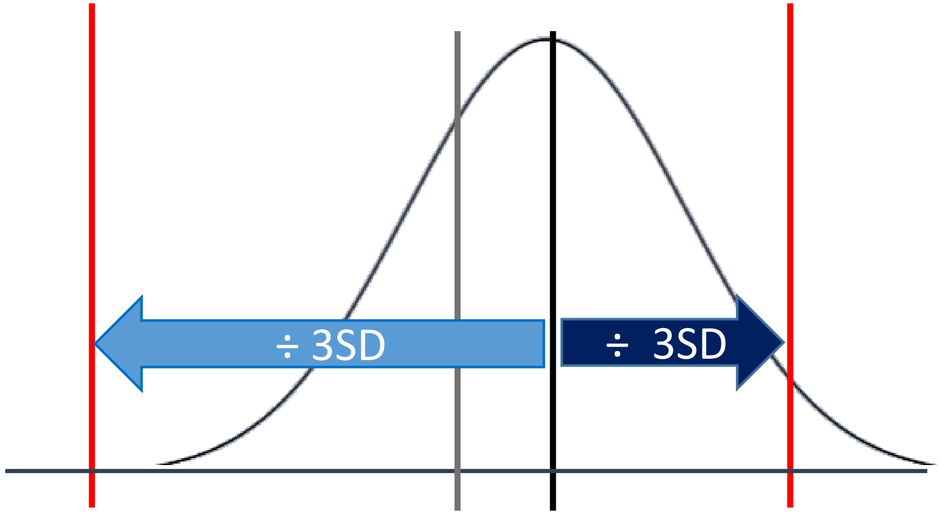
Capability Index

- No shift:

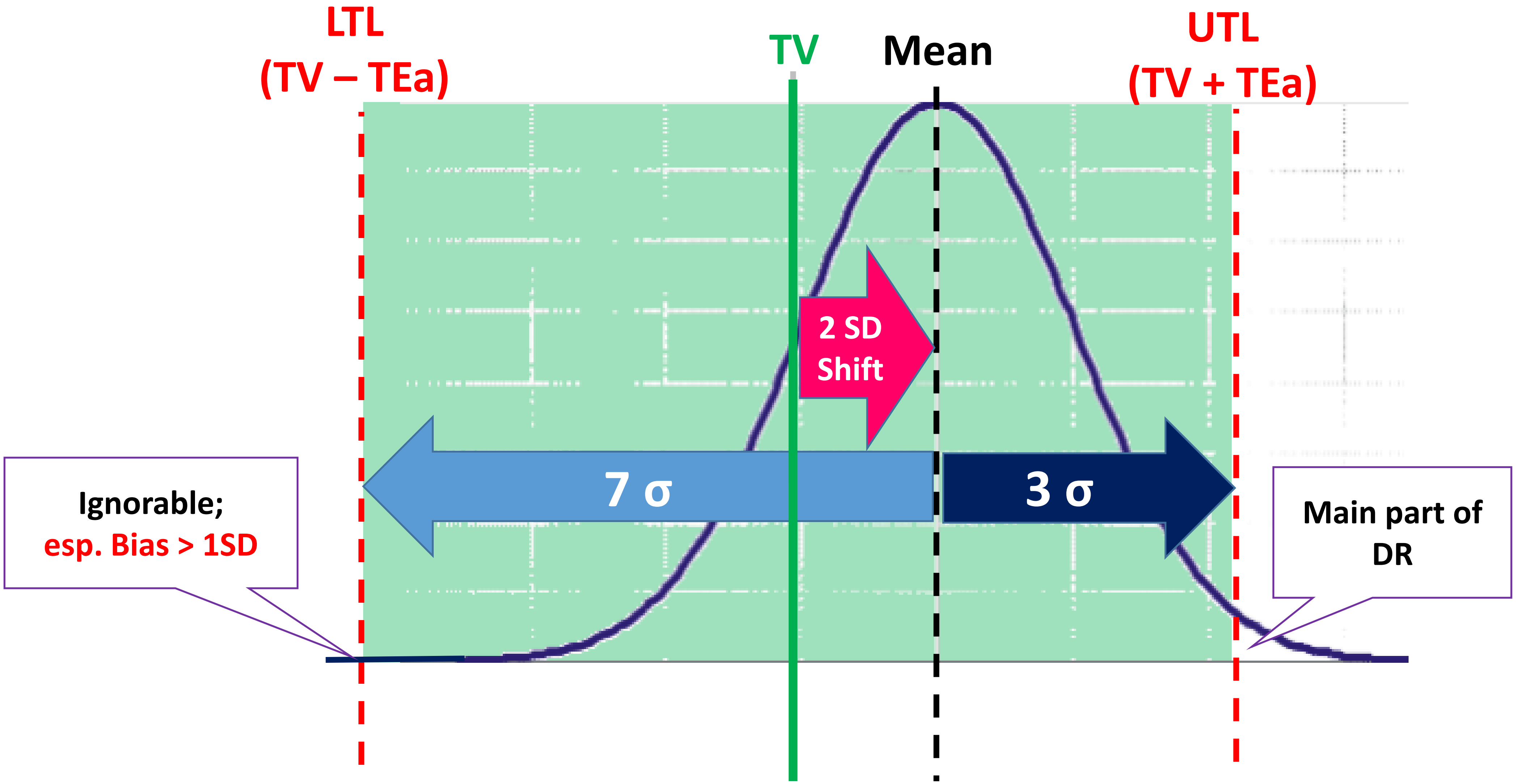


Cp = (UTL – LTL)/6SD

- Shift:

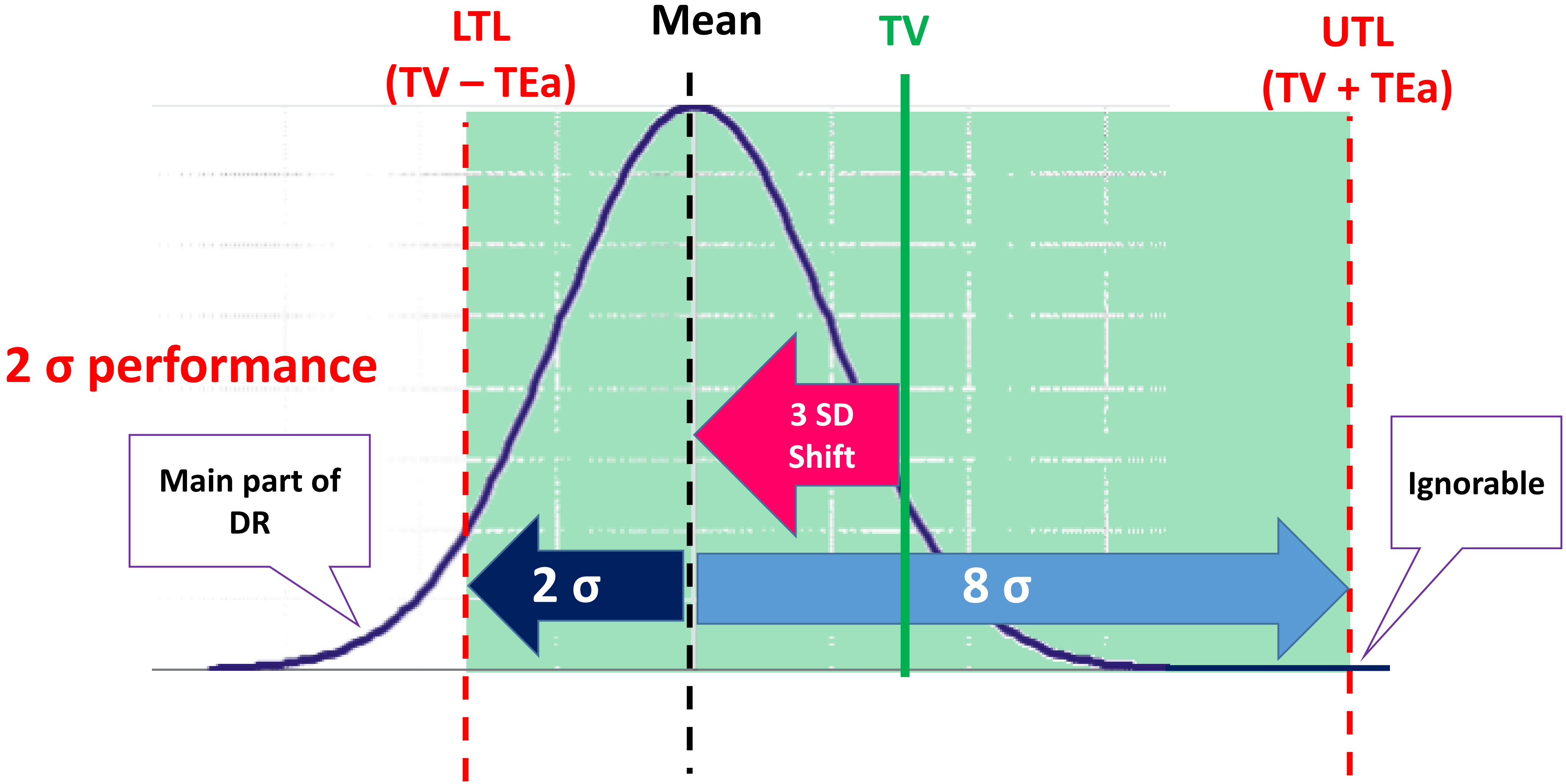


Cpk = min [(μ – LTL)/3SD, (UTL– μ)/3SD]



Concerning Defect Rate, we can call this a "3 σ" performance

Example



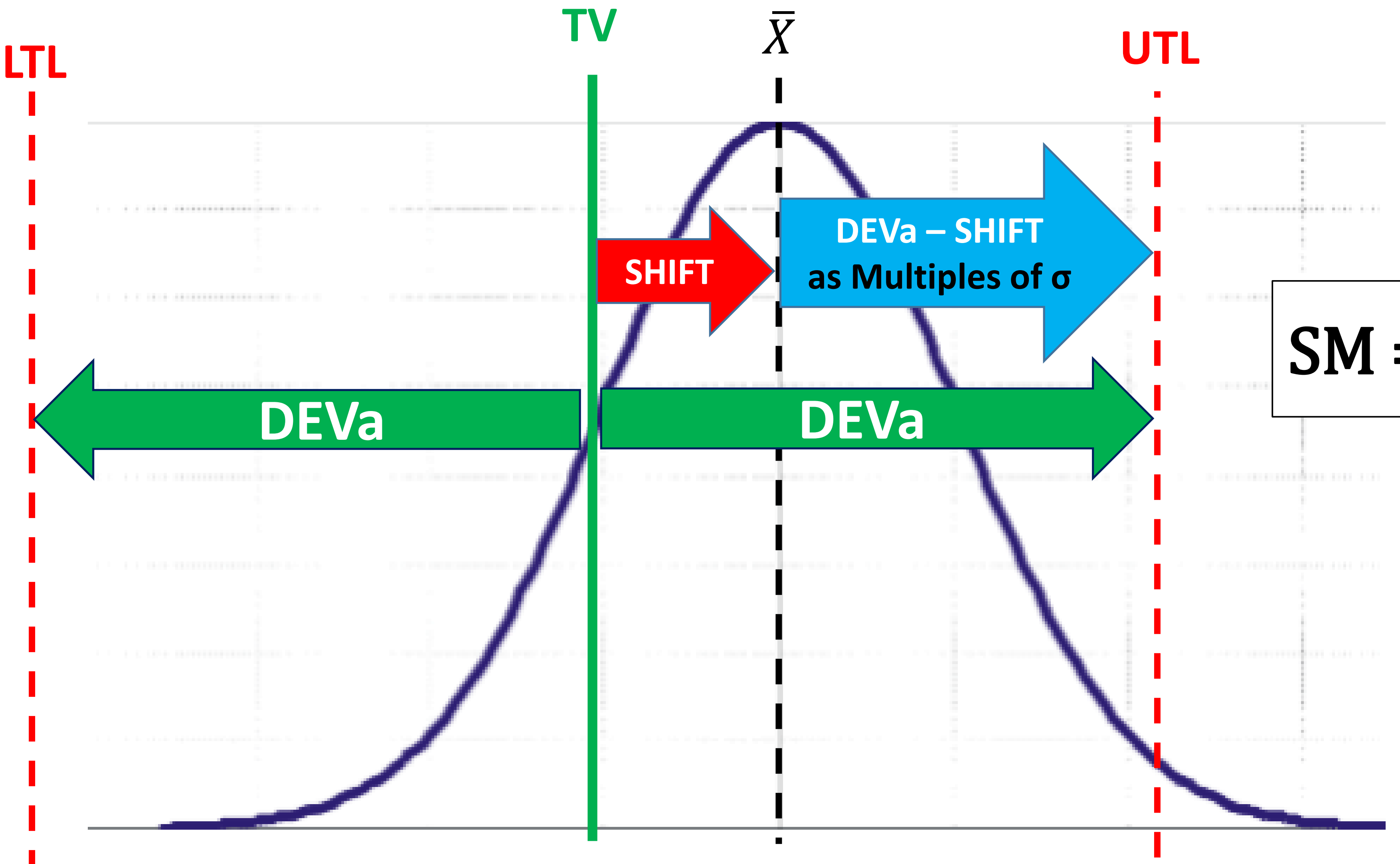
LTL
(TV – TEa)
Mean
TV
UTL
(TV + TEa)
2 σ performance
3 SD
Shift
Main part of
DR
2 σ
8 σ
Ignorable

Definition of SIGMA METRIC

- **Number of Sigmas (SDs) between Mean and the *nearest* TL;**
- **Equals to Z of the nearest TL (Z of TL at the bias side)**

Sigma Metric Equation

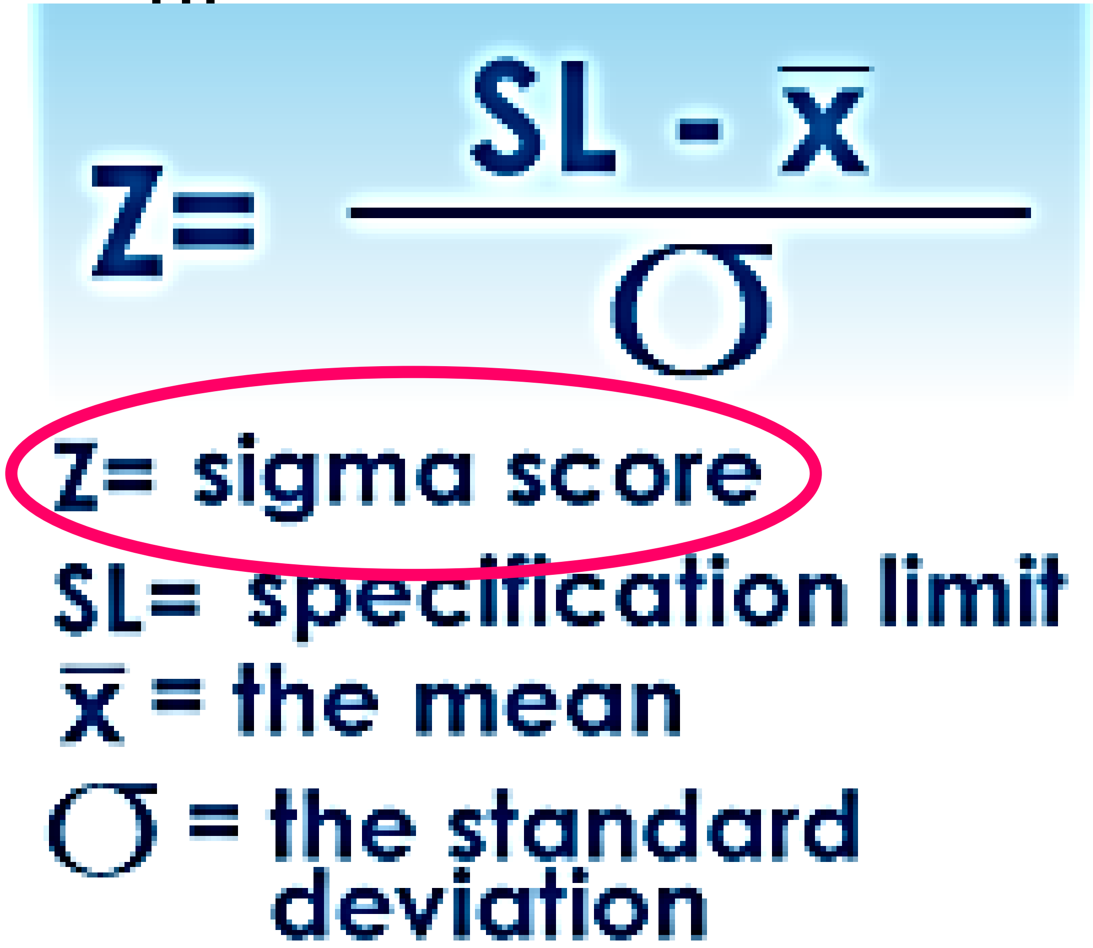
1. Number of SDs between Mean and the nearest TL

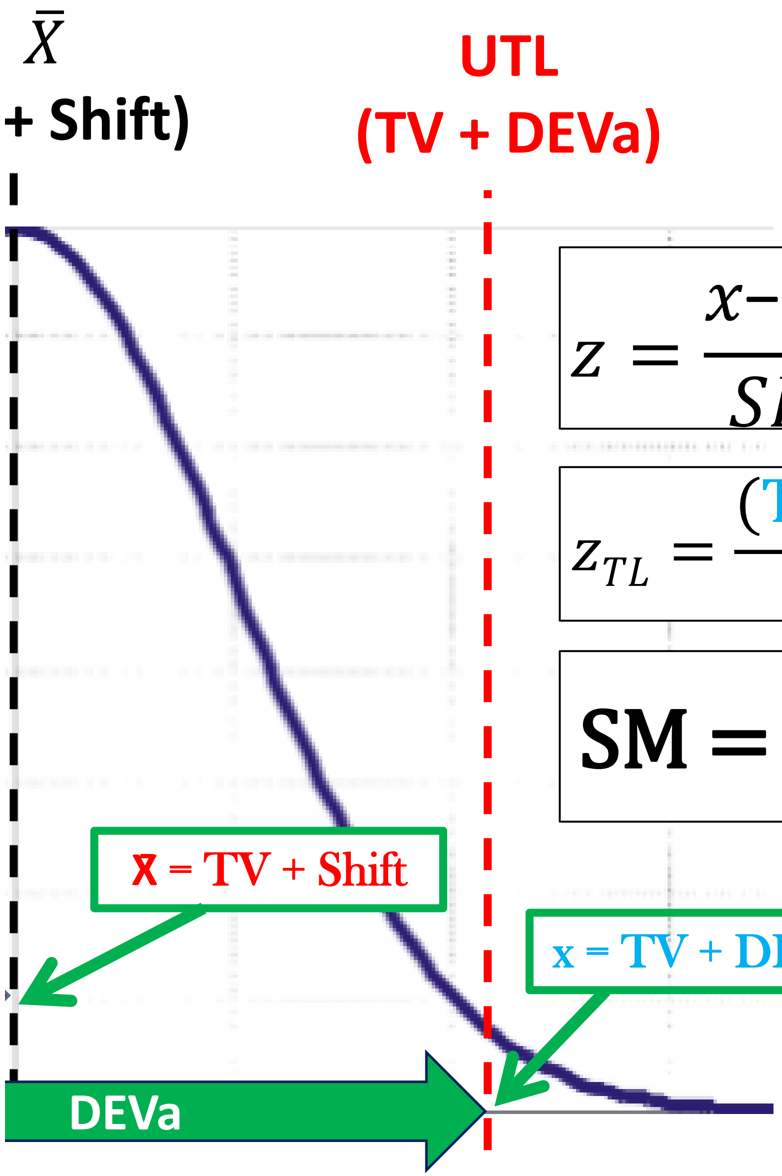


$$SM = \frac{\text{DEVa} - |\text{Shift}|}{\text{SD}}$$

Sigma Metric Equation

2. Z value of the nearest TL to Meant





$$z = \frac{x - \bar{X}}{SD}$$

$$z_{TL} = \frac{(TV+DEVa) - (TV+Shift)}{SD}$$

$$\mathbf{SM} = \frac{\mathbf{DEVa} - |\mathbf{Shift}|}{\mathbf{SD}}$$

https://money.howstuffworks.com/six-sigma4.htm

SM Equation; Adapted for analytical performance

- DEVa equals to **TEa**
- Shift equals to **Bias**

$$SM = \frac{DEVa - |Shift|}{SD}$$

$$SM = \frac{TEa - |Bias|}{SD}$$

Example:

HbA1C

TEa = 5 mmol/mol

Bias = 0.5 mmol/mol

SD = 1.5 mmol/mol

$SM = \frac{5-0.5}{1.5} = 3$

Example:

HbA1C

TEa = 5 mmol/mol

Bias = **-0.5** mmol/mol

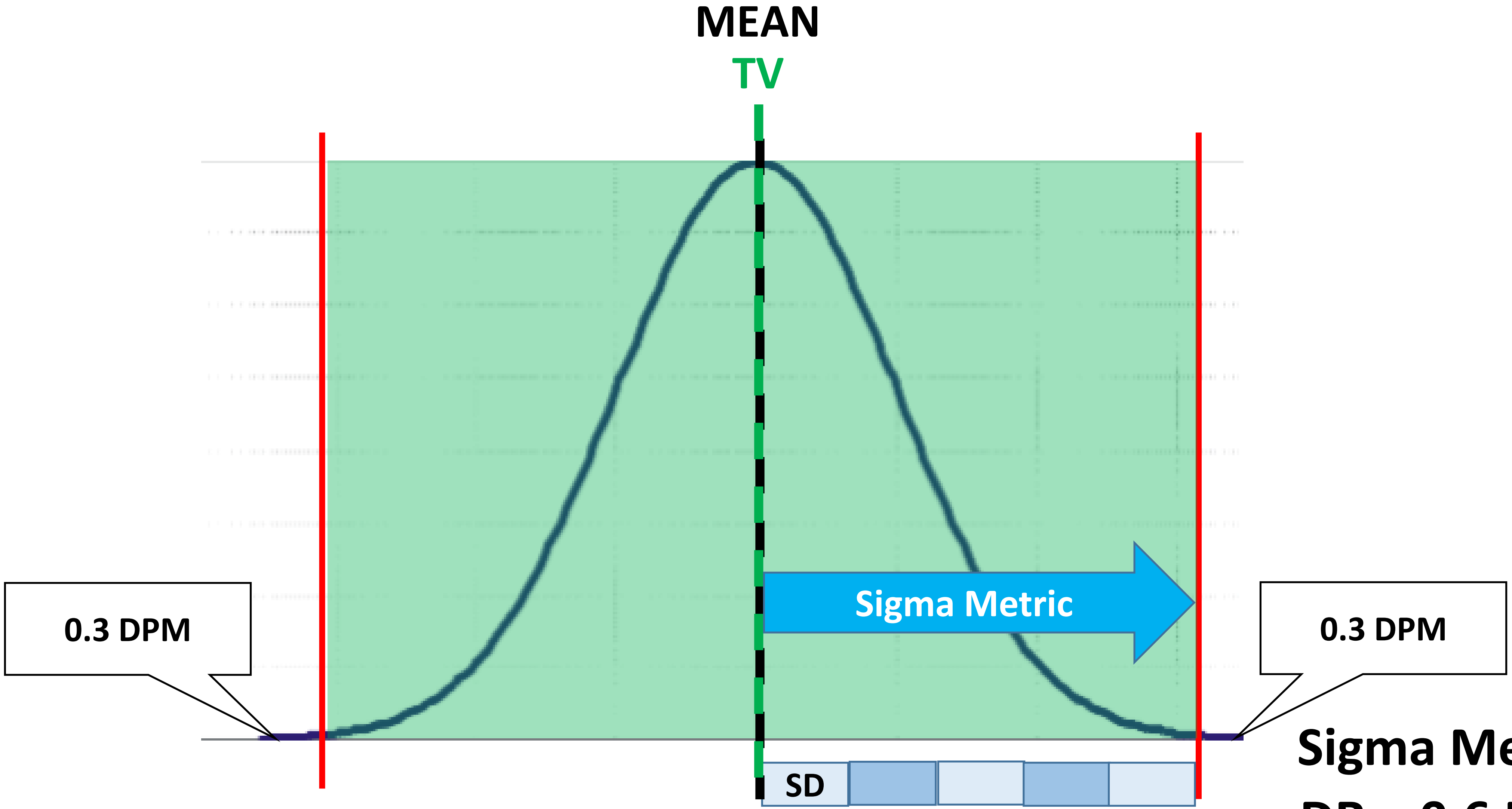
SD = 1.5 mmol/mol

$SM = \frac{5-0.5}{1.5} = 3$

Characteristics of Sigma Metric

1. SM and DR aren’t linearly related
2. Numerical calculations (+, -, x, ÷) can be done on SM values
3. Zero SM means Bias = TEa and Short-term DR = 50%
4. Negative SM means Bias > TEa and Short-term DR > 50%
5. With biased performance, “(TEa-B)/SD” gives correct SM
6. Long-term DR is calculated by subtracting 1.5 from calculated SM
7. One-side calculation is used to determine long-term DR

1. Relation between SM and DR?

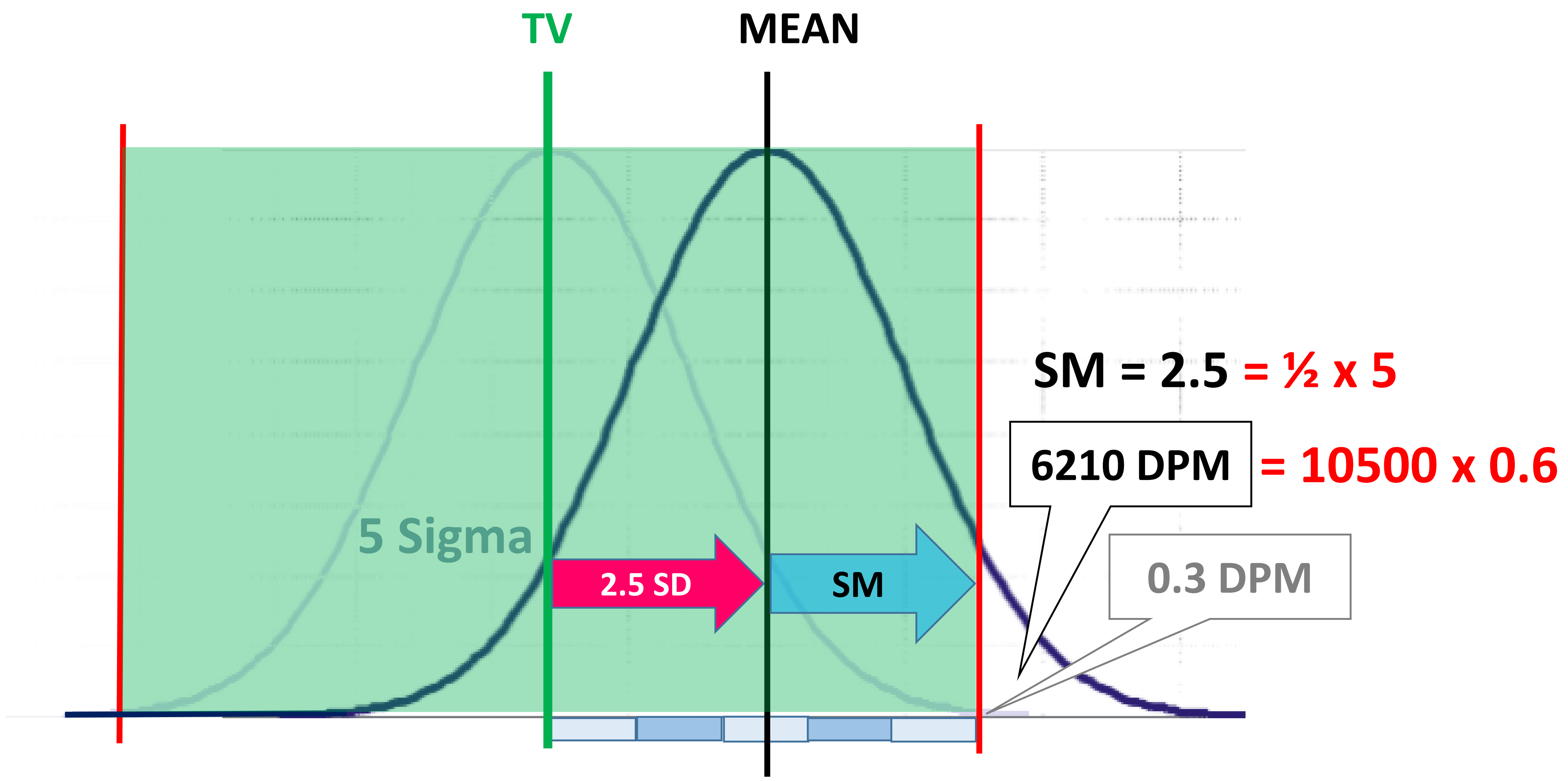


Sigma Metric = 5

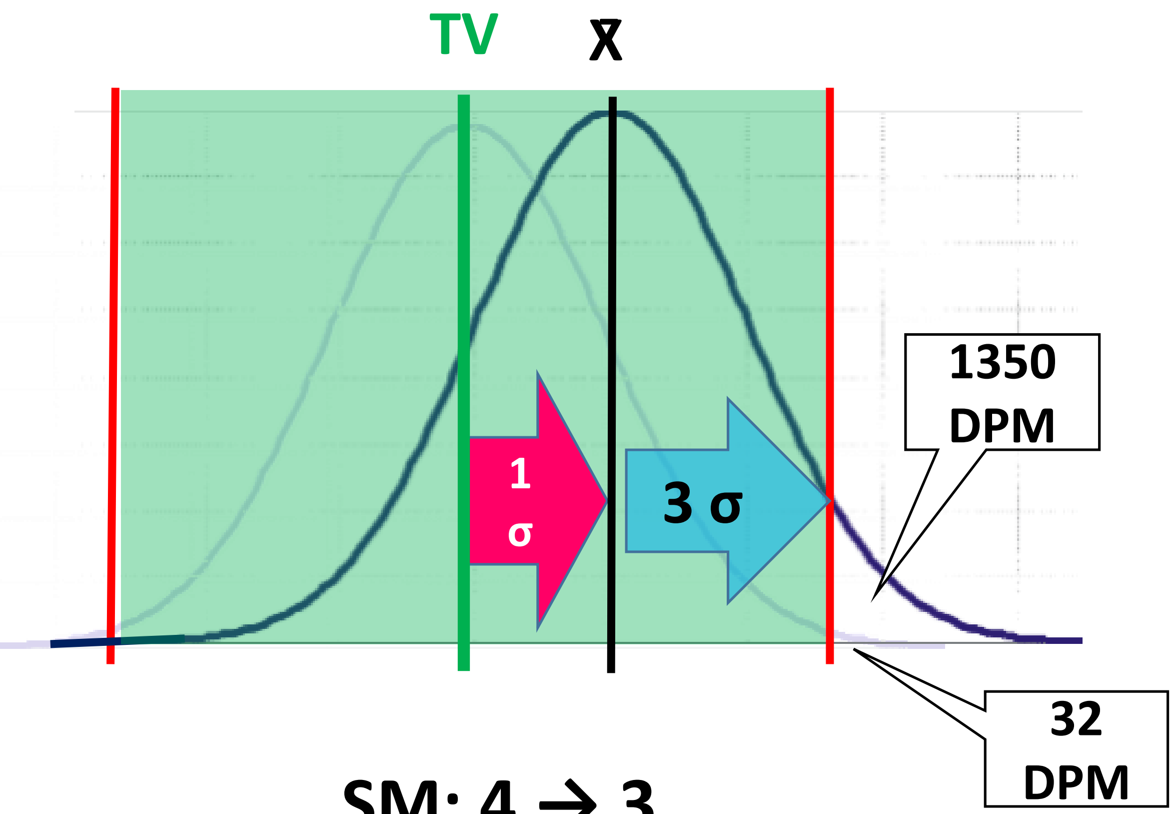
DR = 0.6 DPM

1. Relation between SM and DR?

NOTE 1: SM and DR aren't linearly related.



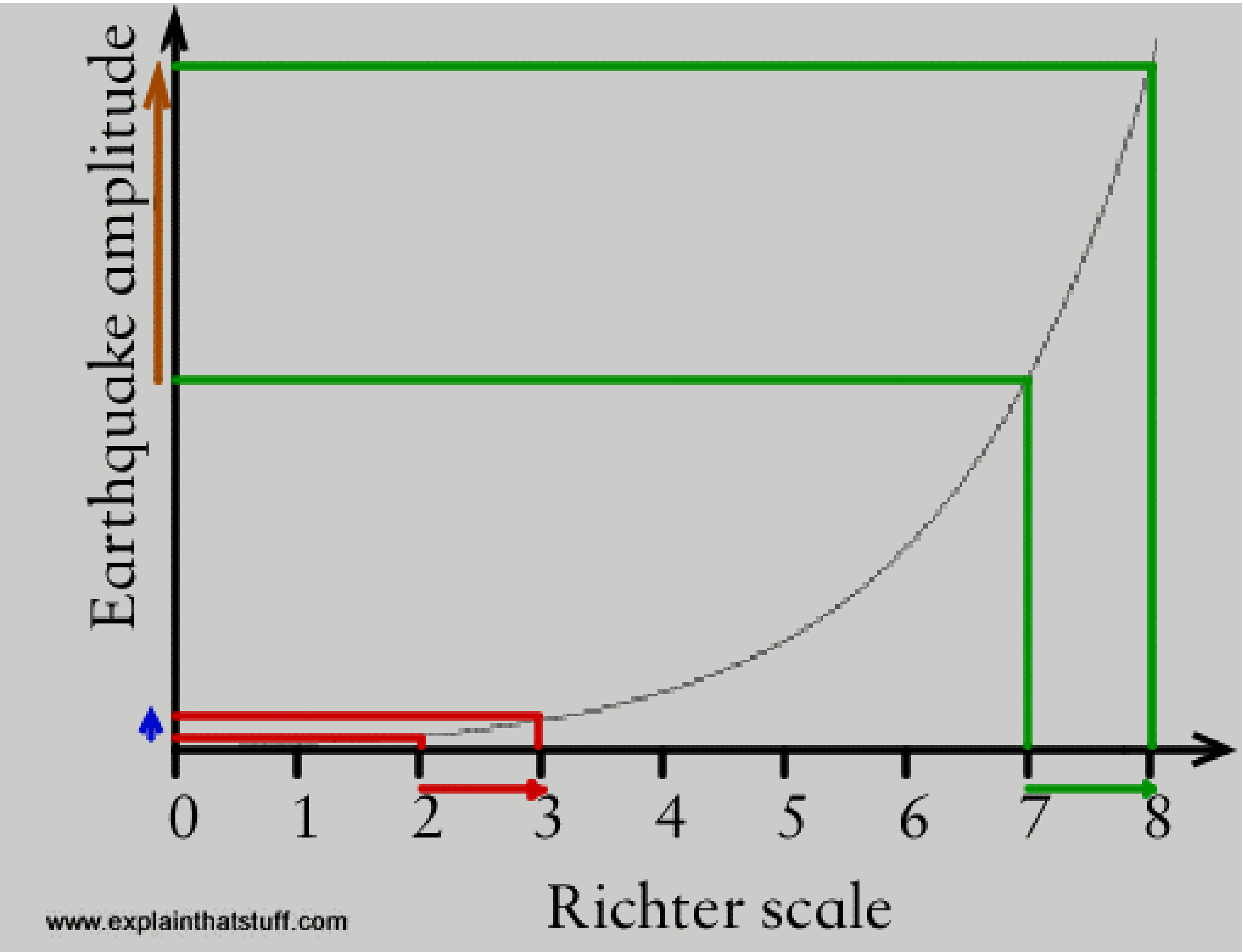
1. Relation between SM and DR?



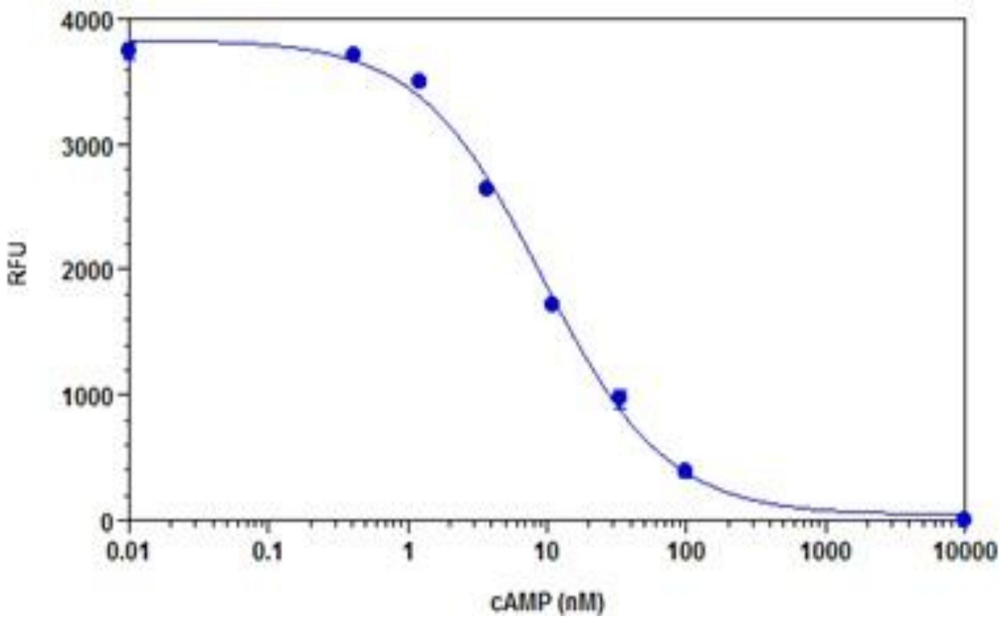
SM: 4 → 3

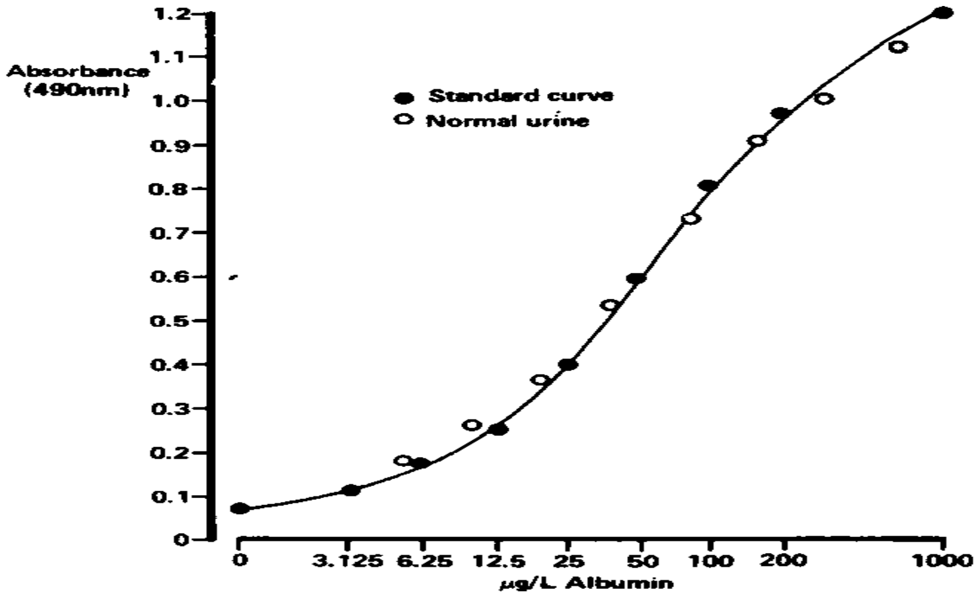
DR: 32 → 1350

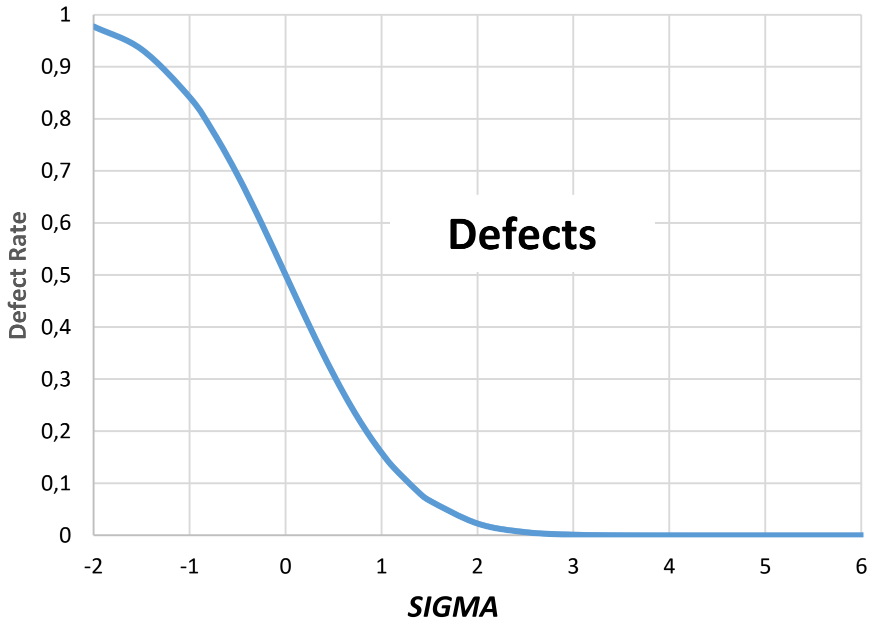
Earthquake amplitude and Richter scale aren't linearly related!

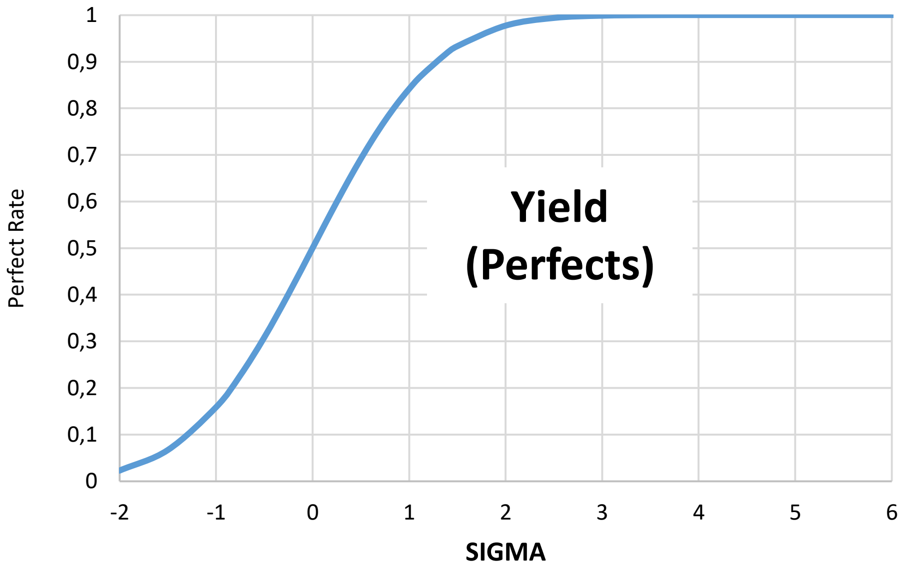


And also, immunoassay Signal/Concentration curves!

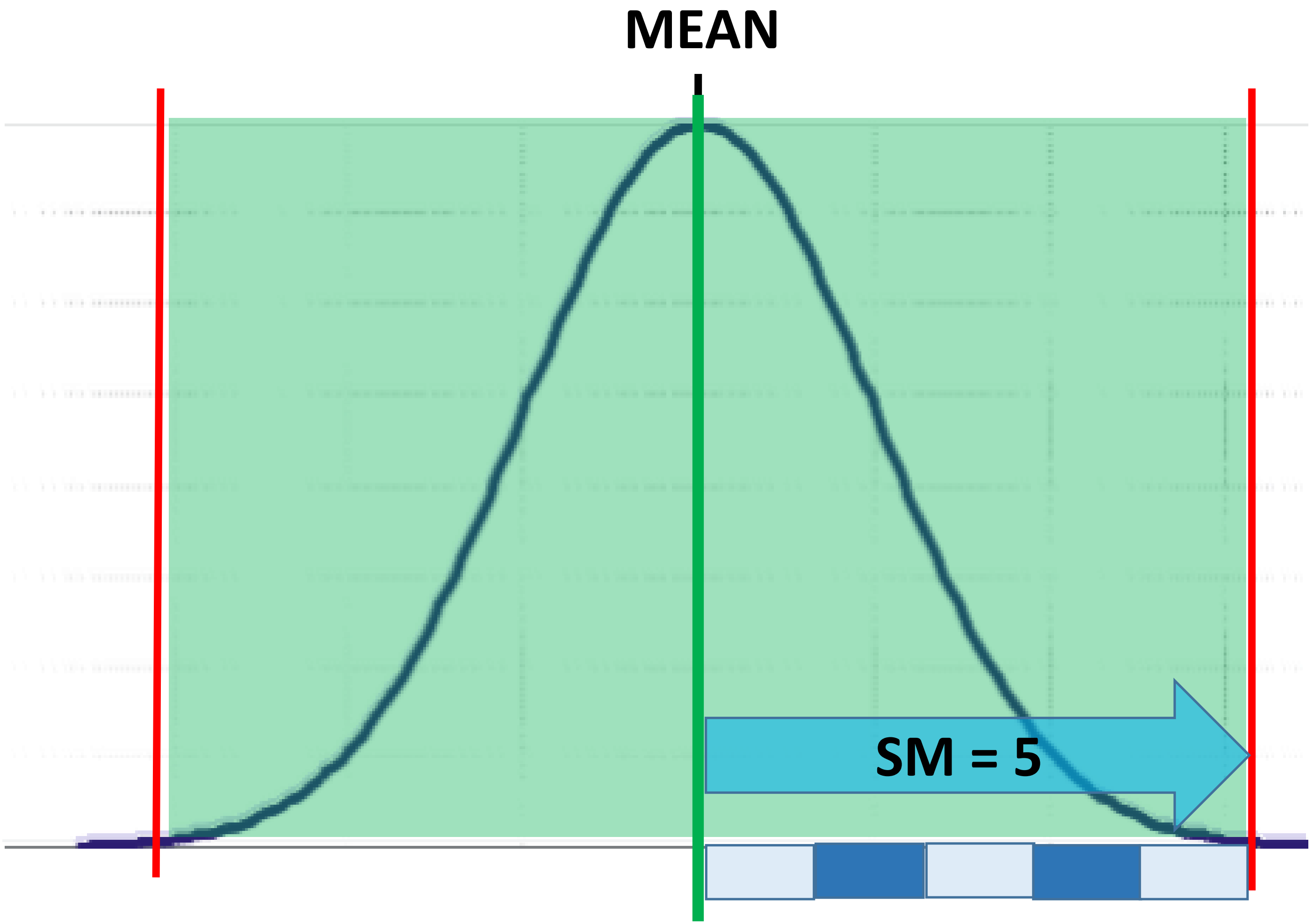




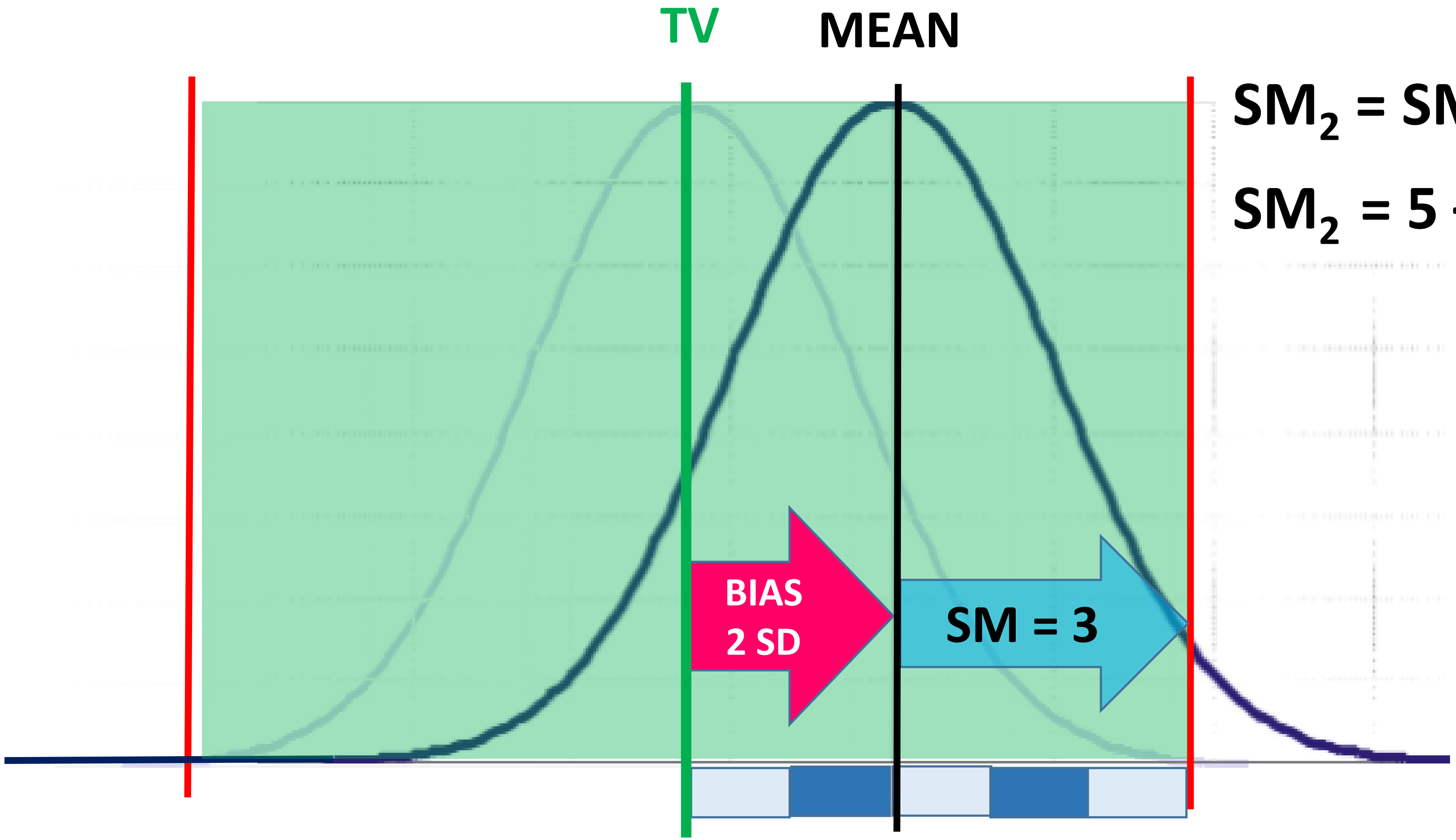




2. Numerical calculations on SM values?



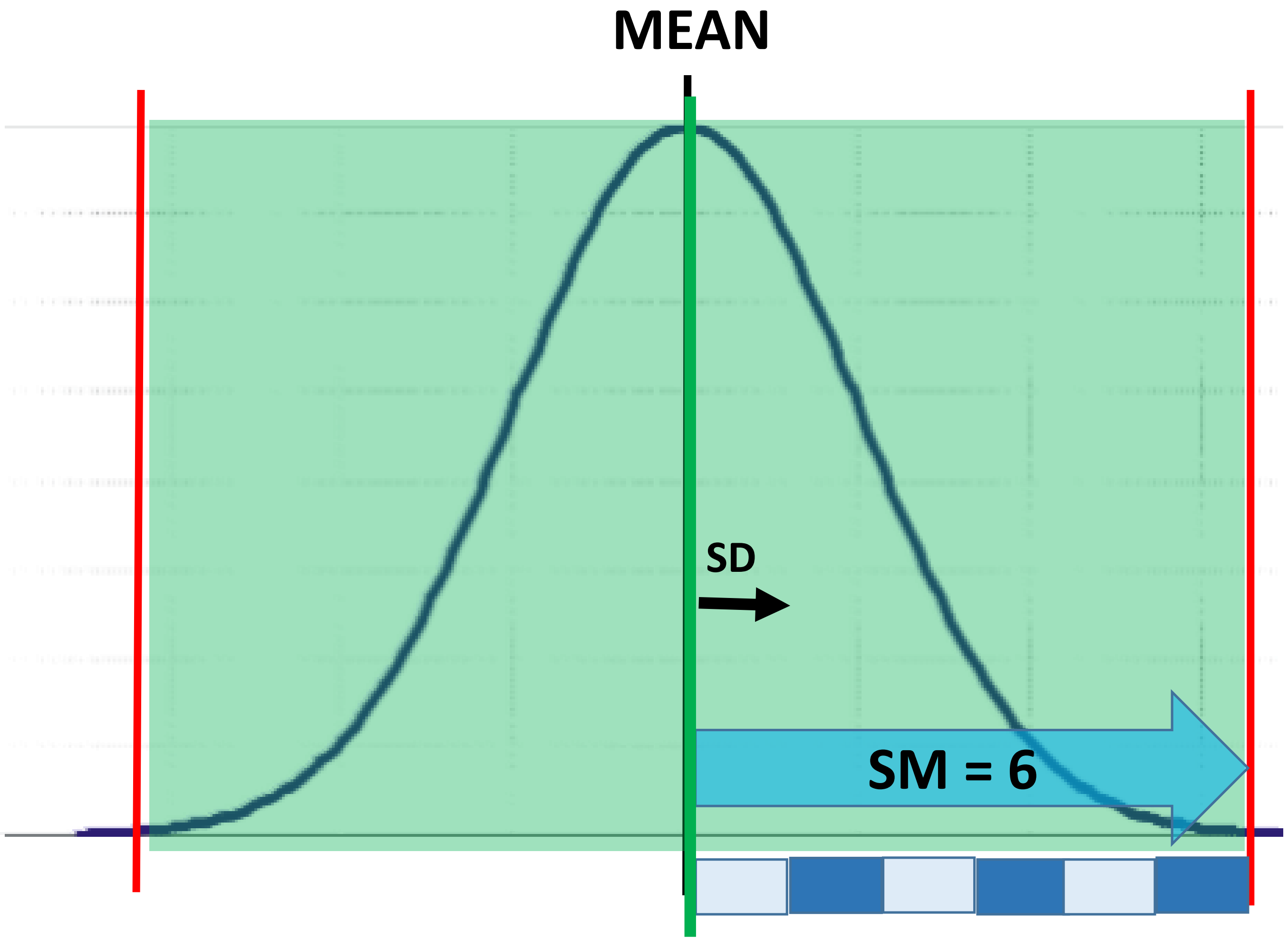
2. Numerical calculations on SM values?



$SM_2 = SM_1 - Bias$

$SM_2 = 5 – 2 = 3$

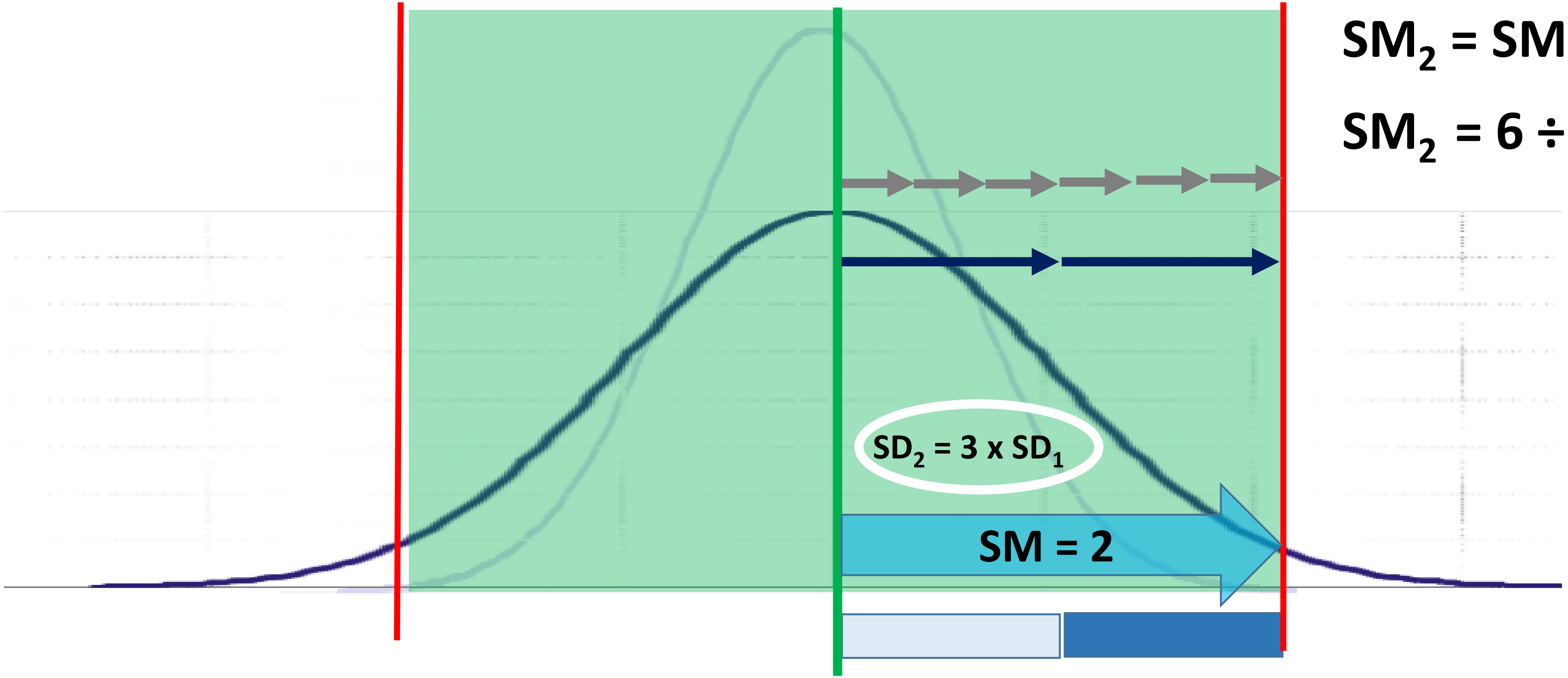
2. Numerical calculations on SM values?



2. Numerical calculations on SM values?

NOTE 2:

- Bias as multiples of SD can be added to- or subtracted from SM; and
- SM can be multiplied or divided by factors.

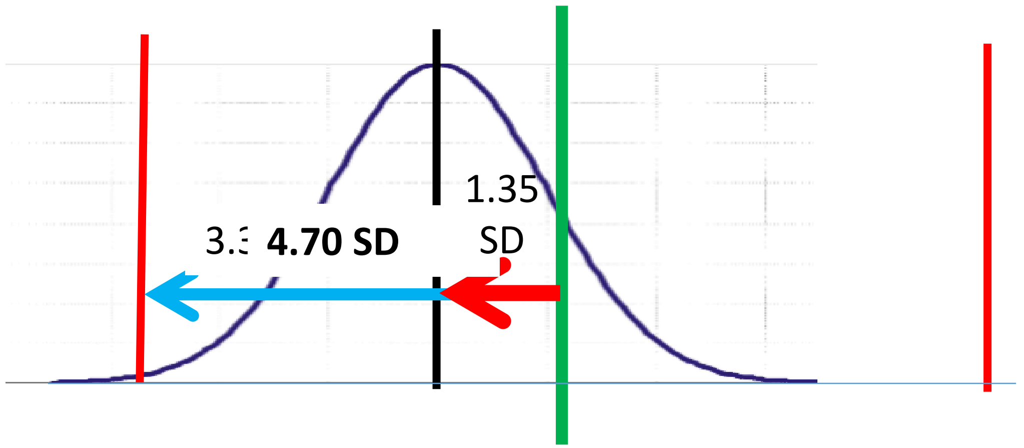


$SM_2 = SM_1 \div 3$

$SM_2 = 6 \div 3 = 2$

2. Numerical calculations on SM values?

Example



TEa = 8

SD = 1.7

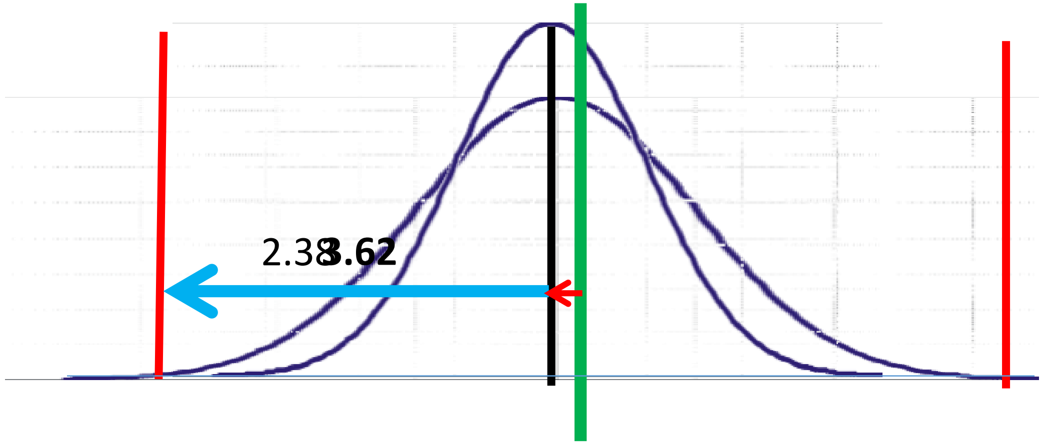
Bias = -2.3 = 1.35 SD → **Recalibration** → Bias = 0

SM = 3.35 → **3.35 + 1.35** → **SM = 4.7** — Only 0.4 times

DR = 404 DPM → **DR = 2.6 DPM** — 30900 times

2. Numerical calculations on SM values?

Example



TEa = 8

SD = 3.2 **Improve Imprecision** SD = 2.1 **F = 2.1/3.2 = 1/1.52**

Bias = -0.4 = 1.35 SD

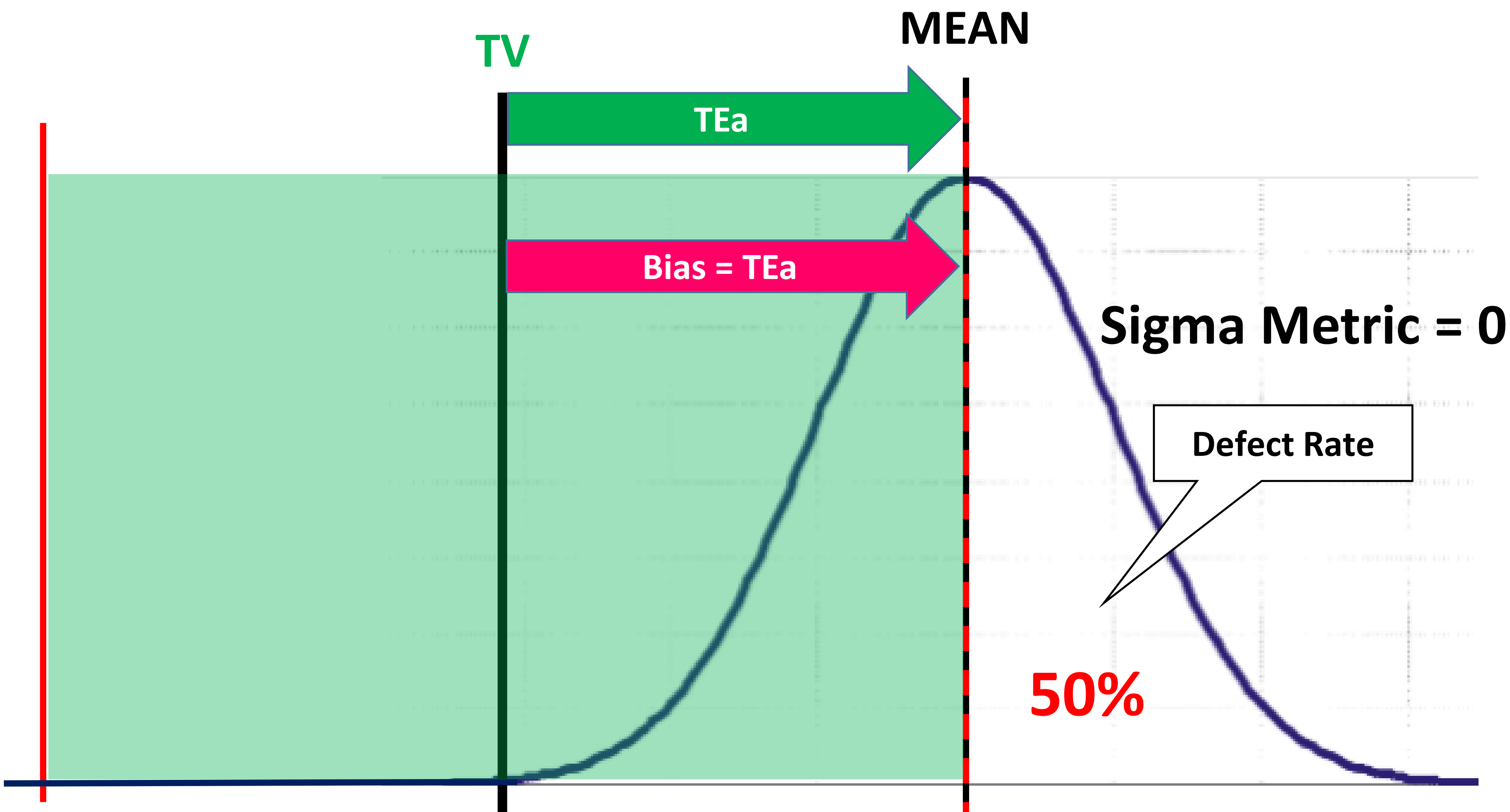
SM = 2.38 **2.38 x 1.52** **SM = 3.62** Only 1.52 times

DR = 17313 DPM **DR = 296 DPM** 5750 times

3. Zero Sigma?

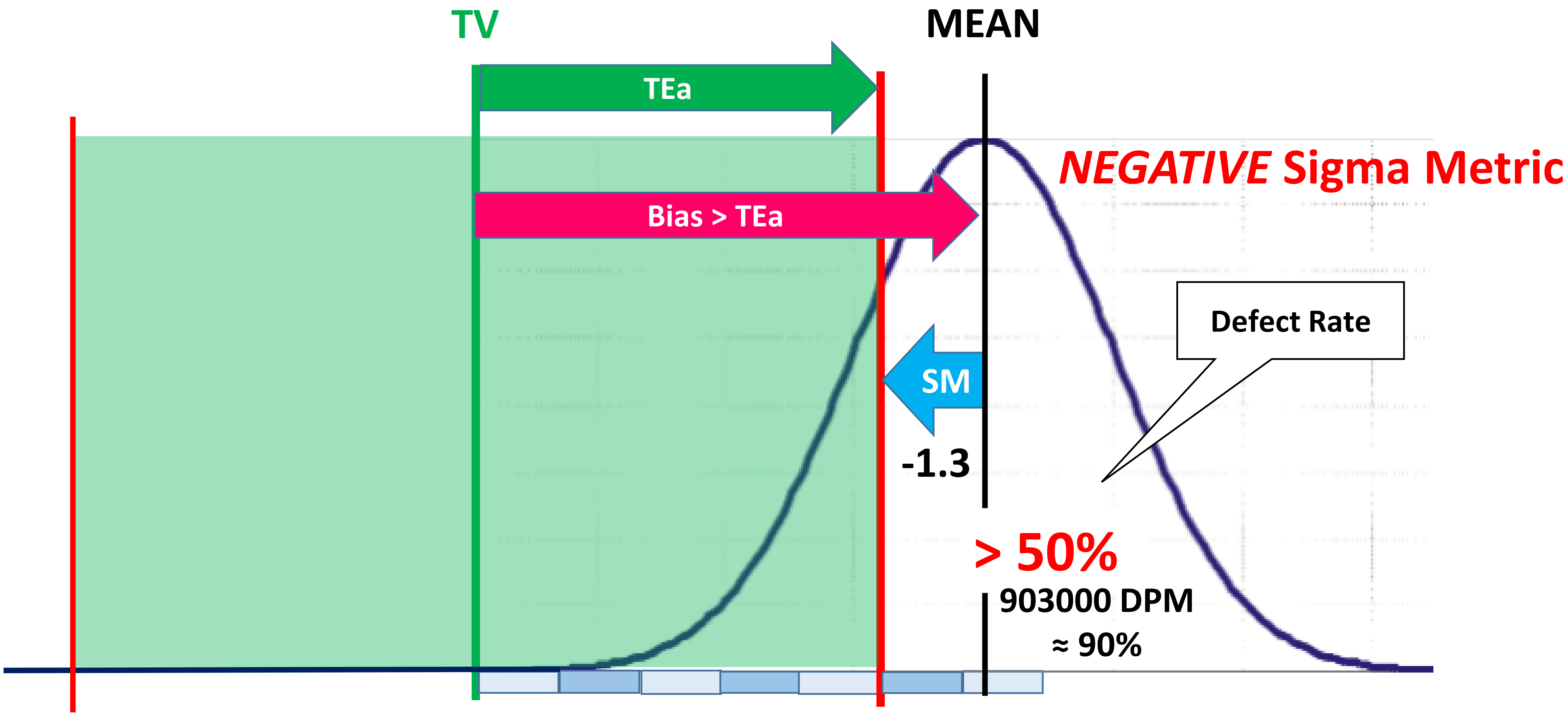
NOTE 3: Zero SM doesn't mean 100% defects (or 0% yield)!

With a SM=0, DR is approximately 50% (and Yield ≈ **50%)**



4. Negative Sigma?

NOTE 4: Negative yield is not meaningful, but negative SM is!
With a negative SM, DR is >50% (and yield is <50%).



5. Which format: (TEa - B)/SD or (TEa% - B%)/CV?

Example 1:

- TV=100 mg/dL
- TEa = 8 mg/dL
- Mean = 100 mg/dL
- Bias = 0 mg/dL
- SD = 2 mg/dL

TEa% = (TE/TV) x 100

B% = (B/TV) x 100

CV = (SD/Mean) x 100

SM = (TEa - B)/SD

SM = (8 - 0)/2 = 4

SM = (TEa% - B%)/CV

SM = (8% - 0)/2% = 4

5. Which format: (TEa - B)/SD or (TEa% - B%)/CV?

Example 2:

- TV=100
- TEa = 8
- Mean = 103
- **Bias = 3**
- SD = 2

SM = (TEa - B)/SD

SM = (8 - 3)/2 = **2.50**

SM = (TEa% - B%)/CV

SM = (8% - 3%)/1.96 = **2.58**

TEa% = (TE/TV) x 100

B% = (B/TV) x 100

CV = (SD/Mean) x 100

5. Which format: (TEa - B)/SD or (TEa% - B%)/CV?

Example 3:

- TV=100
- TEa = 8
- Mean = 97
- **Bias = -3**
- SD = 2

SM = (TEa - B)/SD

SM = (8 - 3)/2 = **2.50**

SM = (TEa% - B%)/CV

SM = (8% - 3%)/2.06 = **2.43**

TEa% = (TE/TV) x 100

B% = (B/TV) x 100

CV = (SD/Mean) x 100

5. Which format: (TEa - B)/SD or (TEa% - B%)/CV?

NOTE 5: When there is bias, (TEa - B)/SD and (TEa% - B%)/CV give a bit different SMs; First one correct.

TV	TEa	X̄	Bias	SD	CV	SM = (TEa-B)/SD	SM = (TEa%-B%)/CV
100	8	103	+3	2	1.94	2.50	2.58
100	8	97	-3	2	2.06	2.50	2.43

$$\frac{A-B}{C} = \frac{\frac{A}{D} - \frac{B}{D}}{\frac{C}{D}}$$

TEa% = TEa x 100/TV

Bias% = Bias x 100/TV

CV= SD x 100/X̄

$$\frac{TEa - B}{SD} \neq \frac{\frac{TEa \times 100}{TV} - \frac{B \times 100}{TV}}{\frac{SD \times 100}{\bar{X}}}$$

$$\frac{TEa-B}{SD} \neq \frac{TEa\%-B\%}{CV}$$

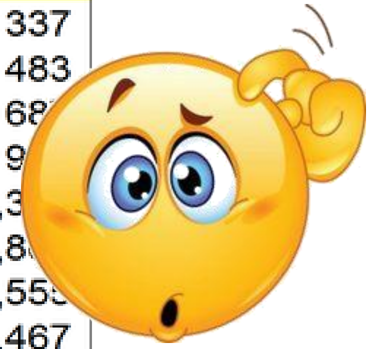
6. Defect Rate: SHORT-TERM vs. LONG-TERM?

Example

- TEa = 6
- Bias = 2
- SD = 1
- SM = 4
- P(Z>4) = **32 DPM**

Short Term Sigma Level	Defects Per Million
6	3
5.9	5
5.8	9
5.7	13
5.6	21
5.5	32
5.4	48
5.3	72
5.2	108
5.1	159
5	233
4.9	337
4.8	483
4.7	68[illegible]
4.6	9[illegible]
4.5	1,3[illegible]
4.4	1,8[illegible]
4.3	2,55[illegible]
4.2	3,467
4.1	4,661
4	6,210 >>>32
3.9	8,198
3.8	10,724
3.7	13,903
3.6	17,864
3.5	22,750

P(Z>2.5) = 6210



Defect Rate: SHORT-TERM vs. LONG-TERM?

ANSWER

- Calculated SM is a *REPORT* about the **PAST!**
- We need to *FORESEE/ASSURE* DR for the **FUTURE!**

Given:

- Usually SM is determined in Short-term evaluation
- The variable factors are not completely evaluated in Short-term
- QC strategies cannot detect small shifts
  - **A higher DR is expected for Long-term**

Defect Rate: SHORT-TERM vs. LONG-TERM?

- **NOTE 6: In Six Sigma methodology, to calculate Long-term DR, 1.5 is subtracted from the SM calculated from Short-term DEVata.**

  - **Assumptions in the Six Sigma methodology:**

- In long-term shifts of different sizes and in both directions happen
- The largest expected shift (the worst case) is 1.5 SD
- The shifts are not detectable and/or correctable
- The shifts are reversed by themselves
- By convention established at Motorola, the Sigma level is adjusted by 1.5 sigma to recognize the tendency of processes to shift over the long term

Long-term DR = P(Calculate SM - 1.5)

Calculated SM corresponds to two defect rates:

- **Short-term DR**

  What did happen?

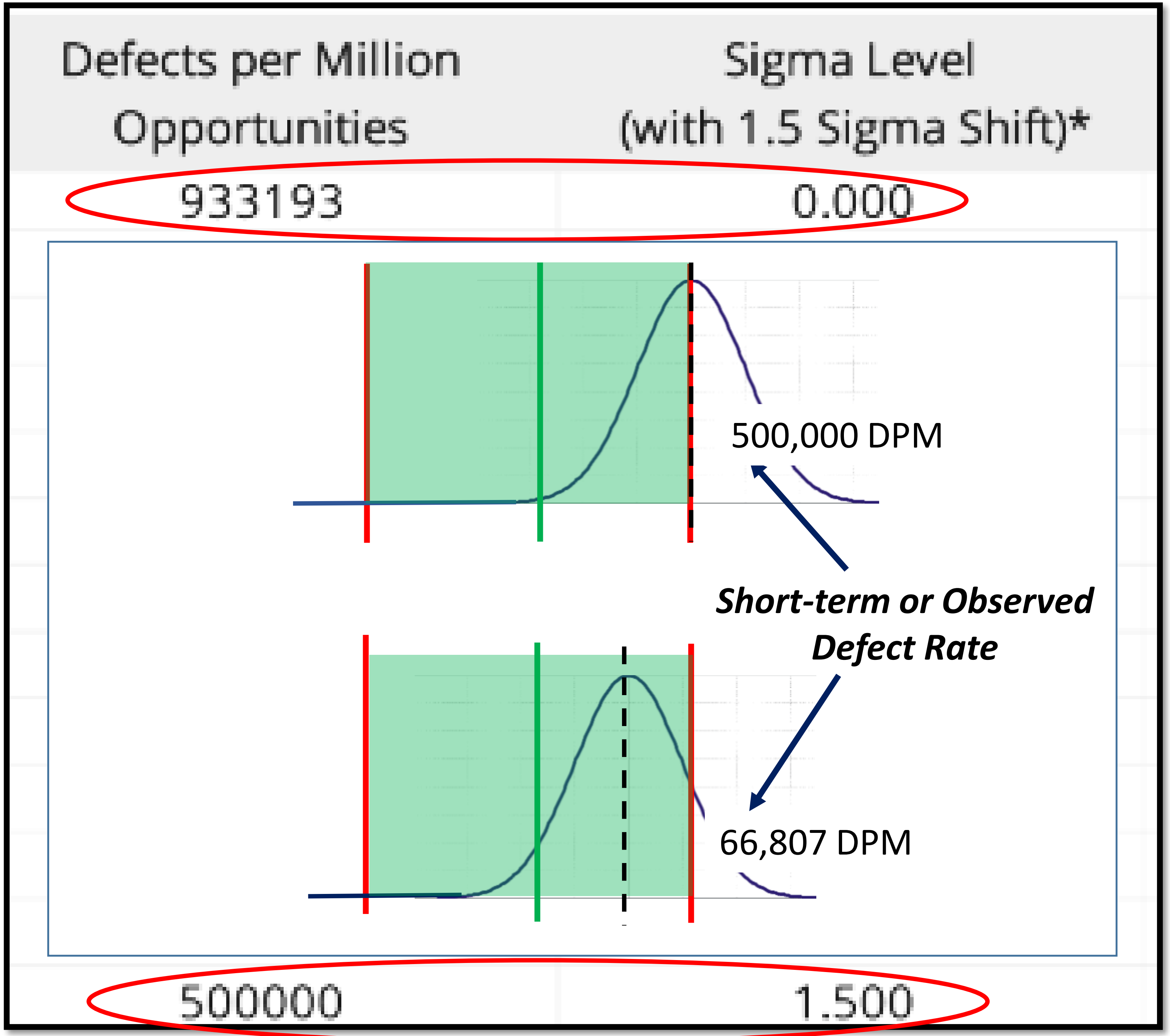
- **Long term**

  What is expected?

Defects per Million Opportunities	Sigma Level (with 1.5 Sigma Shift)*
933193	0.000
915434	0.125
894350	0.250
869705	0.375
841345	0.500
809213	0.625
773373	0.750
734014	0.875
691462	1.000
646170	1.125
598706	1.250
549738	1.375
500000	1.500

Calculated SM corresponds to two defect rates:

- **Short-term DR**
  What did happen?
- **Long term**
  What is expected?



Calculated SM corresponds to two defect rates:

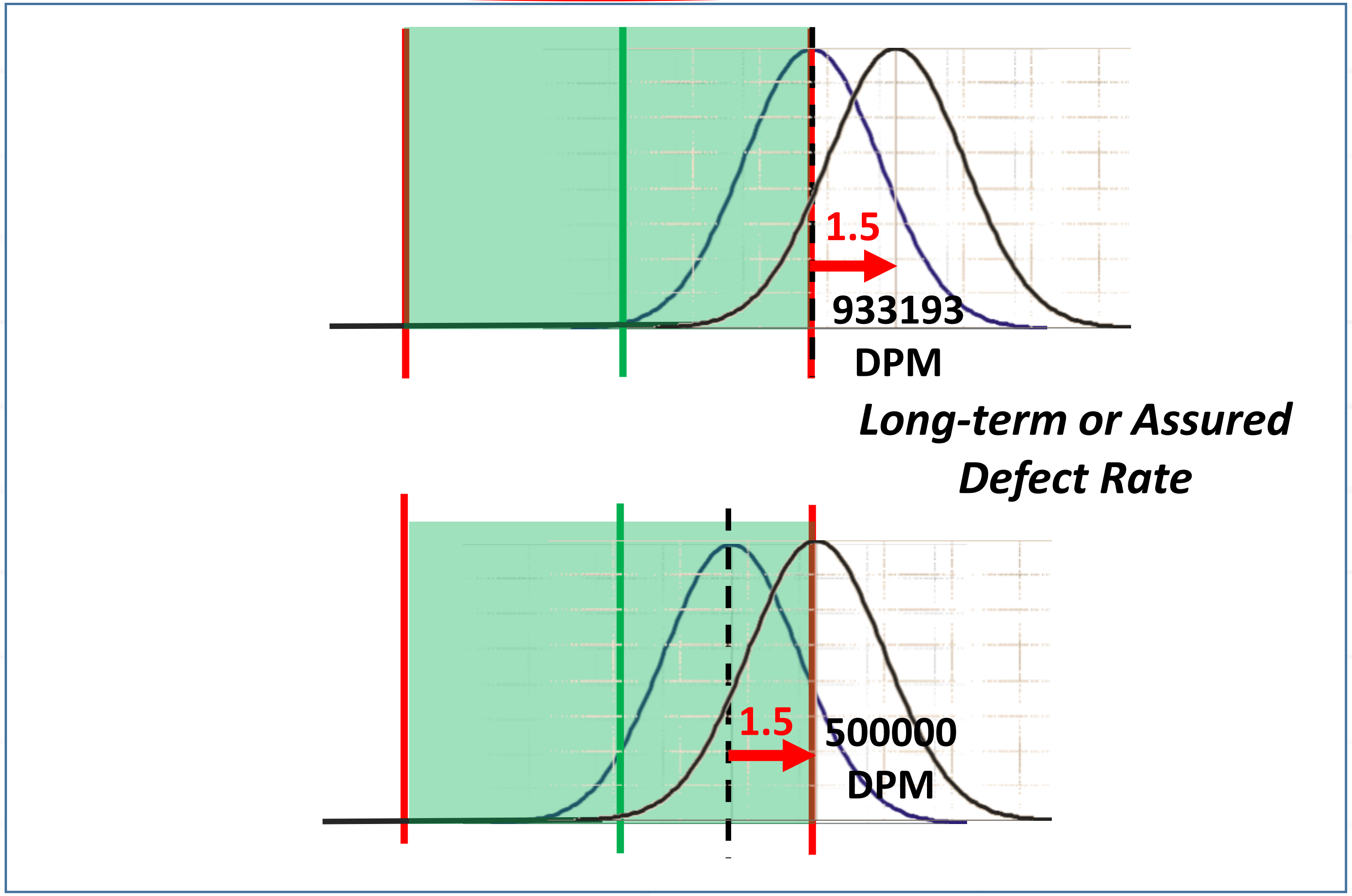
- **Short-term DR**

  What did happen?

- **Long term**

  What is expected?

Defects per Million Opportunities	Sigma Level (with 1.5 Sigma Shift)*
933193	0.000
500000	1.500



7. DR: One-side or Two-side probability?

- **NOTE 7: For calculating long-term DR (e.g. presented in Sigma tables), one-side Gaussian probability is determined.**

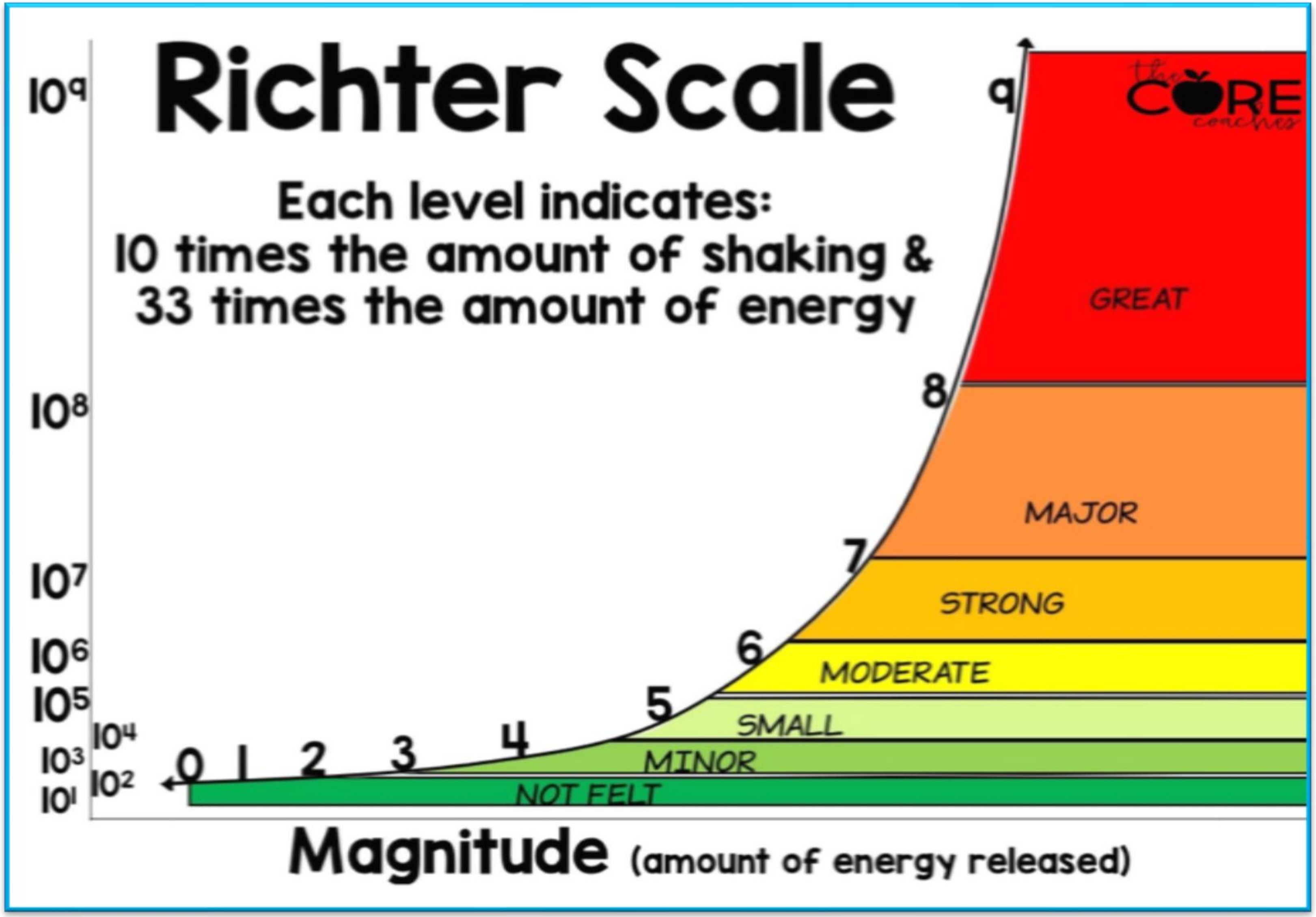
- The long-term DR is calculated assuming 1.5
- When bias>1 SD, the defects at TL away from bias is ignorable
  - For calculating long-term DR, only the tail beyond the TL at bias side matters

Characteristics of Sigma Metric

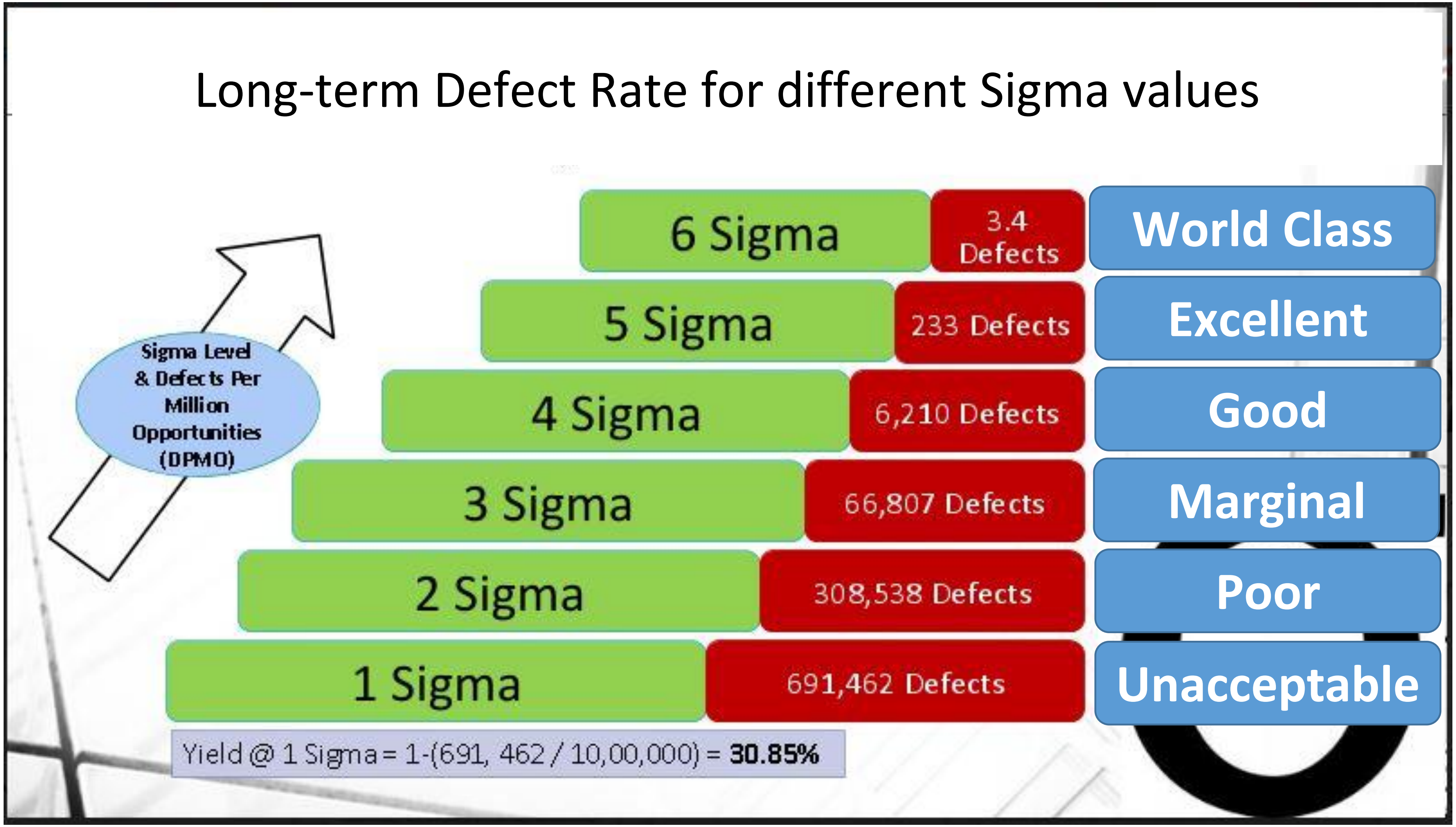
1. SM and DR aren’t linearly related
2. Numerical calculations (+, -, x, ÷) can be done on SM values
3. Zero SM means Bias = TEa and Short-term DR = 50%
4. Negative SM means Bias > TEa and Short-term DR > 50%
5. With biased performance, “(TEa-B)/SD” gives correct SM
6. Long-term DR is calculated by subtracting 1.5 from calculated SM
7. One-side calculation is used to determine long-term DR

Sigma Level or Defect Rate?

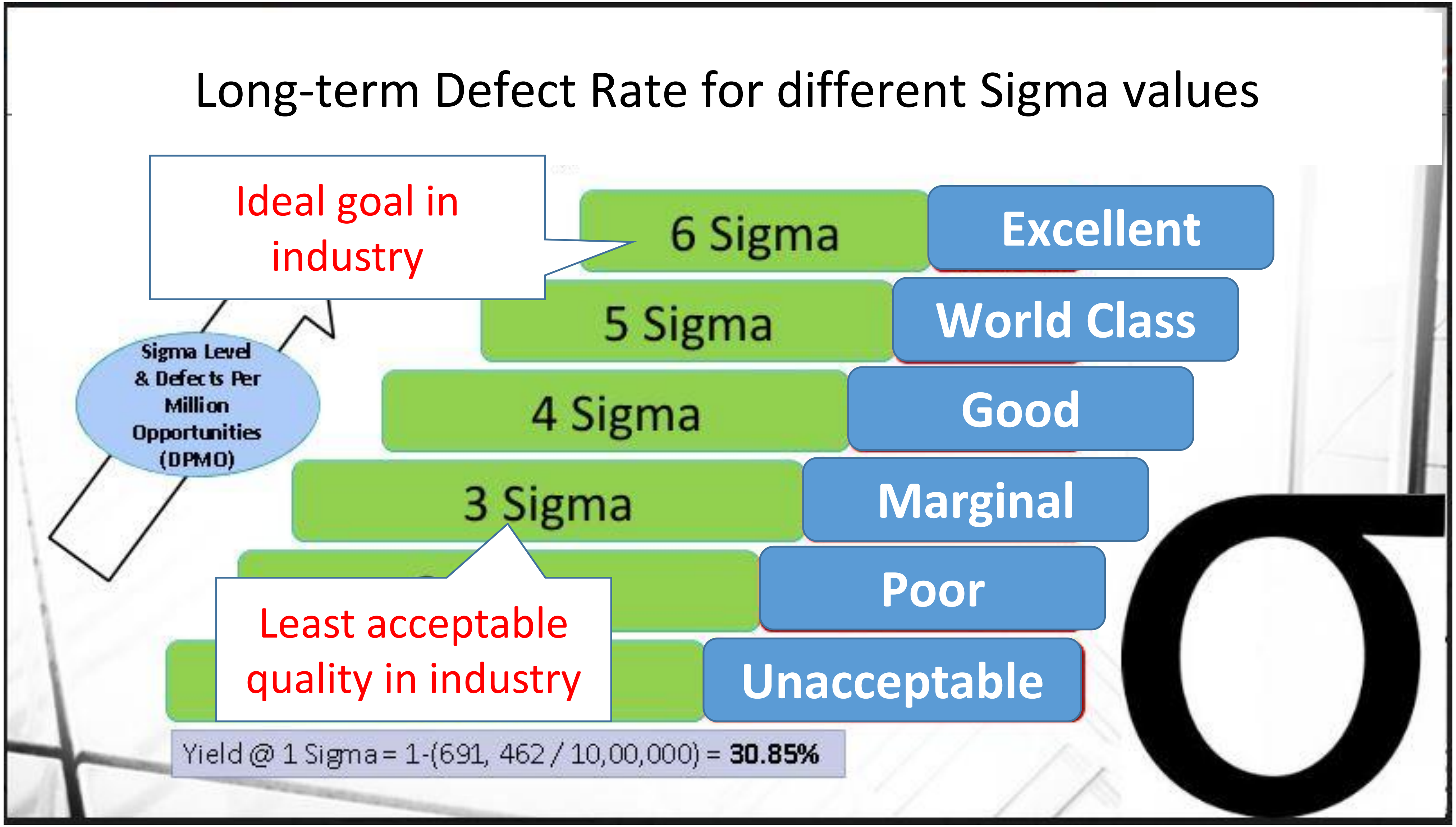
Analogy



Sigma Level Metric or Defect Rate?



Sigma Level Metric or Defect Rate?



Sigma Metric or Defect Rate?

Example:

- ISO 15189:2012; 3-19

  - Quality Indicators: % yield, % defects, DPMO, **Six Sigma scale**

- IFCC-WG on A1C

  - Least acceptable quality of A1C testing: **2 Sigma** for routine testing and **4 Sigma** for clinical trials

Applications of Sigma Metric

1. Goal Setting; Least acceptable SM, SMa

- In the TE model, **‘TE = B + 2SD’** corresponds to the least acceptable quality is **2 Sigma**
- Also **‘TE = B + 3SD’** and **‘TE = B + 4SD’** are recommended that correspond to the least quality of **3 Sigma** and **4 Sigma**
- **Motorola goal: 6 Sigma**
- **ISO 15189** proposes SM as QI
- **Expert groups** such as the IFCC-WG A1C set goals as least acceptable Sigma

Applications of Sigma Metric

2. Method Evaluation; Performance SM

- If SM ≥ SMa → Acceptable

Example; A1C

- SMa = 2 for routine and 4 for clinical trials
- TEa = 5 mmol/mol
- Bias = -0.5 mmol/mol
- SD = 1.5 mmol/mol
- SM = 3

Decision? Acceptable for routine testing, but not for clinical trials

Applications of Sigma Metric

3. QC planning

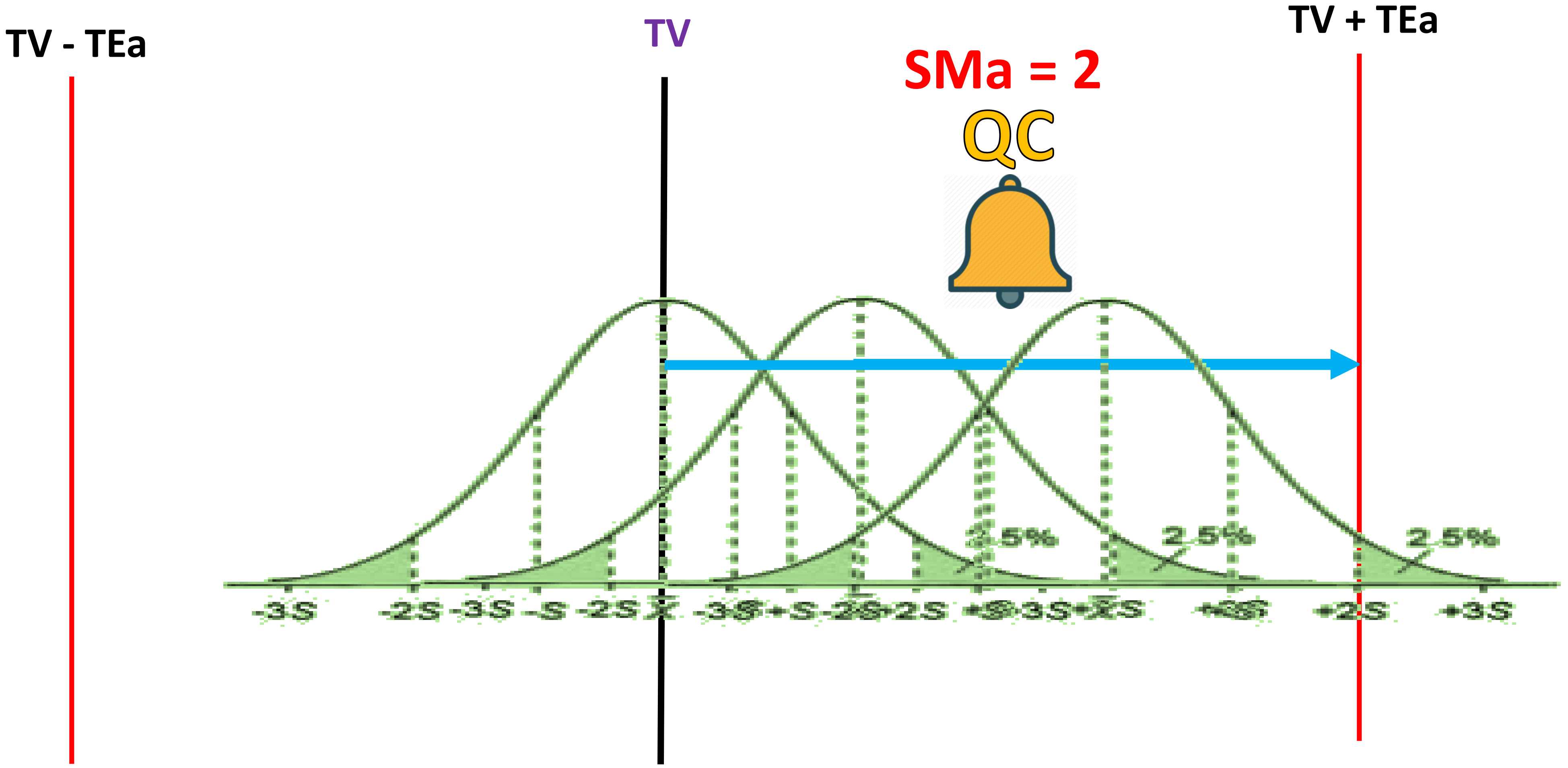
- QC strategies are established to reject performance when quality is less than least acceptable Sigma
- The difference between stable SM and SMa is the most tolerable shift; **Critical Shift**:

$$\text{Shift}_{crit} = \text{SM} \rightarrow \text{SMa}$$

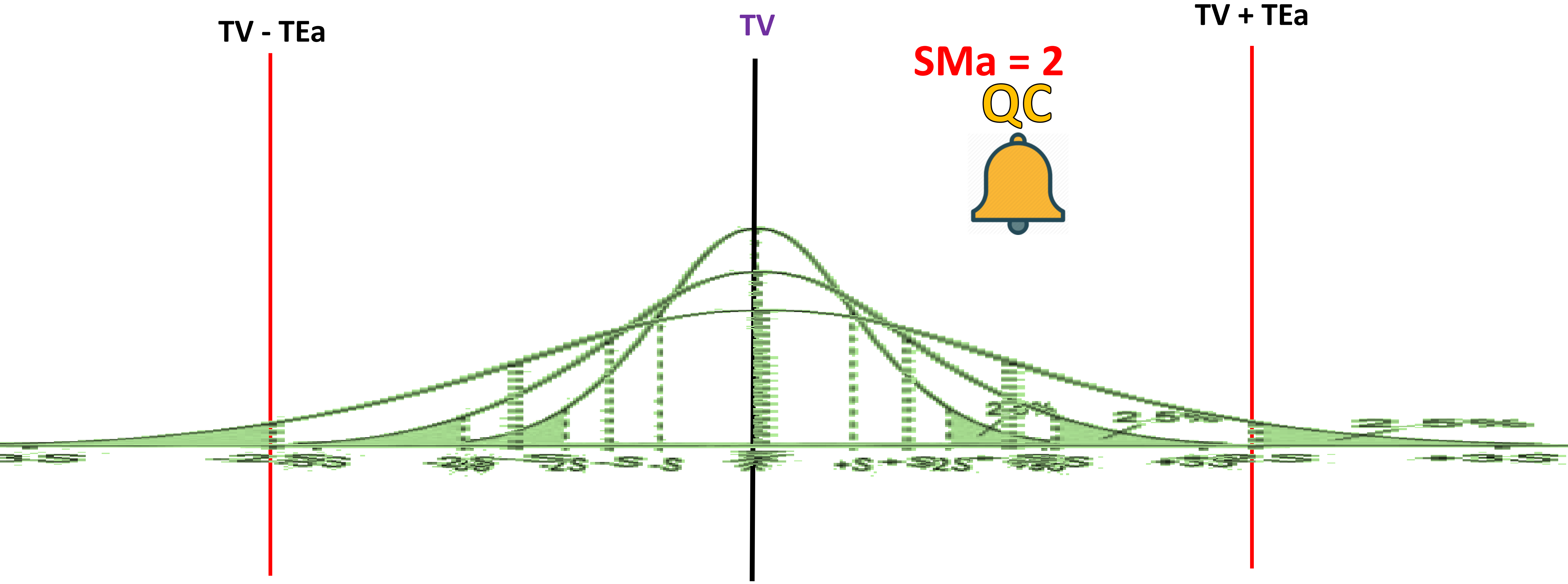
- A certain shift results in more increased defects in a low sigma method than in a high Sigma method

Different SMs → Different critical shifts → Different QC strategies

SM-individualized QC plans



1. Systematic Error: Shift in Calibration



2. **Random Error:** Increase in Imprecision

Example

- The further from edge, the more safety margin (the safer)
- The more safety margin, the less surveillance

1. SE

Example

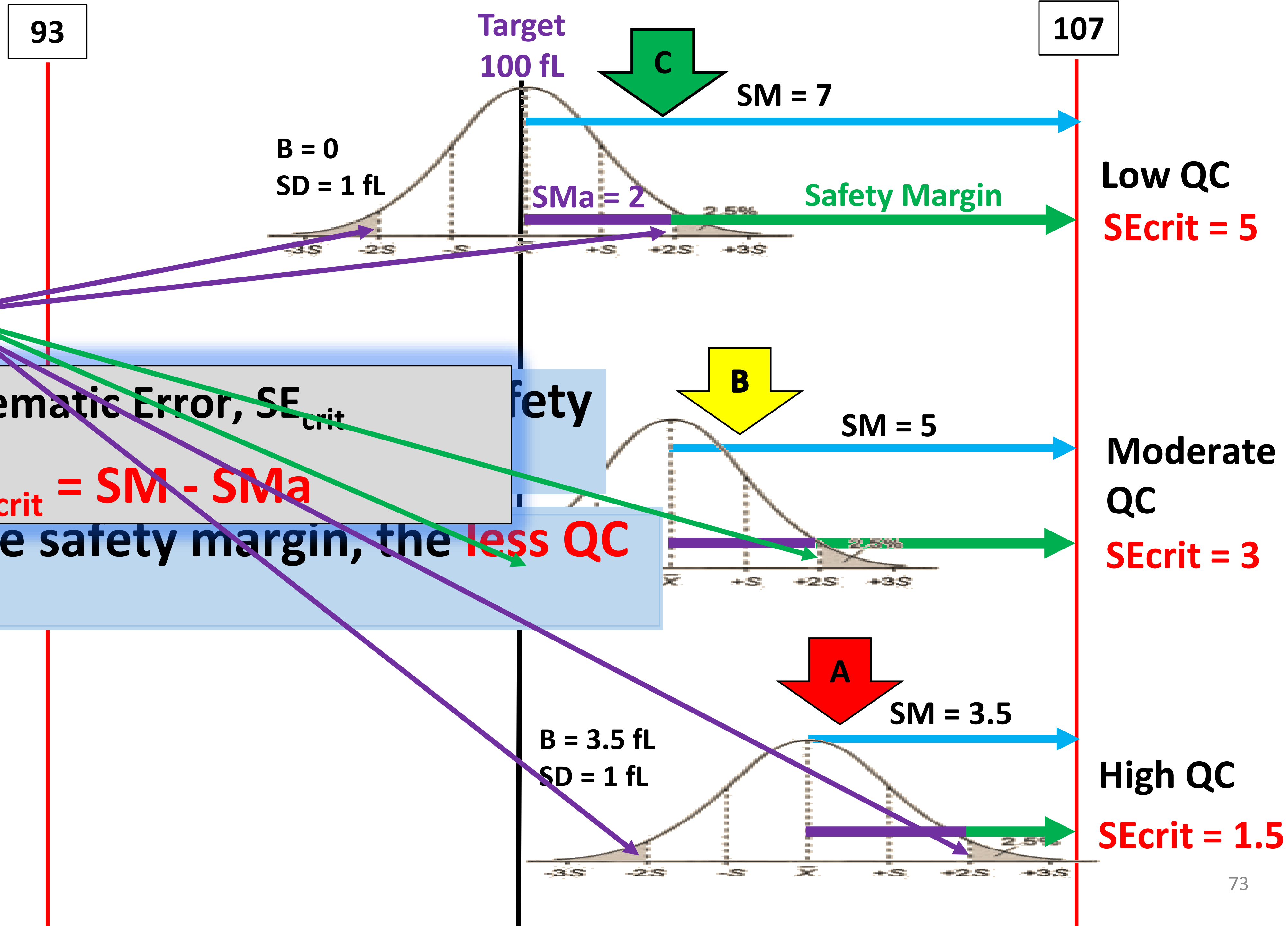
MCV assay

- TEa = 7%
- SMa = 2

Critical Systematic Error, SE_{crit}

$$SE_{crit} = SM - SMa$$

✓ The more safety margin, the less QC

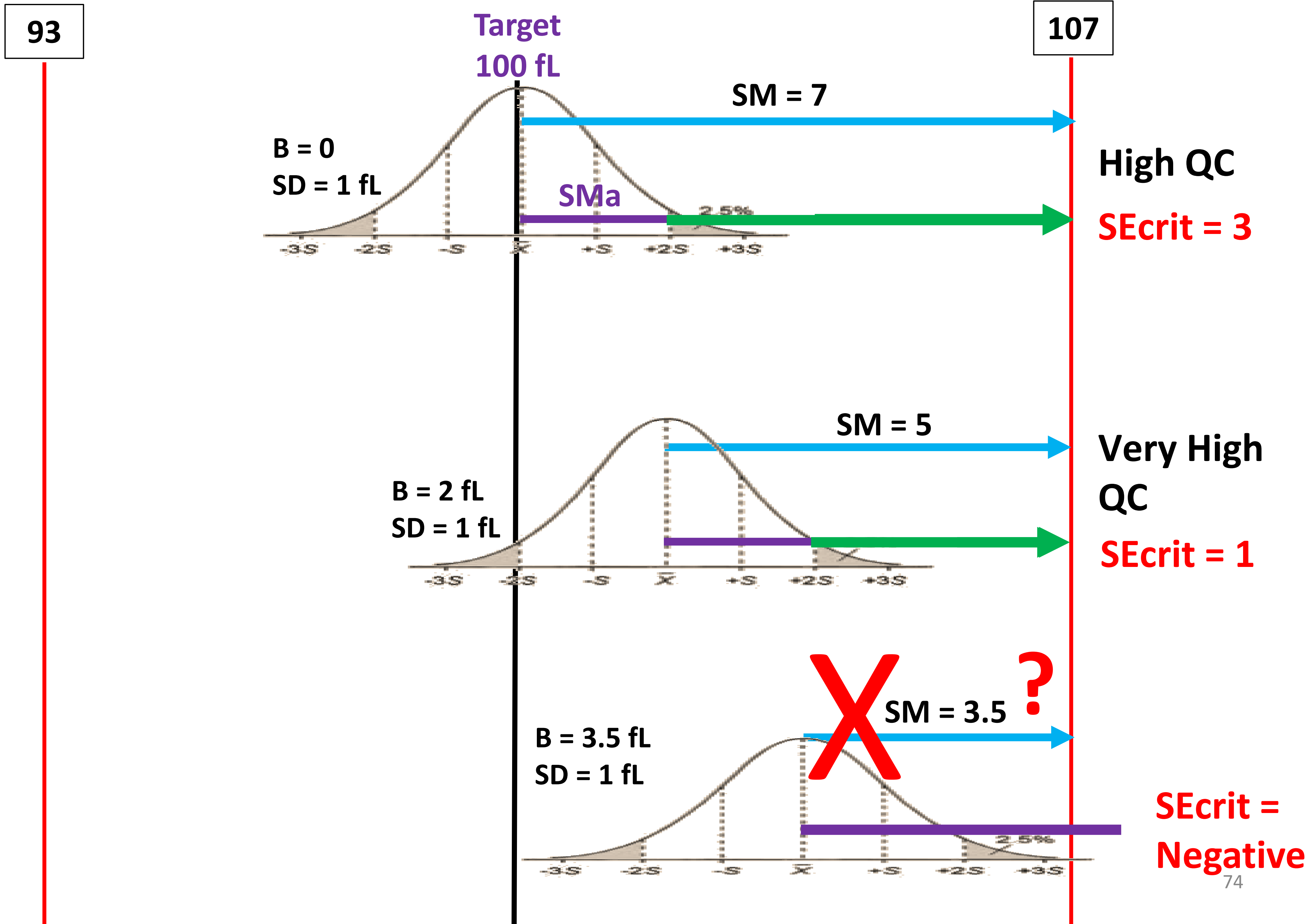


1. SE

Example

MCV assay

- **TEa = 7%**
- **SMa = 4**



2. RE

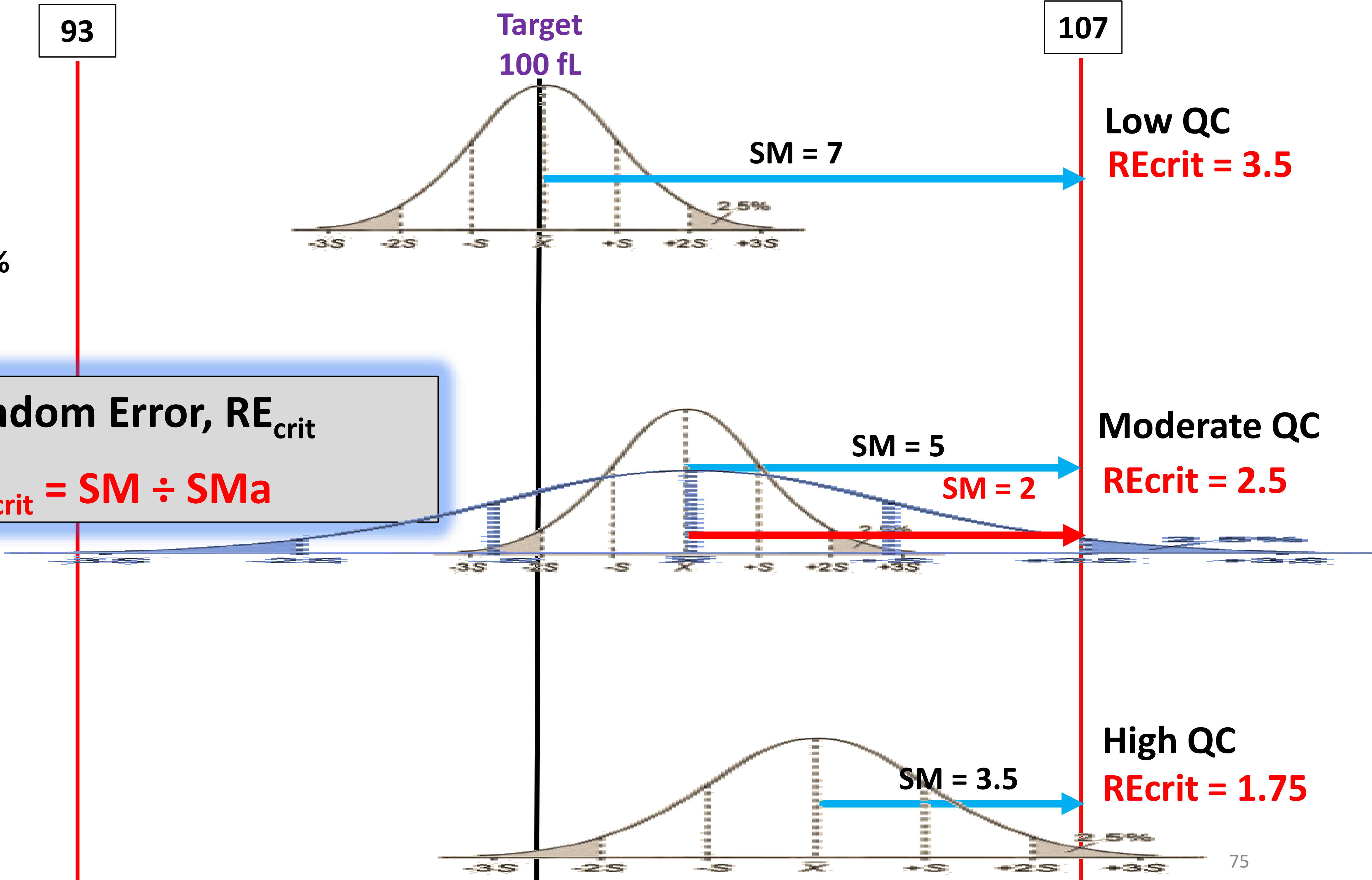
Example

MCV assay

- TEa = 7%
- SMa = 2

Critical Random Error, RE_{crit}

$$RE_{crit} = SM \div SMa$$



2. RE

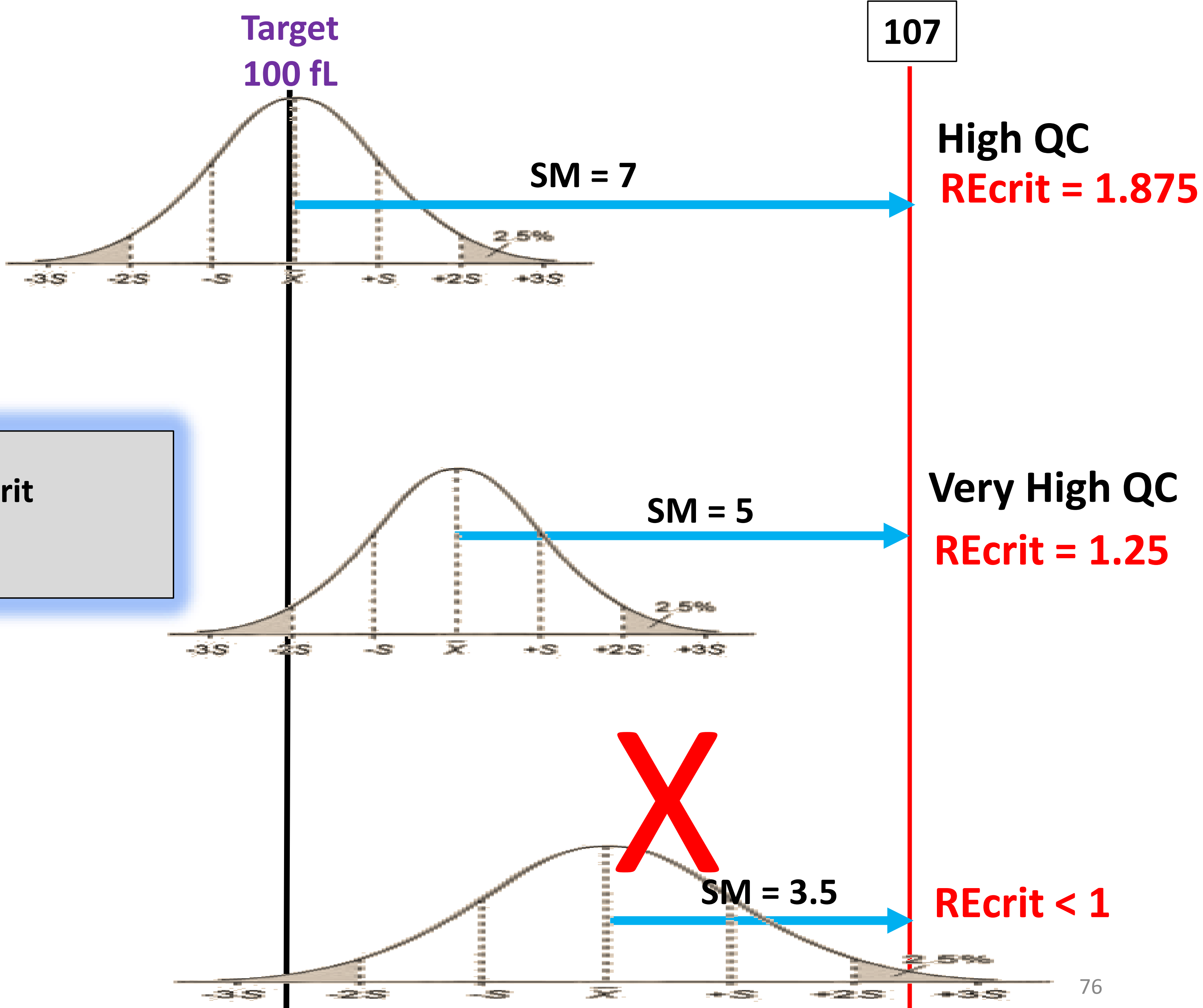
Example

MCV assay

- **TEa = 7%**
- **SMa = 4**

Critical Random Error, RE_{crit}

$$RE_{crit} = SM \div SMa$$



Power Graphs: Tool for choosing appropriate QC

Example

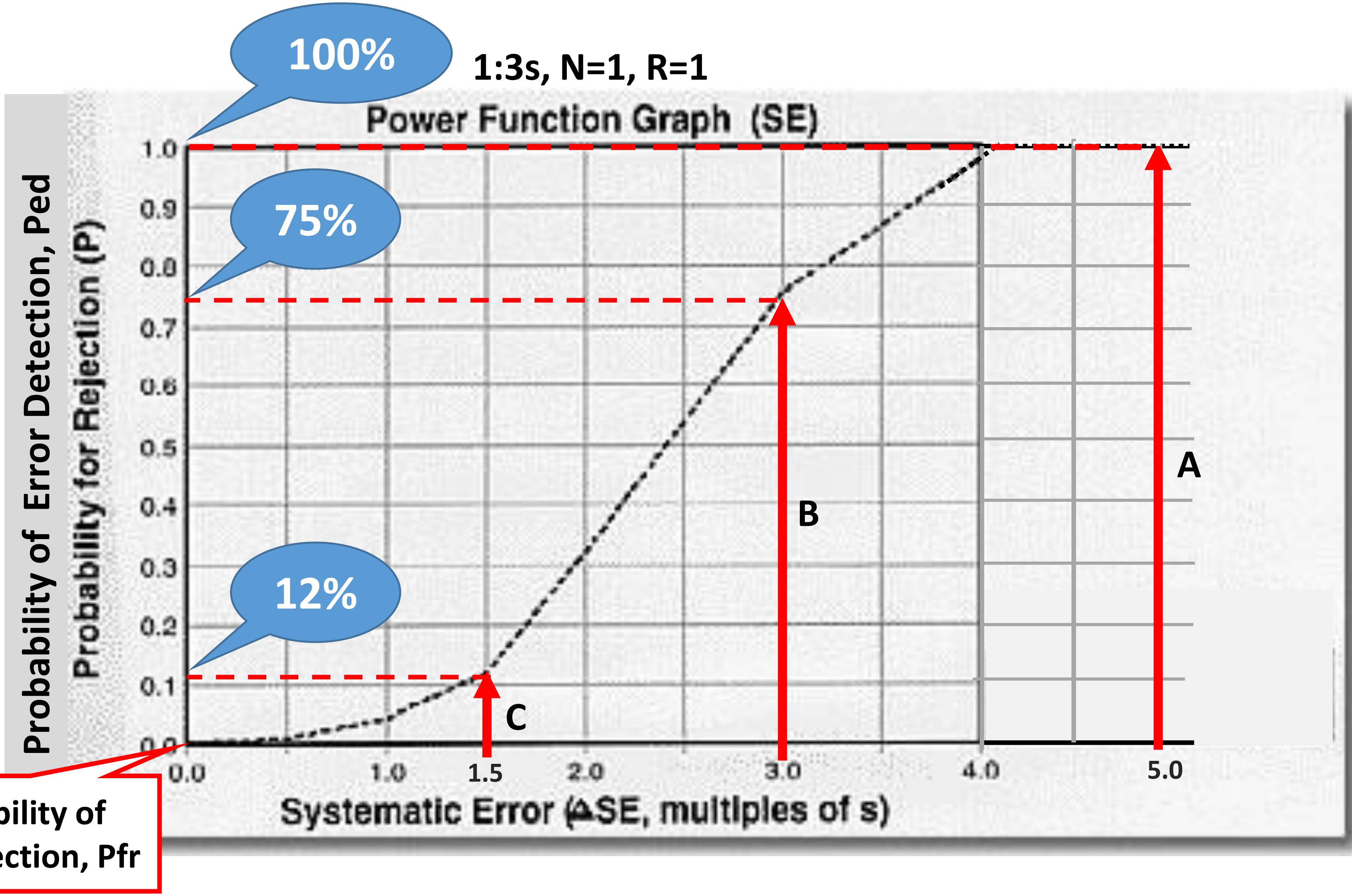
SMa = 2

A. SM=7, SEcrit=5
B. SM=5, SEcrit=3
C. SM=3.5, SEcrit=1.5

Q: Appropriate Ped?

A: Ped ≥ 90% & Pfr ≤ 5

Q: For which performance is this QC appropriate?



Power Graphs

Example

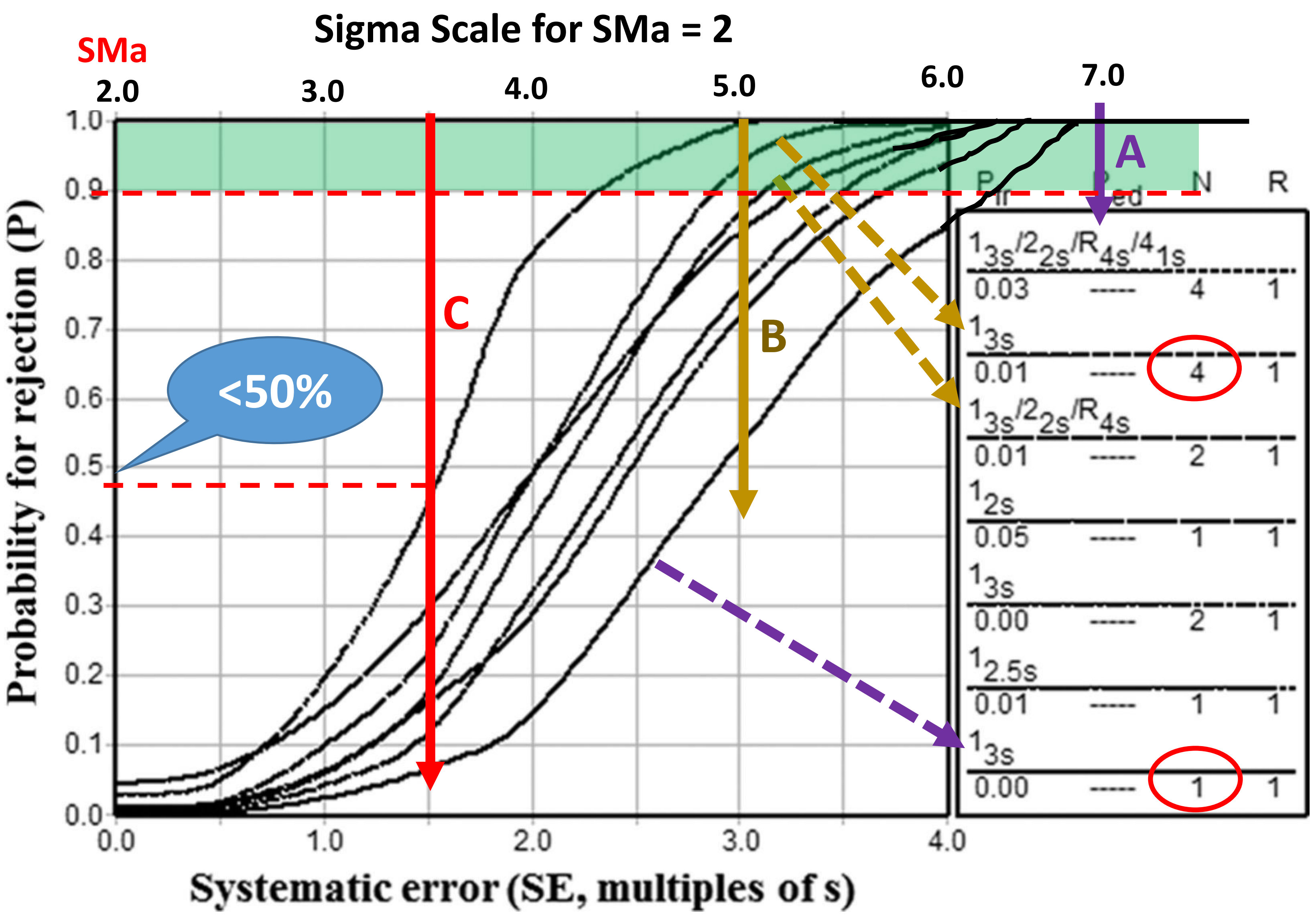
A1C in **routine** testing

SMa = 2

A. SM=7

B. SM=5

C. SM=3.5



Power Graphs

Example

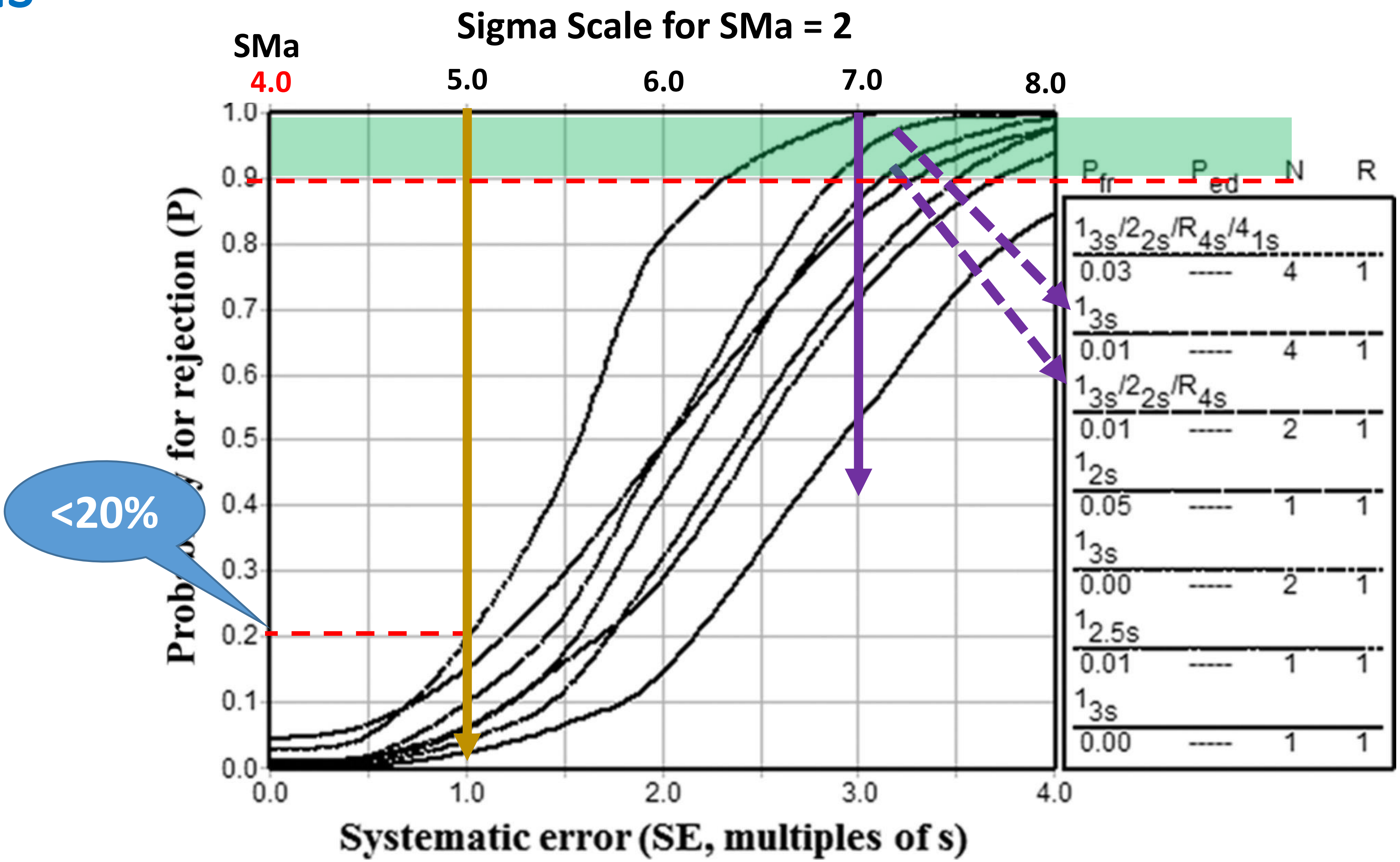
A1C in **Clinical Trials**

SMa = **4**

A. SM=7

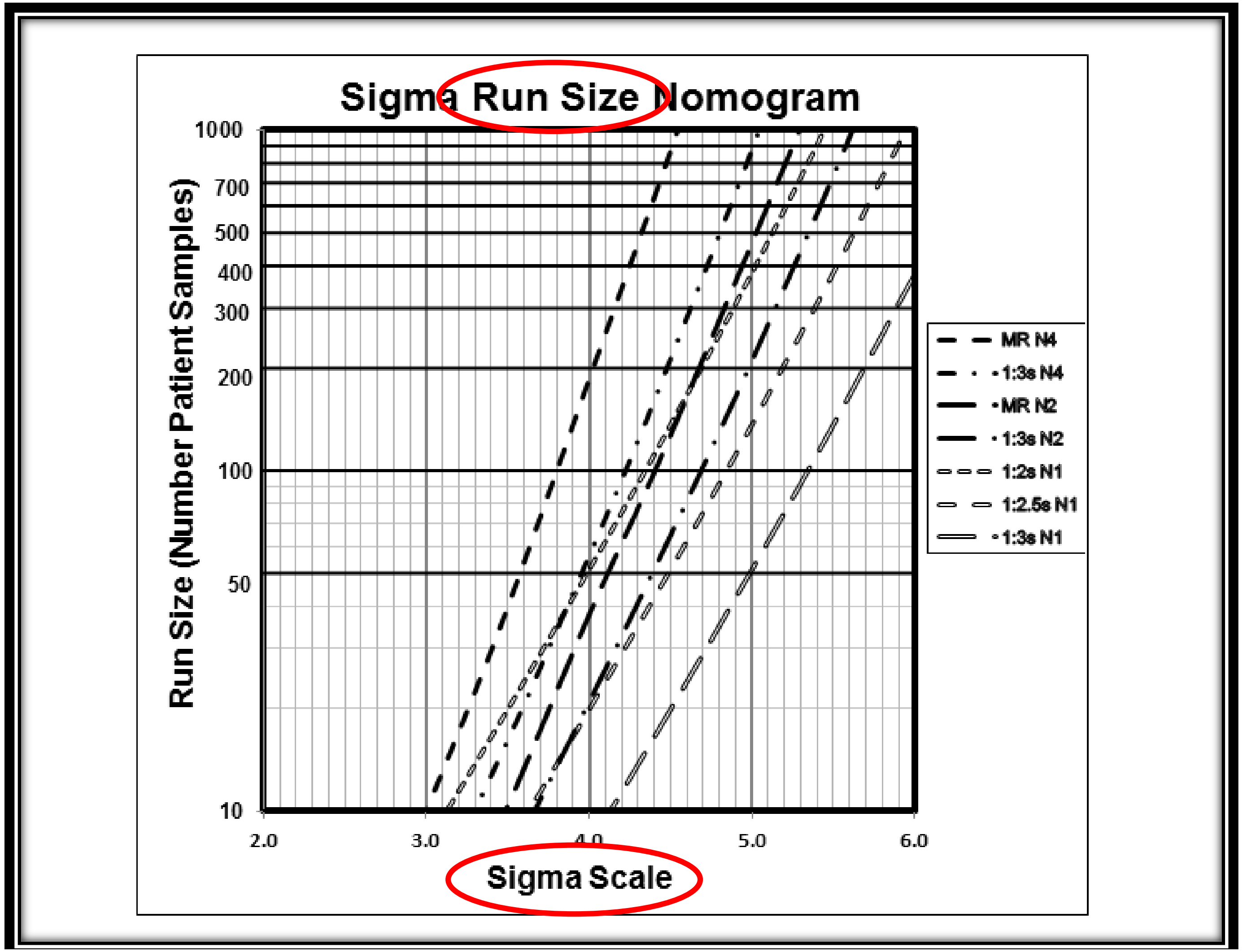
B. SM=5

C. SM=3.5 ✗



Sigma Metric & Max E(Nuf) QC model

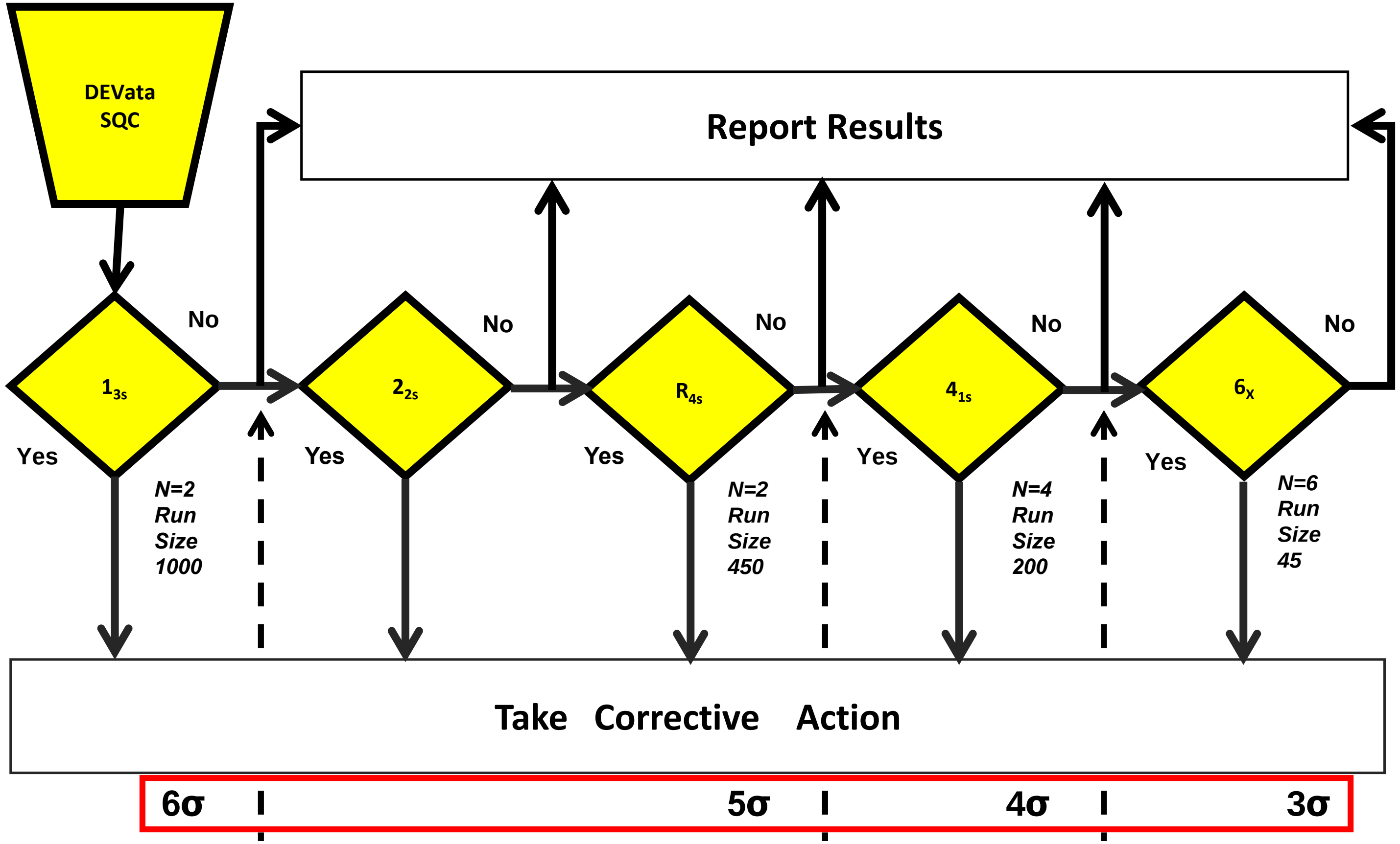
➢ **Optimizing Run Size based on Sigma**



Planning Risk-based SQC Schedules for Bracketed Operation of Continuous Production Analyzers. Westgard JO, Bayat H, Westgard SA

Clinical Chemistry Feb 2018, 64 (2) 289-296

Westgard Sigma Rules® with Run Sizes



- **SM-individualized QC:**

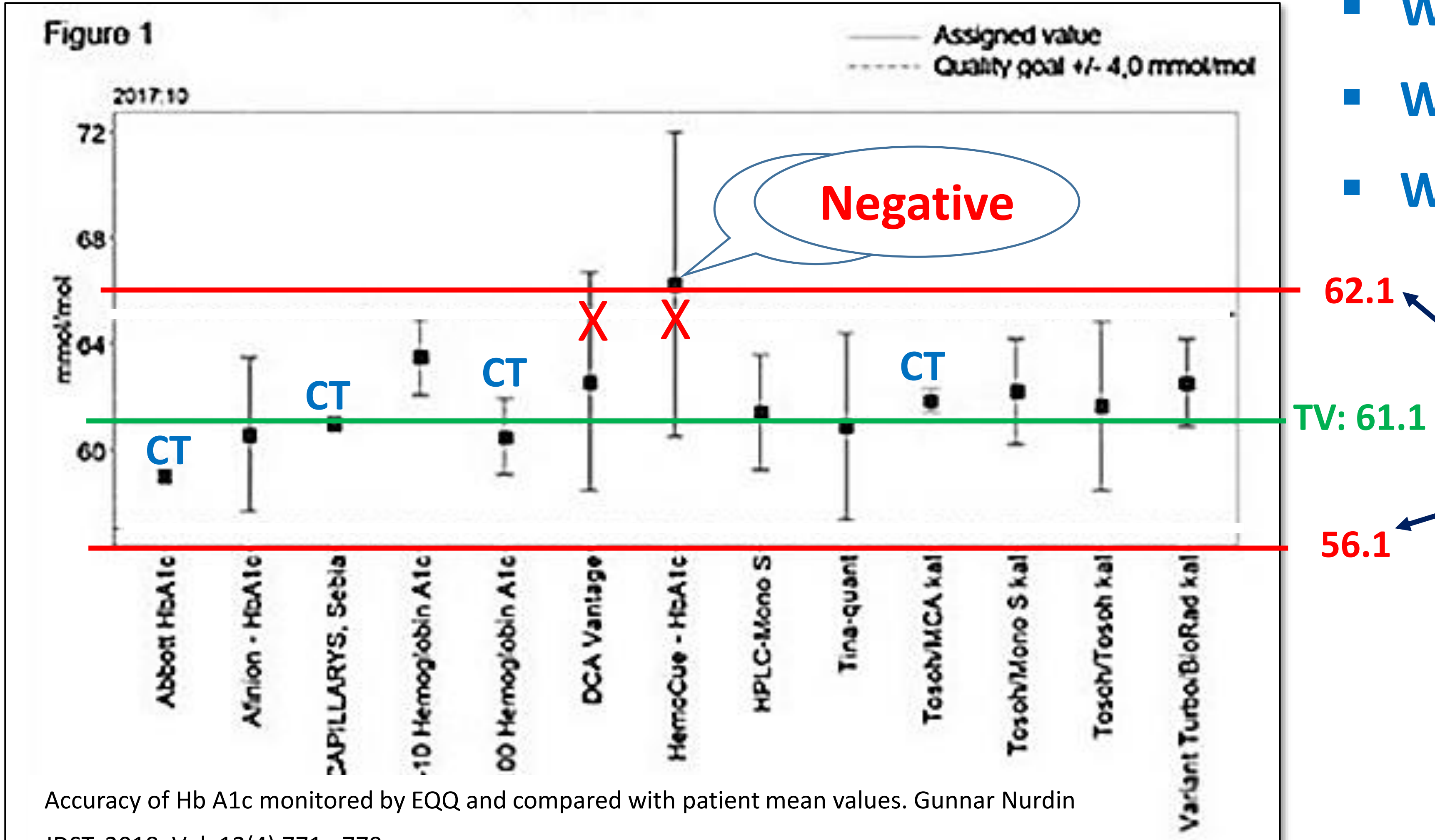
Using SM for planning individualized QC Strategies ***N, R, Rules, Number of Rules, Run size***

Establishing Evidence-Based Statistical Quality Control Practice. Westgard JO, Westgard SA.

Am J Cling Pathol 2018

Applications of Sigma Metric

4. EQAS



Accuracy of Hb A1c monitored by EQQ and compared with patient mean values. Gunnar Nurdin

JDST. 2018, Vol. 12(4) 771 –779

Question:

- Which for Routine testing?
- Which for Clinical Trials?
- What about QC?

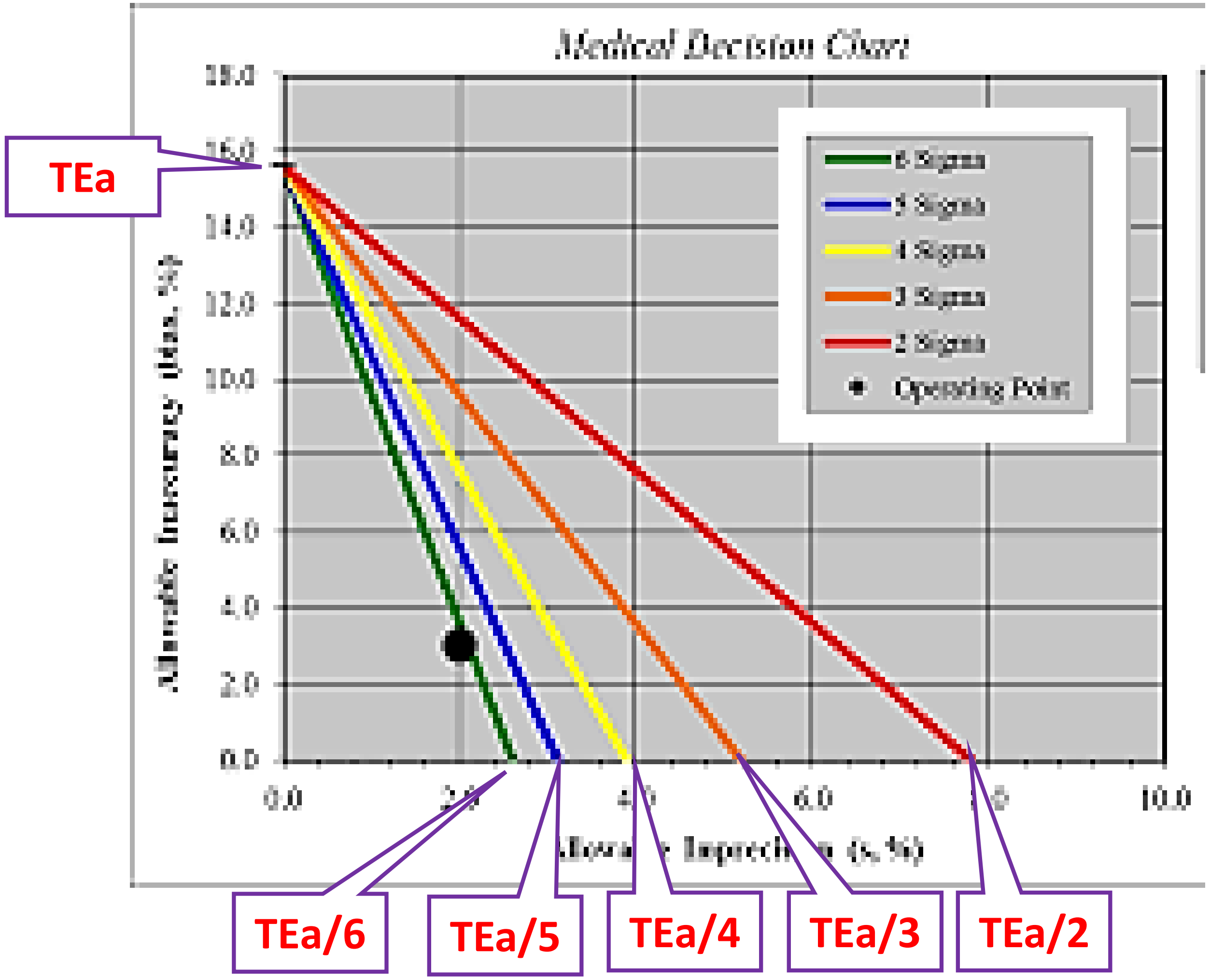
IFCC –WG A1C

- TEa = 5 mmol/mol
- SMa:
  - Routine = 2
  - Clinical Tr. = 4

5. Improving Performance

Sigma Decision Charts

- Bias vs SD
- Operating Point

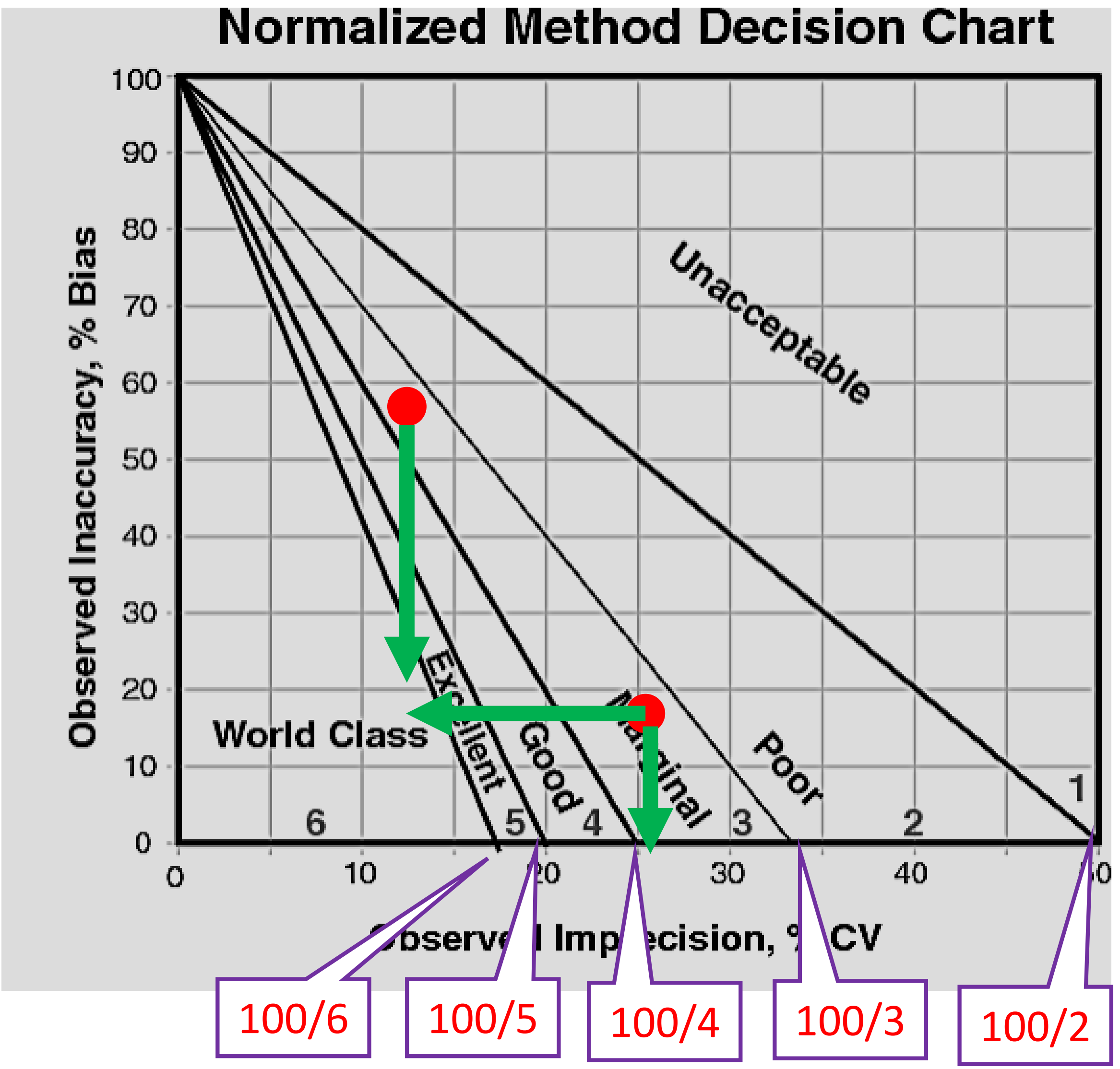


Applications of Sigma Metric

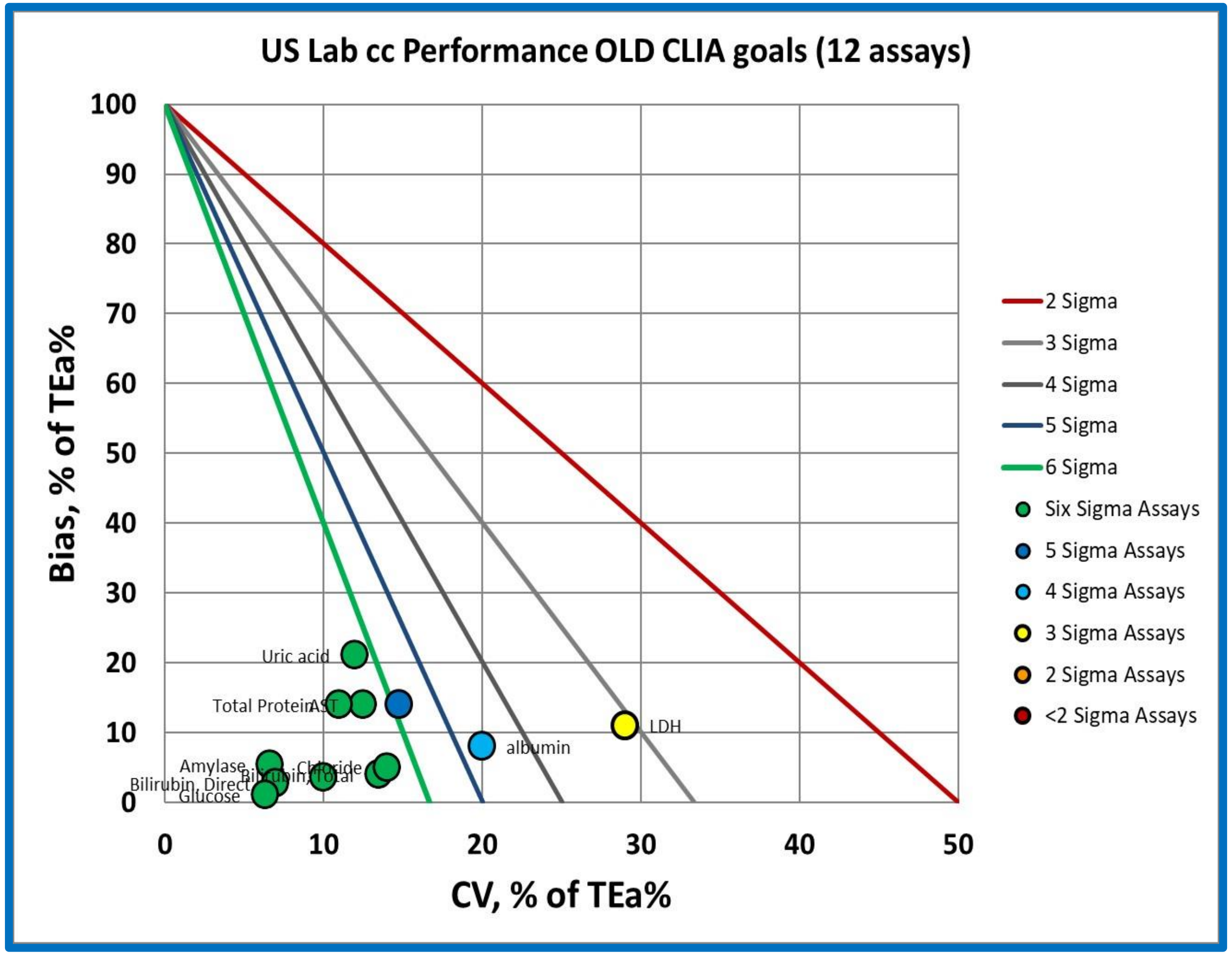
5. Improving Performance

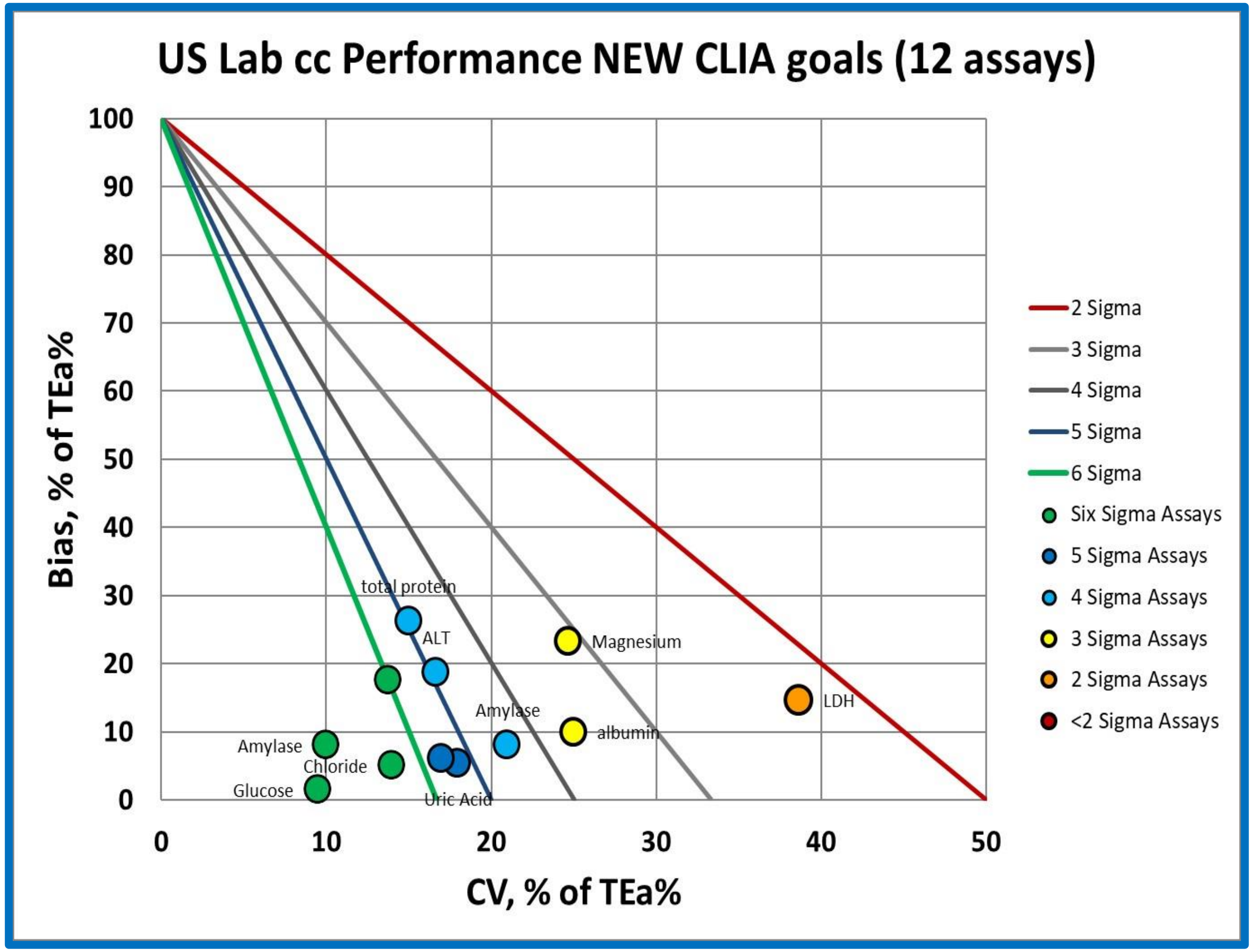
Normalized Sigma Decision Charts:

- B/TEa% vs SD/TEa%
- Differentiae between the effects of bias and imprecision on SM
- Compare different performances
- Which influence factor (B or SD) must be decreased to improve performance



Normalized Sigma Decision Charts
Comparison of Different APS





1.5 SD shift in Medical Laboratory?

Shifts assumed in Six Sigma:

- the worst case shift is 1.5 SD
- revers by themselves

Shifts in Medical Laboratory:

- are **not always** less than 1.5 SD
- **do not reverse** by themselves
- we use **QC** to detect **critical** shifts and fix them

Example:

Worst Quality

$6\sigma \xrightarrow{-3.7} 2.3\sigma$

$5\sigma \xrightarrow{-3.7} 1.3\sigma$

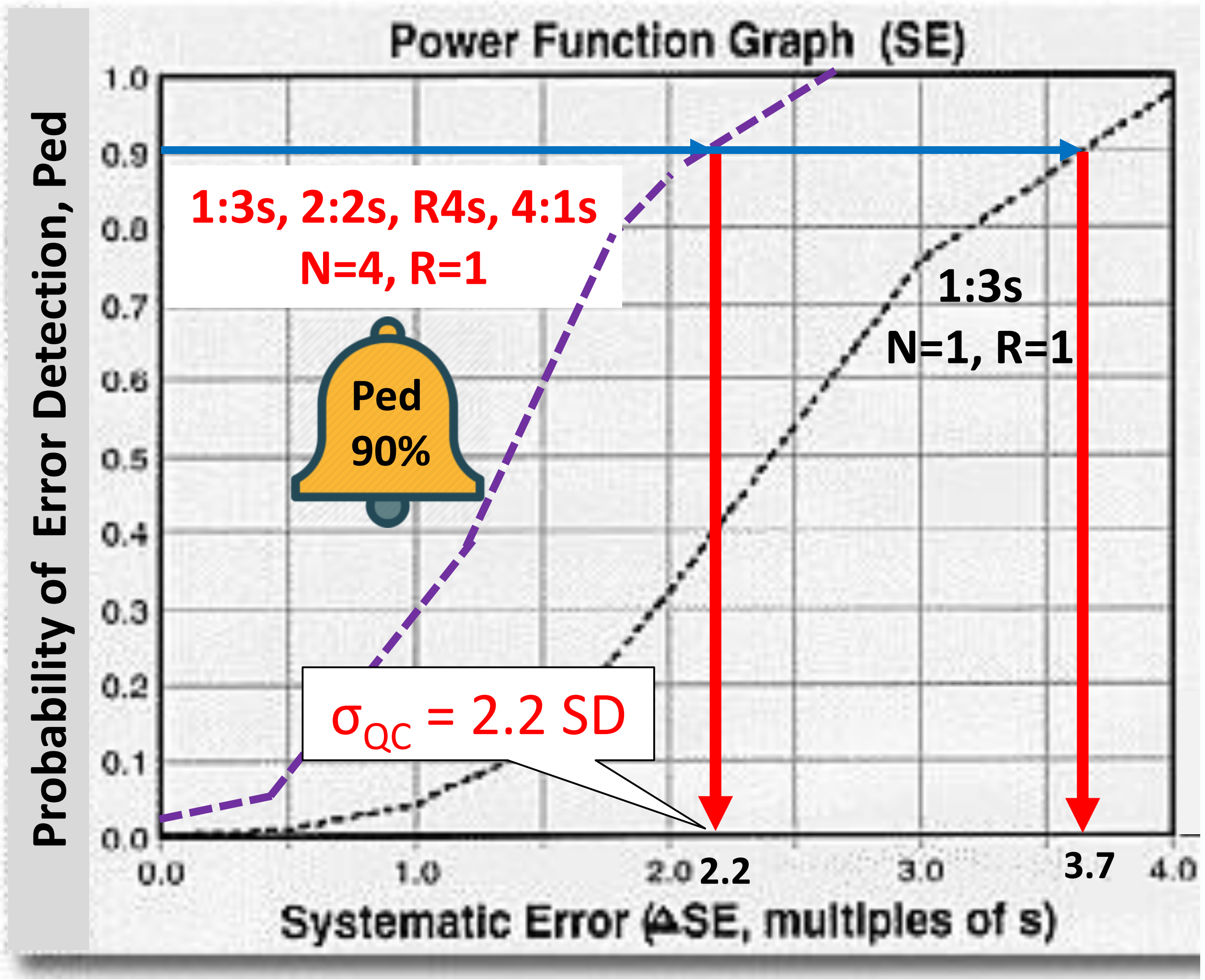
$3.5\sigma \xrightarrow{-3.7} -0.2\sigma$

σ_{QC}

Shift necessary for QC to reach the intended Ped

Worst SM = SM - σ_{QC}

Stable SM	Stable DR
6 σ	0.002
5 σ	0.3
3.5 σ	233



The more powerful is QC, the lower is the shift necessary to reach the intended Ped

1.5 SD shift in Medical Laboratory?

	Defect Rate		
		Worst Case	
SM	Stable State (No Shift)	1:3s N1; R1 (σ_{QC} = 3.7)	1:3s, 2:2s, R4s, 4:1s N=4, R=1 (σ_{QC} = 2.2)
6 σ	0.002	10700	72
5 σ	0.3	96800	2555
3.5 σ	233	508000	96800

- Even with the practically toughest QC, long-term DR is much more than expected in Six Sigma methodology (assuming 1.5 SD shift as the worst case)!

- Long-term Defect Rate is determined by the sensitivity of QC (i.e. σ_{QC}), not 1.5 SD shift

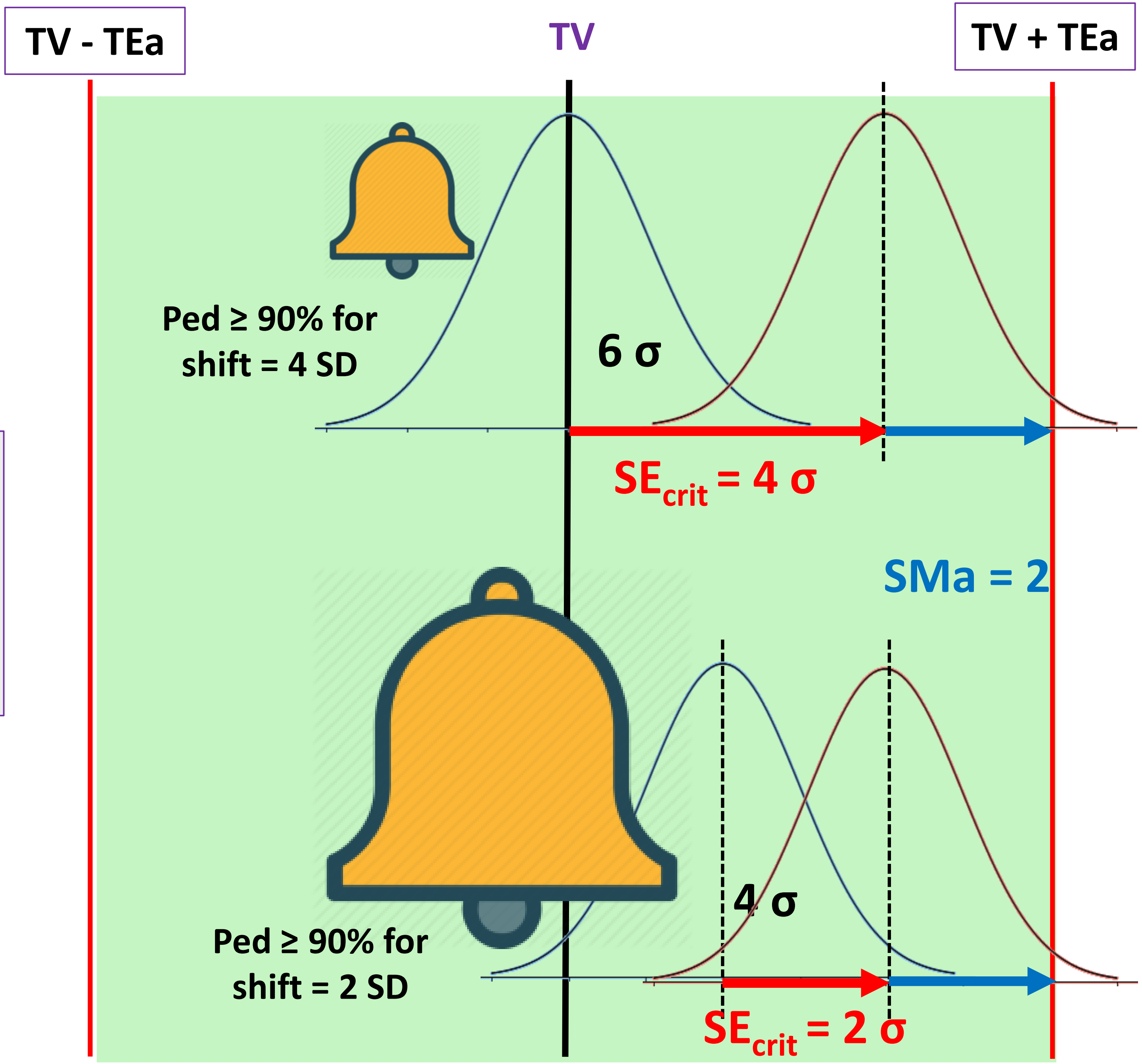
Example

Defect Rate (DPM)		
	Stable State	
6 σ	0.0002	
4 σ	1350	

right QC

Reaches the intended Ped at SE_{crit};

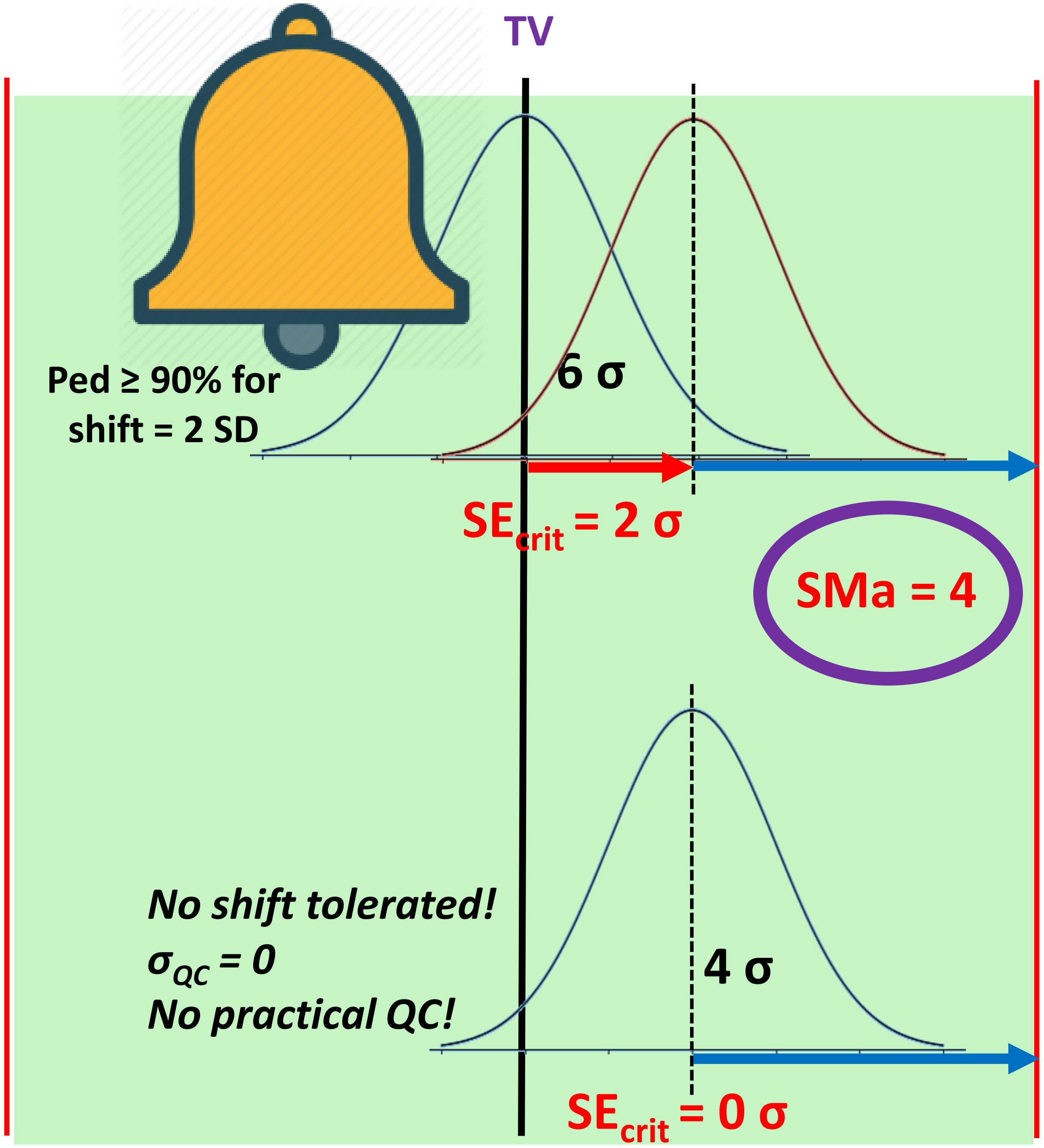
$$\sigma_{QC} = SE_{crit}$$



Example

Sigma Level	Defect (DPM)	
	Stable State	Worst Case
		SMa = 2
6 σ	0.0002	22750
4 σ	32	22750

With right QC, Long-term Defect Rate is determined by the least acceptable quality, i.e. SMa.



Short-term/Long-term: Equivalent terms in medical laboratory

Short-term DR

Stable/Observed DR

- Determined by stable performance
- DR = P(Z>SM)

Long-term DR

Worst/Assured DR

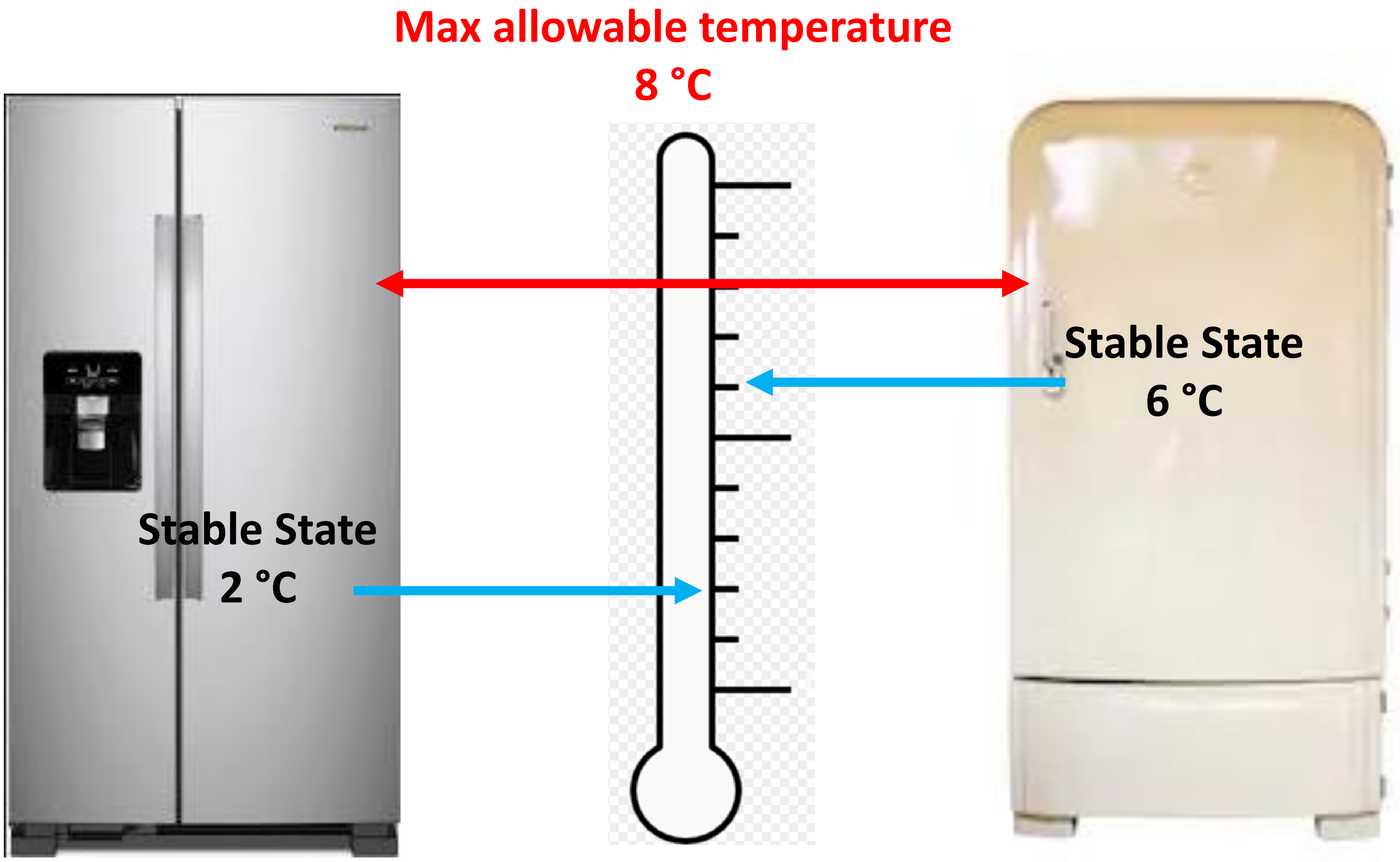
- Determined by QC abil
- P(Z>(SM – σ_{QC})

Risk based QC planning
CLSI; C24 (2016)

➢ ***Degree of risk for patients is determined by the ability of QC***

Expected long-term defect rate of analytical performance in the medical laboratory: Assured Sigma vs. observed Sigma

*Biochem Med (Zagreb) 2018;28(2):**020101.** https://doi.org/10.11613/BM.2018.020101*


Max allowable temperature
8 °C
Stable State
2 °C
Stable State
6 °C

Short-term/Long-term: Practice in medical laboratory

- Evaluate performance

  Determine Bias & SD

- Calculate SM
- Is SM > SMa?
- If yes, Plan ***right*** QC strategy to assure SMa

FORGET 1.5 SD ASSUMED SHIFT!

Teşekkürler