

Six Sigma Quality

New Metrics vs Old Myths

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<http://www.westgard.com/sixsigprimer.htm>

Myths vs Metrics

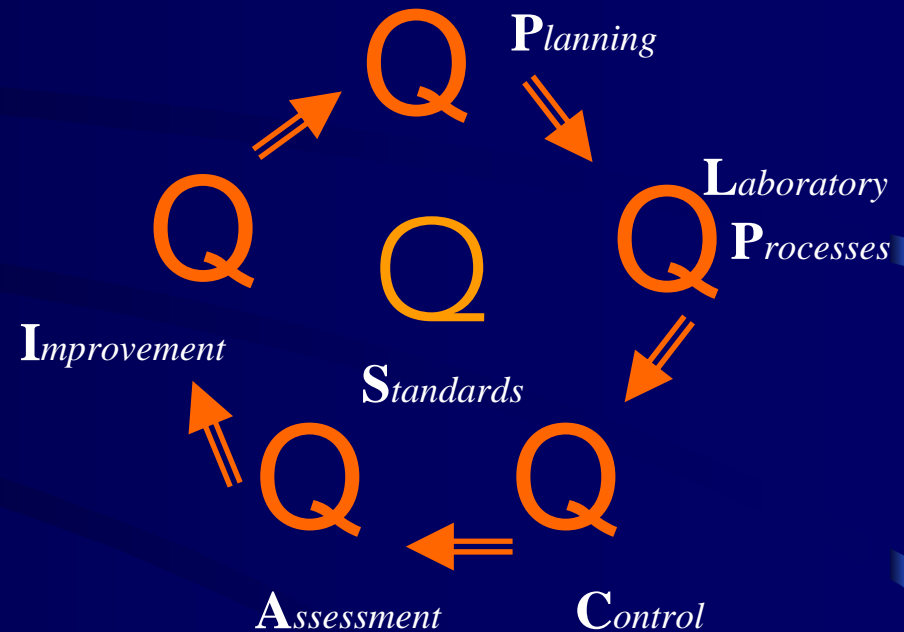
- Analytical performance is better than needed for medical purposes!
 - What metrics describe performance?
- There is no need for further improvement in test performance!
 - What quality is needed for lab tests?
- Minimal QC to be in compliance with CLIA is still too much QC!
 - What QC is appropriate based on the quality needed and the performance observed?

What is Six Sigma Quality Management?

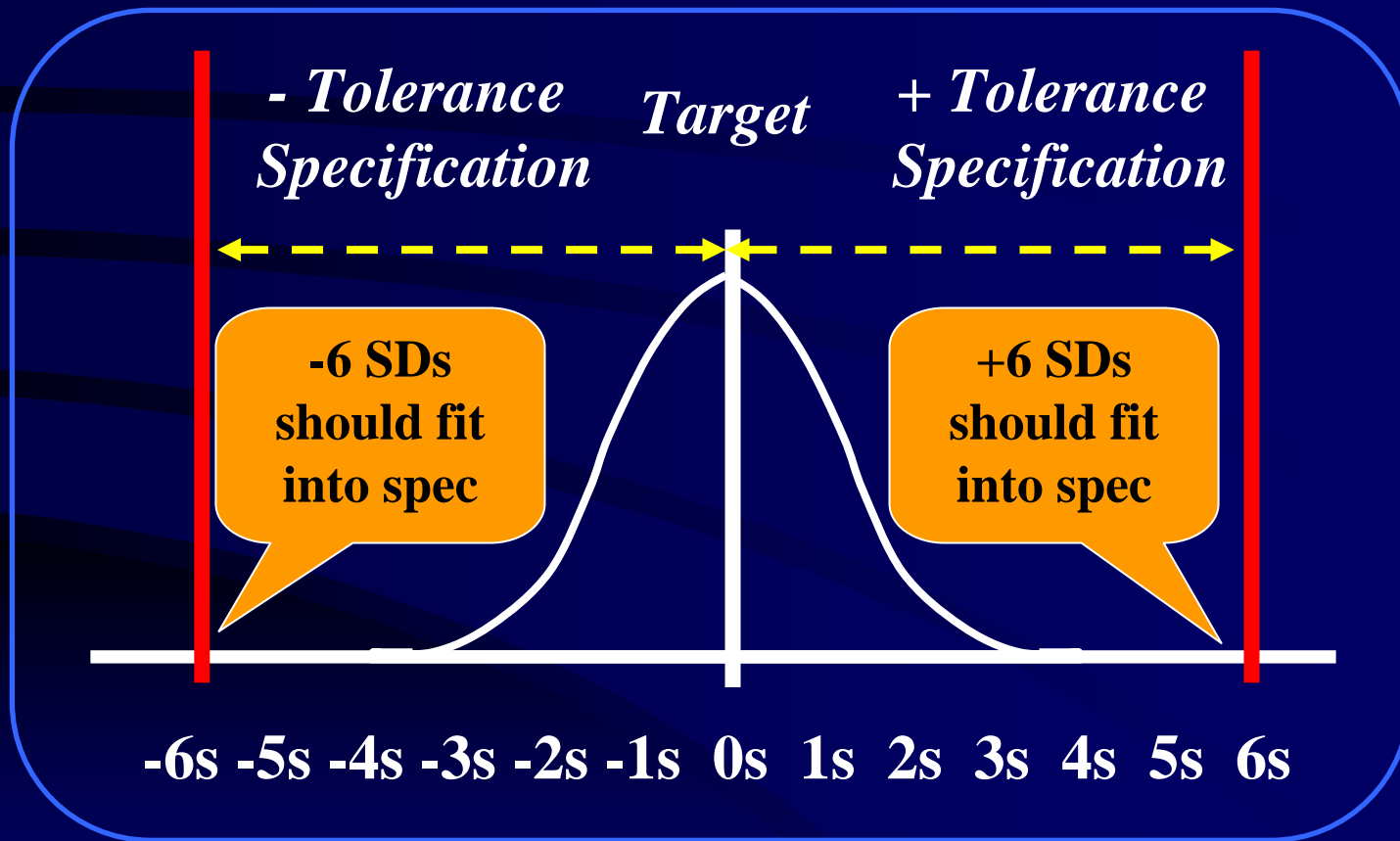
- Latest version of Total Quality Management
- Major improvements include
 - Quantitative goal for process performance
 - Achieve “six sigma” performance
 - Universal measure of process performance
 - Measure Defects Per Million (DPM)
 - Emphasis on the definition of tolerance limits for process or quality requirements for product

What is Total Quality Management?

- TQM Process
 - Quality Laboratory Processes
 - Quality Control
 - Quality Assessment
 - Quality Improvement
 - Quality Planning
 - Quality Standards

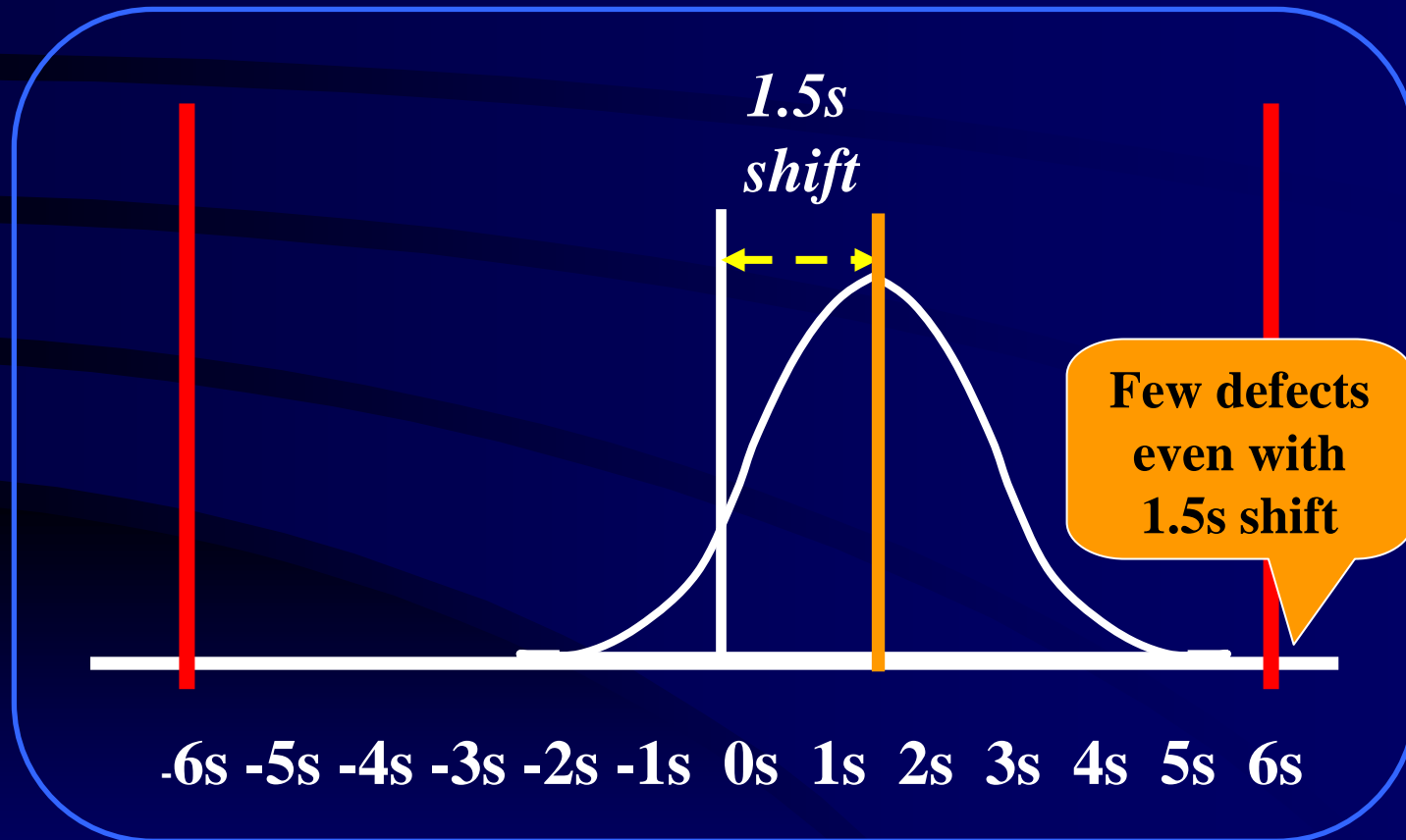


What does Six Sigma mean?



What's the rationale?

Low DPM even with 1.5s shift

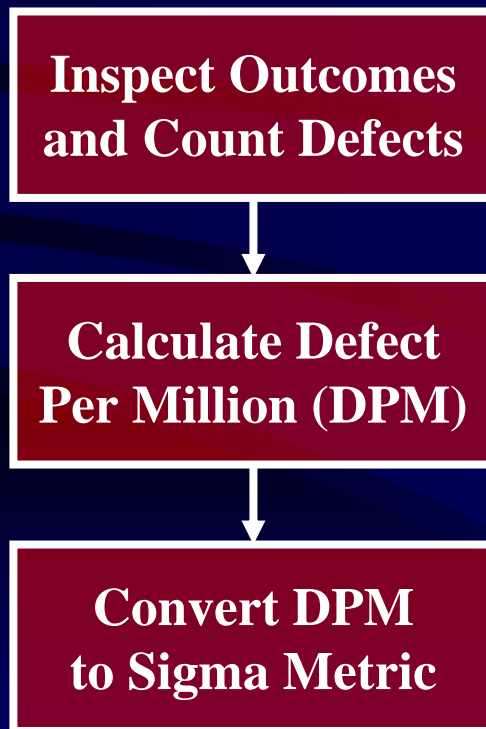


What's a defect?

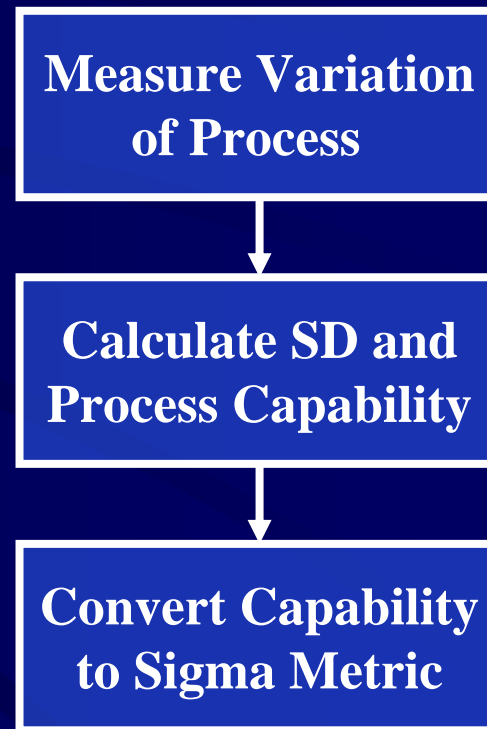
- A product that doesn't meet specifications
 - Must define the specification or tolerance limits
 - Then compare product to specification
- A test result that is in error
 - Can use CLIA proficiency testing criteria as specifications or tolerance limits
 - Compare observed errors to allowable limits of error – if greater, it's a defective result

How determine process performance in Sigma units?

Measure Outcome



Measure Variation



How do you calculate DPM?

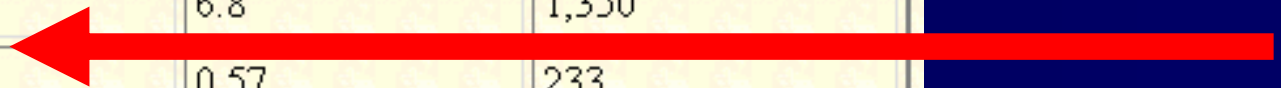
- Example: Tiremaker for Ford SUVs
 - 6,000,000 tires
 - 2000 accidents
 - 100 deaths
- $DPM = \text{accidents} / \text{million tires}$
 - $2000 / 6,000,000$ or 333 DPM

How convert DPM to Sigma?

Sigma Metric	DPM without shift	DPM with 1.5s shift
1.00	317,400	697,700
2.00	45,400	308,637
2.50	12,419	158,686
3.00	2,700	66,807
3.50	465	22,750
4.00	63	6,210
4.50	6.8	1,350
5.00	0.57	233
5.50	0.038	32
6.00	0.002	3.4

**Approx
4.9-5.0**

333 DPM



What are some benchmarks?

- World Class Quality is 3.4 DPM or 6 sigma
- Airline baggage handling
 - 4000 DPM or 4.15 sigma process
- Airline safety (passenger fatalities)
 - 0.43 DPM, better than 6 sigma process
- Typical business process is 4 sigma
- Initial Six Sigma target is 5 sigma
- Firestone tire production is 5 sigma

What performance is seen in labs?

Q-Probe QUALITY INDICATOR	% ERROR	DPM	SIGMA*
Order accuracy	1.8 %	18,000	3.60
Duplicate test orders	1.52	15,200	3.65
Wristband errors (not banded)	0.65	6,500	4.00
TDM timing errors	24.4	244,000	2.20
Hematology specimen acceptability	0.38	3,800	4.15
Chemistry specimen acceptability	0.30	3,000	4.25
Surgical pathology specimen accessioning	3.4	34,000	3.30
Cytology specimen adequacy	7.32	73,700	2.95
Laboratory proficiency testing	0.9	9,000	3.85
Surg path froz sect diagnostic discordance	1.7	17,000	3.60
PAP smear rescreening false negatives	2.4	24,000	3.45
Reporting errors	0.0477	477	4.80

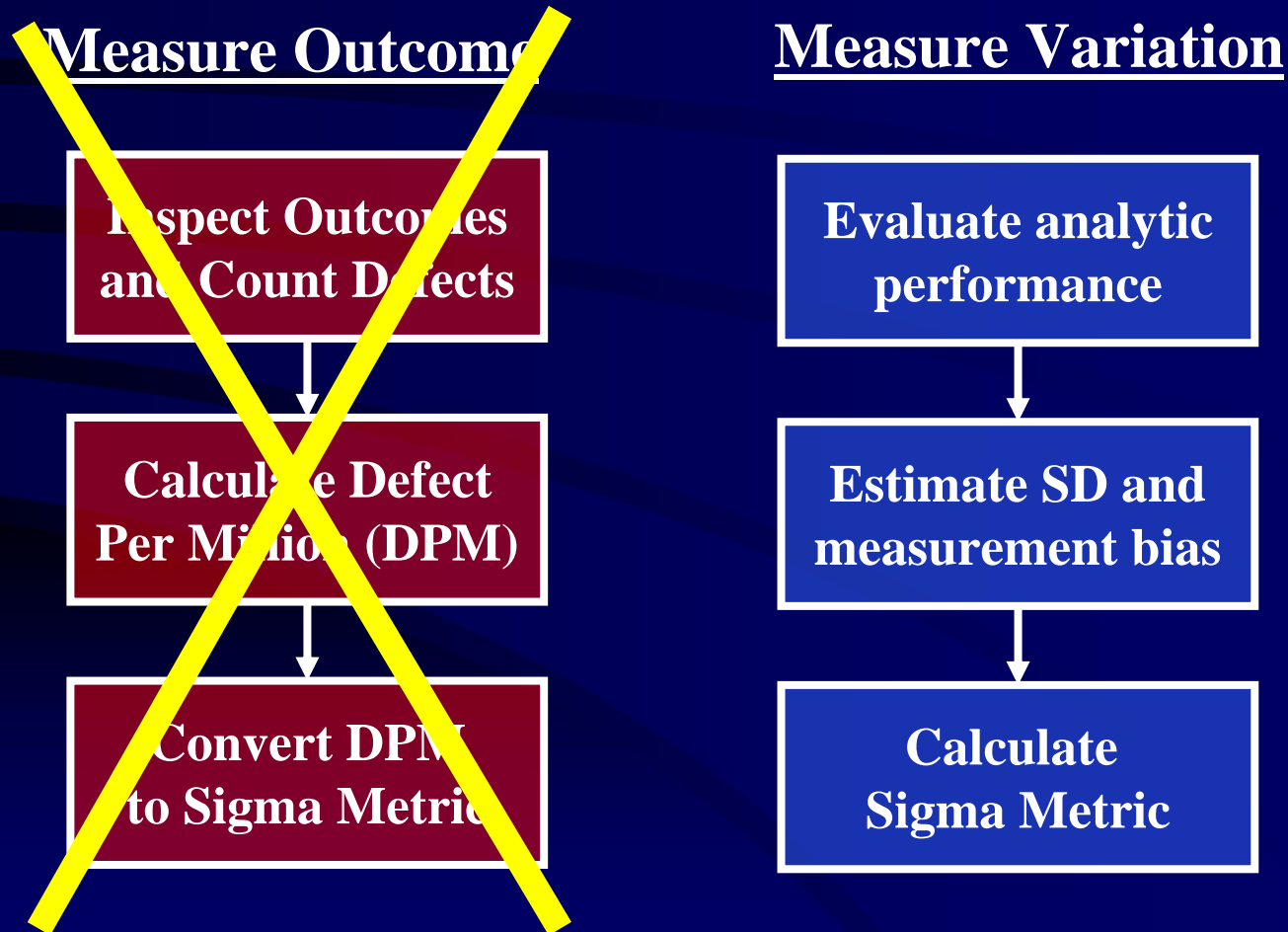
*Conversion using table with allowance for 1.5s shift

Nevelainen et al. Evaluating laboratory performance with the six sigma scale. Arch Pathol Lab Med 2000;124:516-9.

How about diagnostic tests?

- **Do you know the Sigma metric for each of your test methods?**
- **Depends on**
 - **Tolerance limits or quality requirement for the test (TEa)**
 - **Imprecision of the method (SD or CV)**
 - **Inaccuracy of the method (bias)**

How determine Sigma metrics for laboratory tests?



How calculate Sigma metric?

- Sigma metric = $(TEa - Bias)/CV$
 - TEa=12%, Bias=0%, CV=2%
 - Sigma metric is $(12-0)/2$ or 6 sigma
 - TEa=12%, Bias=0%, CV=4
 - Sigma metric is $(12-0)/4$ or 3 sigma
 - TEa = 12%, Bias = 3%, CV=2%
 - Sigma metric is $(12-3)/2$ or 4.5 sigma

What's the Sigma metric for a cholesterol method that satisfies CLIA PT and NCEP performance guidelines?

- TEa = 10% CLIA PT criterion
- Bias = 3%, CV=3% NCEP specifications
 - Sigma metric is $(10-3)/3$ or 2.33 sigma
 - Process is not suitable for production according to industrial management guidelines!!!!!!!

What performance is really needed for cholesterol?

- TEa = 10%, Bias = 0%, CV=2%
 - Sigma metric is $(10-0)/2$ or **5.0 sigma**
 - This is the performance that is actually needed to have a reliable, controllable, routine production method
 - A CV of 1.7% would be better! **6.0 sigma**

What CVs are desirable based on CLIA criteria?

• Examples	5-sigma	6-sigma
– Cholesterol	2.0%	1.7%
– Glucose	2.0%	1.7%
– Digoxin	5.0%	4.0%
– Erythrocyte count	1.2%	1.0%
– Hemoglobin	1.4%	1.2%
– Prothrombin time	3.0%	2.5%

What QC is required?

General Guidelines

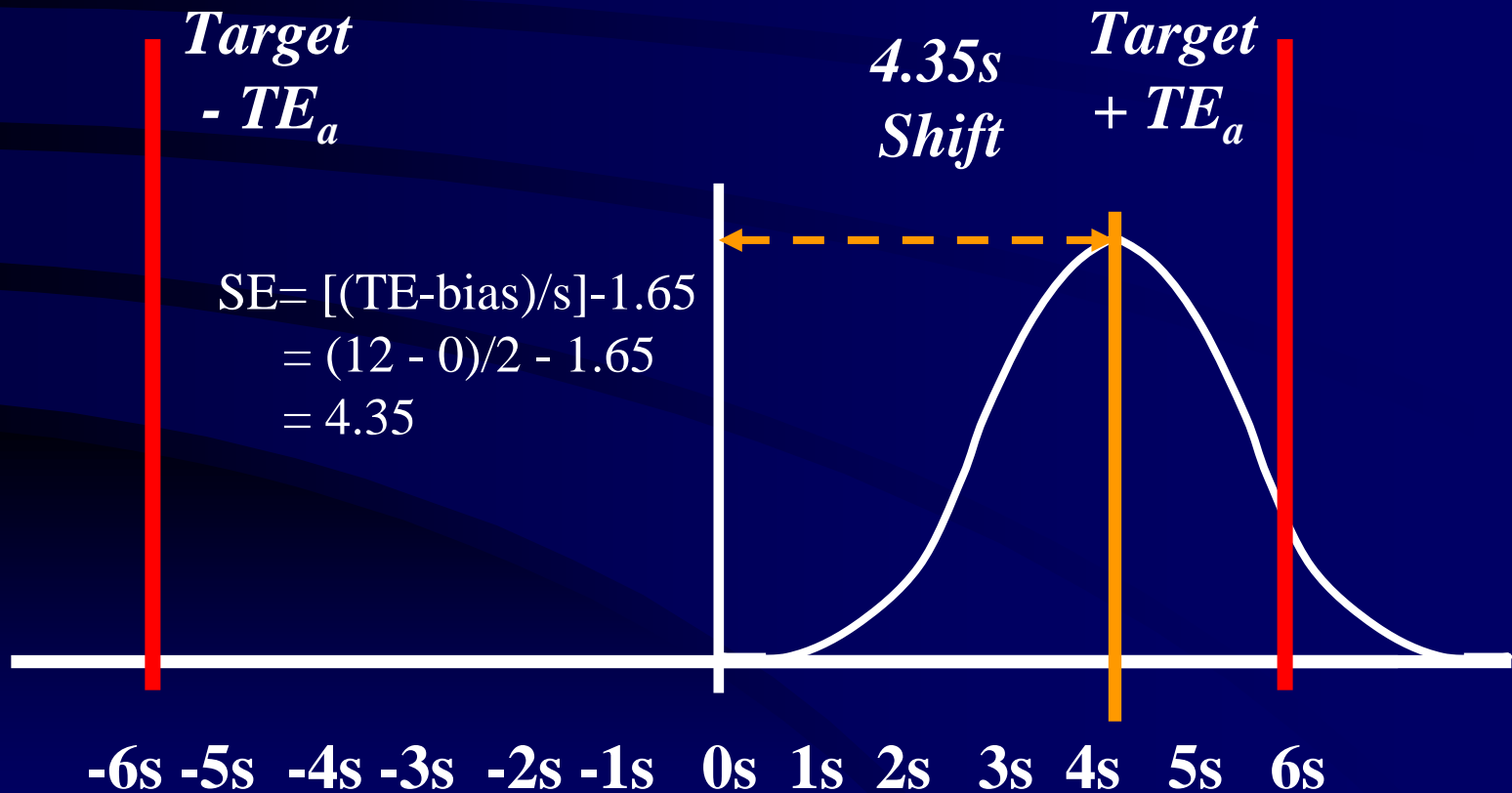
- **6 sigma process** - any QC will do!
- **5 sigma process** - single rule QC with 3.0s limits and N of 2-3
- **4-sigma process** – single rule QC with 2.5s limits or multirule QC with Ns of 3-6
- **3-sigma process** – no practical QC
 - Can't afford to run enough controls to detect medically important errors!

What QC is required?

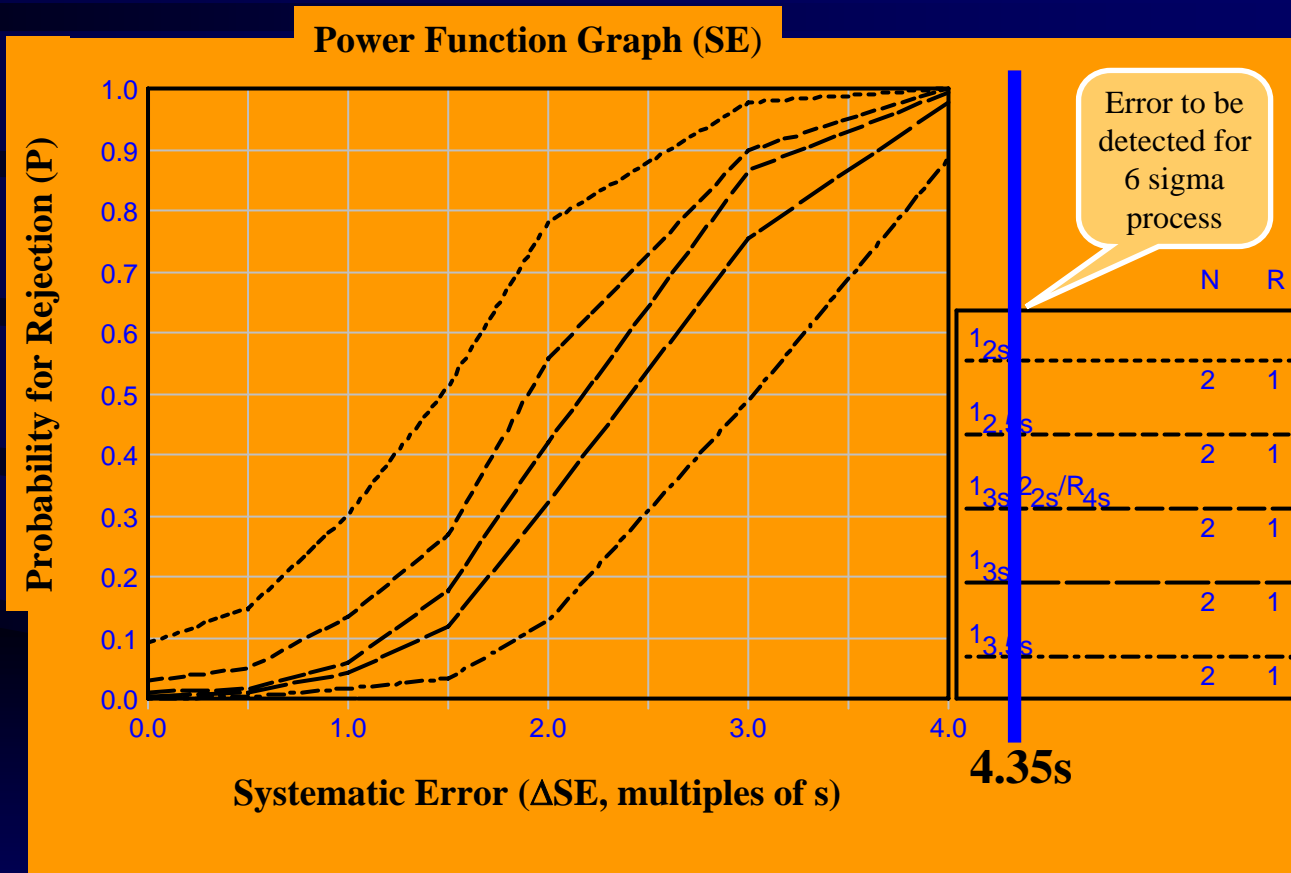
Specific Guidelines

- Critical Systematic Error is the sigma metric for selection/design of QC procedures
 - $\Delta SE_{crit} = [(TEa - bias_{meas})/s_{meas}] - z$
 - where TEa is allowable total error expressed in %
 - $bias_{meas}$ is the observed inaccuracy for the method expressed in %
 - s_{meas} is the observed imprecision for the method expressed in %
 - z commonly set as 1.65 to set maximum defect at 5% before a run is rejected

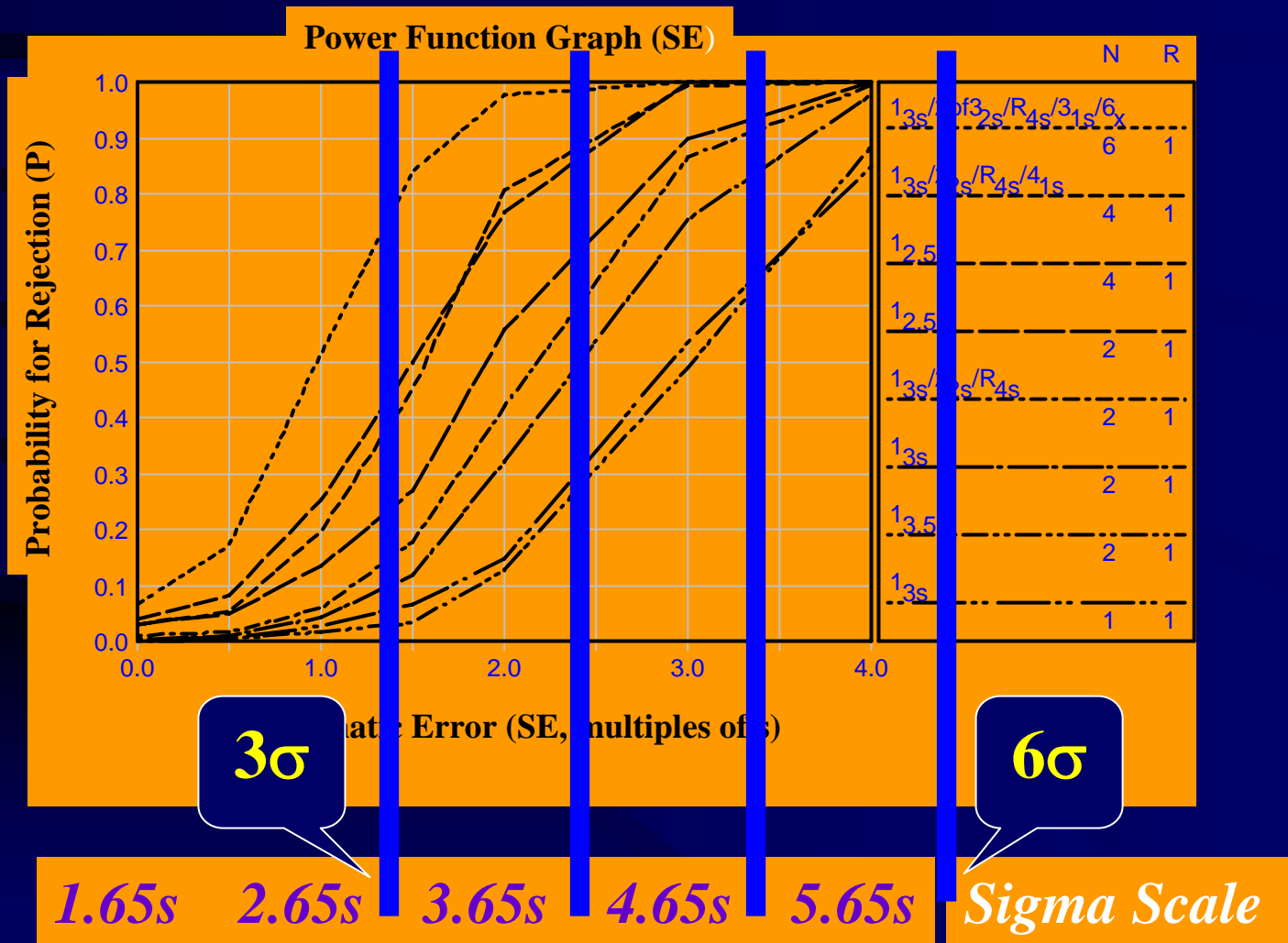
What systematic error must be detected in a 6 sigma process?



What QC will detect 4.35s SE?

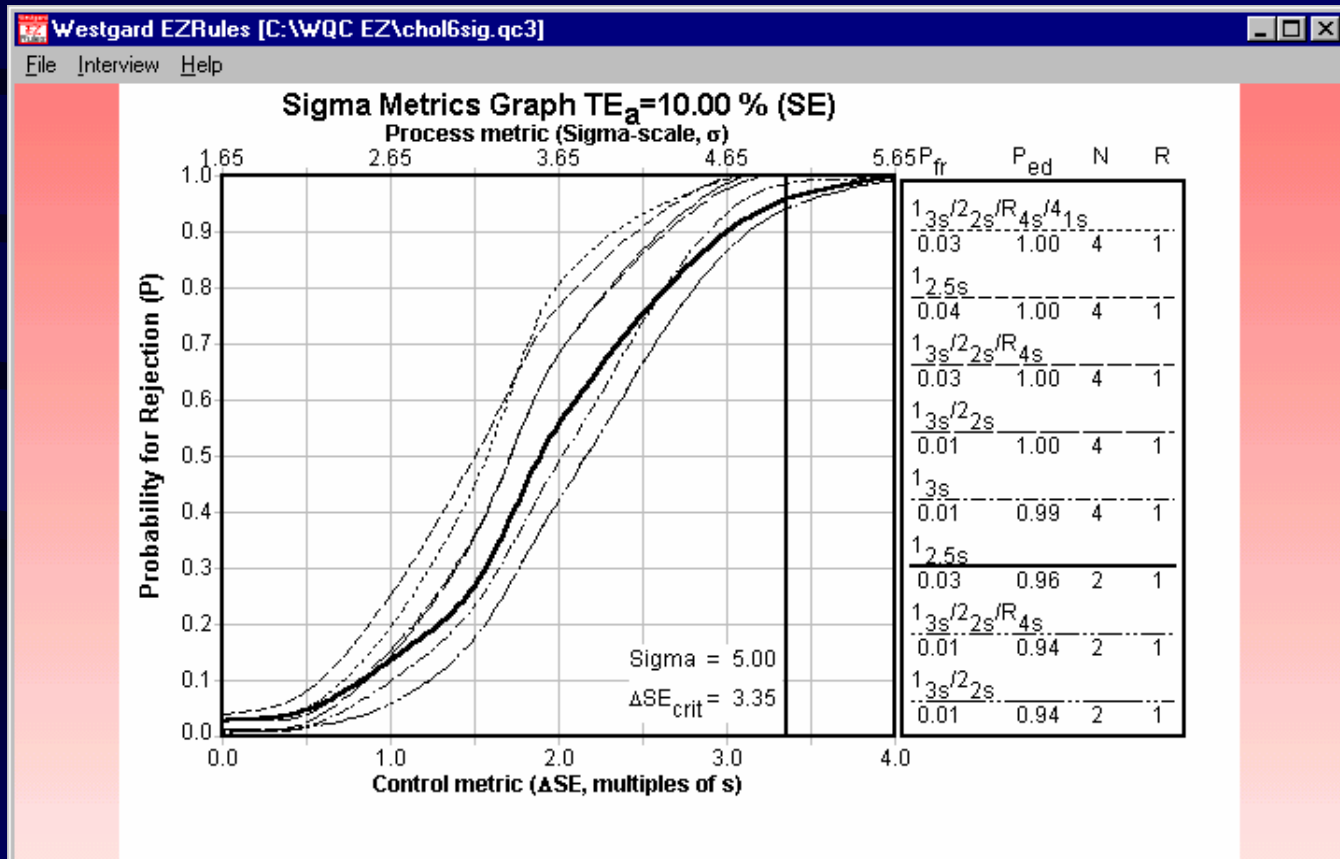


How does QC depend on Sigma?



How determine QC design?

EZ Rules program!



Where find Six Sigma training?

- American Society for Quality (ASQ)
 - <http://www.asq.org>
 - <http://www.sixsigmaforum.com>
 - Master Black Belt, Black Belt, Green Belt, Champion, and Executive training
- Many private consultants and trainers
 - See advertisements in Quality Progress
 - Magazine from ASQ

Where find Six Sigma training for laboratory applications?

- **Internet at <http://www.westgard.com>**
- Six Sigma Quality Design and Control book
 - Available through AACCC bookstore
- Six Sigma Design and Control Workshop
 - Madison, WI – May 21-22, 2002
 - Includes Six Sigma book and EZ Rules computer program

What Six Sigma books are available in local bookstores?

- Mikel Harry and Richard Schroeder
 - Six Sigma: The Breakthrough Management Strategy Revolutionizing the World's Top Corporations
 - Currency, New York, 2000
- George Eckes
 - The Six Sigma Revolution: How General Electric and Others Turned Process into Profits
 - John Wiley & Sons, 2001