

NEW RULES of PROCESS IMPROVEMENT

How to use GMP, ISO, Lean & Six Sigma to
Optimize Productivity and Minimize Cost

Carl Perini

International Specialty Products, Wayne NJ

ASQ North Jersey Education Committee

New Rules of Process Improvement

- Objectives
- National Coin Flipping Contest
- Background
- The New Rules
- Case Studies #1 & #2

New Rules of Process Improvement

Objectives

- Introduce the New Rules of Process Improvement
- Show how the New Rules can lead to:
more competitive process management systems

New Rules of Process Improvement

2008 NORTH JERSEY ASQ SPRING QUALITY CONFERENCE

North Jersey ASQ Spring Quality Conference 2008

"Thirty Years of Quality"

Thursday, April 3, 2008

7:30am - 4:00 pm

There will be four concurrent tracks with presentations from experts in quality, management and related fields.

0.8 RUs WILL BE EARNED BY ATTENDEES (upon request)

Hanover Marriott, 1401 Route 10 East, Whippany, NJ (¼ mile West of 1-287)

100% SMOKE FREE POLICY (SMOKING IS PROHIBITED IN ALL GUEST ROOMS AND PUBLIC AREAS)

New Rules of Process Improvement



New Rules of Process Improvement

2008 NORTH JERSEY ASQ SPRING QUALITY CONFERENCE

TIME	TRACK ONE	TRACK TWO	TRACK THREE	TRACK FOUR
ROOM	Salon D	Gallery	Hanover	Salon C
7:20 - 8:20 am	REGISTRATION & CONTINENTAL BREAKFAST			
8:20 - 9:20 am	KEYNOTE SPEAKER: Dr. Joseph A. Lannon, Director of ARDEC at Picatinny Arsenal <u>"The Baldrige Award: ARDEC's Journey to Performance Excellence"</u>			
9:30 - 10:30 am	(1) <u>Strategies for a Successful FDA/ISO Audit</u> Elaine Lehecka Pratt Lehecka Pratt Associates	(5) <u>Lean Six Sigma: A Roadmap and Tools</u> Donelle Denery US Army ARDEC	(9) <u>The Baldrige Award: Institutionalizing the Journey</u> Donelle Denery US Army ARDEC	(13) <u>Conquering Workplace Anxiety, Fears and Phobias</u> Dr. Ronald Glassman Clinical Practice
10:30 - 10:45pm	COFFEE BREAK / NETWORKING / EXHIBITS			
10:45 - 11:45 am	(2) <u>Inspection Approach to Laboratories and Computer Systems</u> Nancy Rolli FDA	(6) <u>Improving Operational Excellence Through Six Sigma</u> Perry Walker Tunnell Consulting	(10) <u>The Human Side of Change</u> Stanley Cherkasky Change Management Consulting Inc.	(14) <u>What if... Everyone in Your Organization was a Leader</u> Jack Frost Firm Foundations, LLC
11:45 - 1:30 pm	LUNCH/EXHIBITS			
1:30 - 2:30 pm	(3) <u>The New Rules of Process Improvement</u> Carl Perini International Specialty Products	(7) <u>A Blueprint for Success With Lean Six Sigma</u> Brad Thorne Change Management Consulting	(11) Session (10) Continues	(15) <u>Performance Measurement: the Basis for Project and Enterprise Excellence</u> Cheryl Jones US Army ARDEC
2:30 - 3:00 pm	ICE CREAM REFRESHMENT BREAK / NETWORKING / EXHIBITS			
3:00 - 4:00 pm	(4) <u>Revenue Enhancement Through Six Sigma</u> Anthony J. Romagnole CWI Consulting Inc.	(8) <u>Internal Auditing - A Management Tool</u> Ron Williams Optimum Business Concepts	(12) <u>Presenting with PowerPoint: the Good, the Bad and the Ugly</u> Dr. Ronald Rockland NJIT	(16A) <u>Embedding Reliability in Software Processes</u> Dale Borja BAE Systems (16B) <u>Your Electronic Health Records</u> Dr. Robert N. Charette ITABHI Corp.

New Rules of Process Improvement

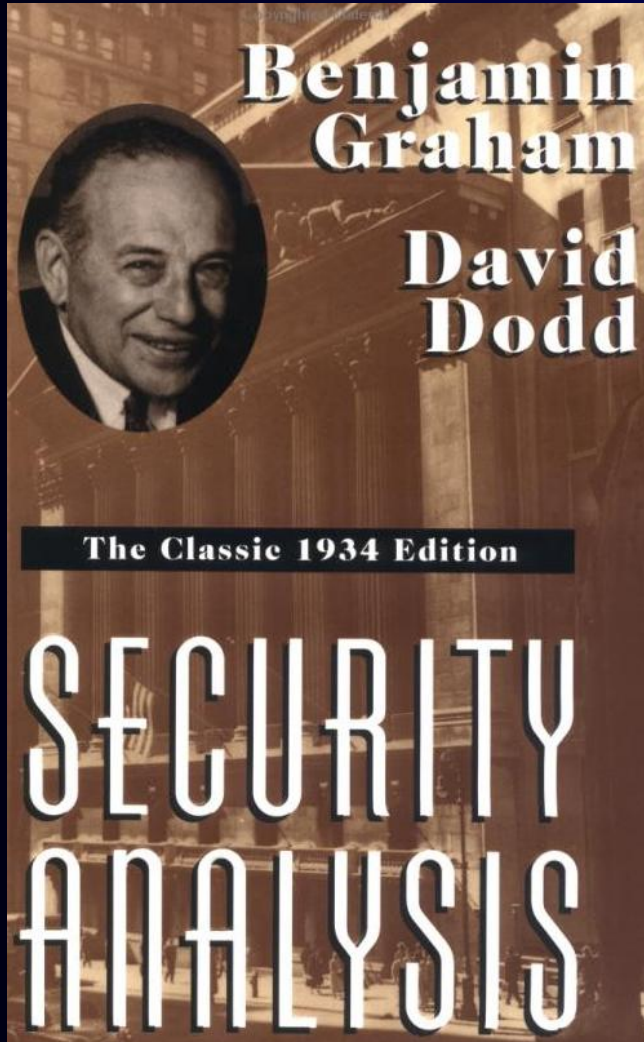
To gain maximum benefit

- Keep an open mind
- Ask questions – when alignment is not clear
- Share your experiences
- Take 100% responsibility for getting what you came for

New Rules of Process Improvement

Processes of interest???

National Coin-Flipping Contest



The Superinvestors of Graham-and-Doddsville by Warren E. Buffett

National Coin-Flipping Contest

- 300 million Americans
- first day: one flip & \$1 wager
- Loser: drops out
- Winner: bets total \$\$ next day

National Coin-Flipping Contest

- Stakes build / include previous winning
- On 10th day ~ 290,000 correct callers
~ \$1,000 winnings each
- Decreasing modesty

National Coin-Flipping Contest

- Stakes build / include previous winning
- On 20th day ~ 290 correct callers
~ \$1,050,000 winnings each
- Decreasing sense of reality

National Coin-Flipping Contest

- Celebrity status
- “If it can’t be done, then why are there 290 of us?”
- *‘How I Turned a Buck into a Million Dollars in 20 Mornings Working 30 Seconds’*

National Coin-Flipping Contest

- Business School Professor:

If 300 million chimpanzees started contest,
then same results after 20 days:

290 winning chimpanzees

National Coin-Flipping Contest

- 300 MM Chimps distributed like US census
- 100 of the 290 winners from the Bronx Zoo
- Scientific inquiry: geographic origin
- Query zookeeper for exceptional causes

National Coin-Flipping Contest

- Village with high rate of success
- Super-intelligent Village
- Can't be explained by chance
- Scientific inquiry: intellectual origin

National Coin-Flipping Contest

- One persuasive village leader & 99 followers
- Scientific inquiry: influence factor
- 100 winning members in group
- Only 1 winning method

National Coin-Flipping Contest

- Scientific inquiry: intellectual influence
- Unsurpassed investment insight
- Village: Graham-and-Doddsville
- Students evolve legacy – Warren Buffett

National Coin-Flipping Contest

- Scientific inquiry: intellectual influence
- Unsurpassed process behavior insight
- Village: Taylor-and-Shewhartville
- Students evolve legacy

The Superinvestors of Graham-and-Doddsville by Warren E. Buffett

Taylor-and-Shewhartville

- F. W. Taylor (1856 – 1915)



- W. A. Shewhart (1891 – 1967)



Taylor-and-Shewhartville

Frederick Winslow Taylor



‘The Principles of Scientific Management’ -1911

Analyze process actions into simple, discrete, easily mastered steps → higher wages & productivity

Taylor-and-Shewhartville

Frederick Winslow Taylor



Bethlehem Steel Company - pig iron tonnage/day

Best worker productivity - shovel load:

15, 20, 25, or 30 pounds?

Taylor-and-Shewhartville

F. W. Taylor Bethlehem Steel Co - pig iron

Answer: 21 pounds per load

by selection of shovel dimensions

- Tons per piece-worker per day: 16 -> 59
- Cost per ton: \$0.072 -> \$0.033

Taylor-and-Shewhartville

Walter A. Shewhart



May 1924 – Process Behavior Chart

‘Economic Control of Manufactured Product’
1931

Taylor-and-Shewhartville

Walter Shewhart

Variation : 'a' exercise

Taylor-and-Shewhartville

Variation: Routine vs. Extreme

Cause: Common vs. Assignable/Special

Process Behavior: Predictable vs. Unpredictable

Taylor-and-Shewhartville

Process Behavior Analysis

- Confirms type of variation present
- Process management using clear windshield
- Reveals ‘Voice of the Process’

Taylor-and-Shewhartville

W. Edwards Deming
(1900 – 1993)



Fourteen Points (1982)

#1 – Create constancy of purpose for
continual improvement of products & services

Taylor-and-Shewhartville

Genichi Taguchi (1924 -)



Process goal - Loss function

Process types:

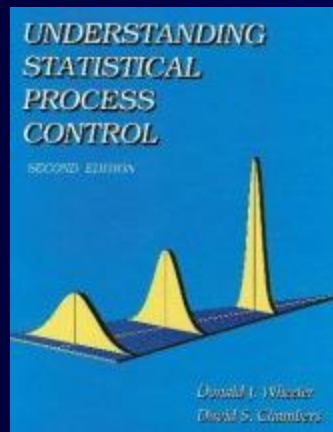
bigger-the-better

smaller-the-better

nominal-the-best

Taylor-and-Shewhartville

David S. Chambers & Donald J. Wheeler



“The Four Process States” page 12

Taylor-and-Shewhartville

Lynne Hare

ASQ North Jersey Fellow 1986

Kraft Foods Director of Statistics



‘Improved Performance by Statistical Thinking’
Spring Quality Conference 2006

“Always, always, always, without exception...
do what?””

New Rules of Process Improvement

“What are standard process requirements?”

New Rules of Process Improvement

FDA/GMP Basics

- Validated process
- Change control
- Final inspection \neq guarantee safety/efficacy

New Rules of Process Improvement

ISO 9001 Basics

- Quality Management Systems
- Process approach
- Customer perception
- Continual improvement

New Rules of Process Improvement

Lean Engineering Basics

- Eliminate waste
- Reduce waiting time
- Increase productivity
- Reduce costs

New Rules of Process Improvement

Six Sigma Basics

- DMAIC project
- Near zero defects
- Minimum process variation

New Rules of Process Improvement

PROCESS IMPROVEMENT OBJECTIVE

- Align improvement implementation method with all standard process requirements.***

New Rules of Process Improvement

- Rule 1 *'On Target with Minimum Variation'* Taguchi
- Rule 2 *'Let your Process State be your Guide'*
Chambers & Wheeler
- Rule 3 *'Always, always, always, without exception:
Plot the Data'* Hare
- Rule 4 *Maintain 'Constancy of Purpose'* Deming

New Rules of Process Improvement

- Rule 1 On Target with Minimum Variation
= Process Goal

Genichi Taguchi

- Conformance to requirements is incomplete
- Process target is minimum cost - Loss function

1. On Target with Minimum Variation

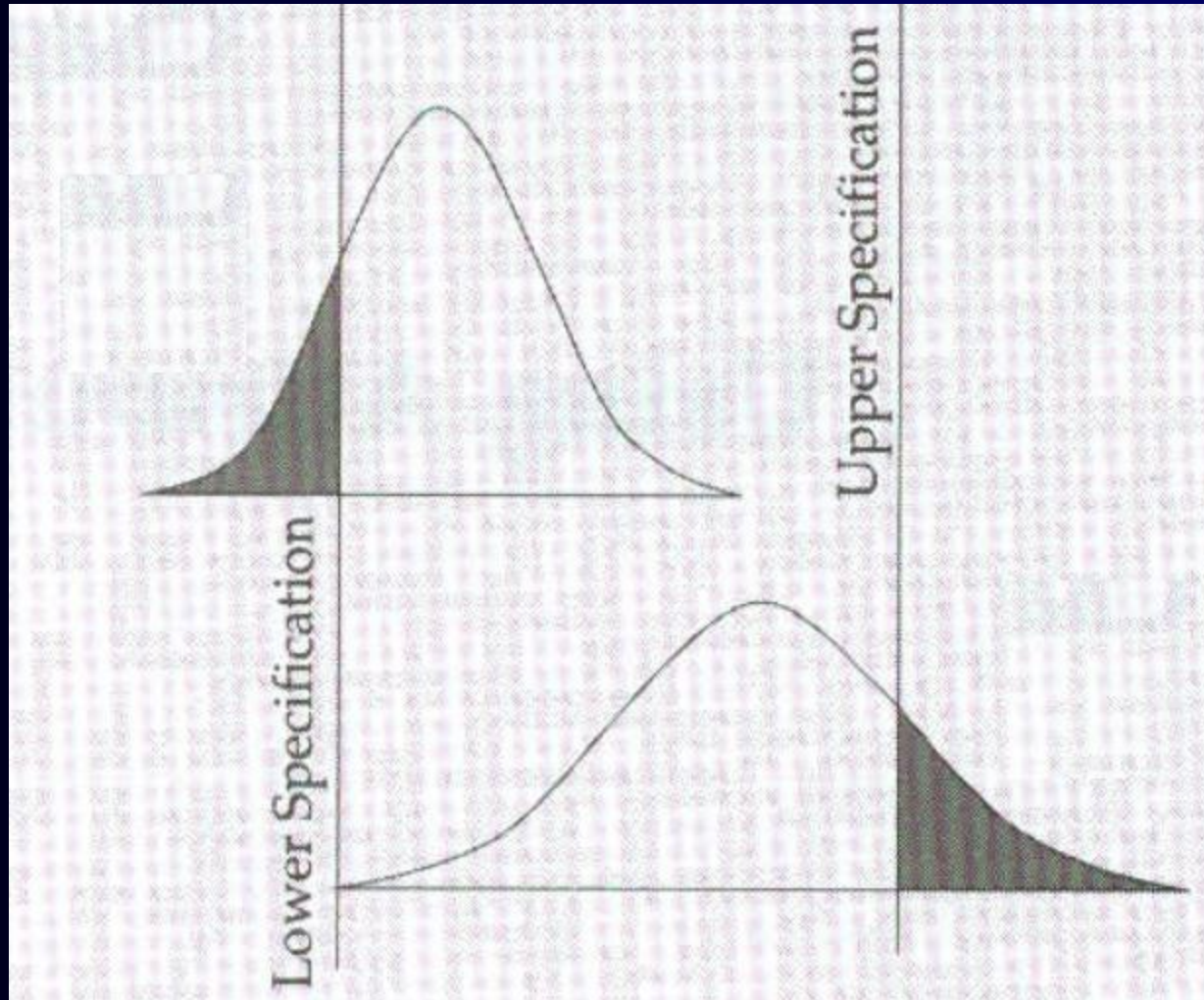
Requirement weaknesses

Commercial Objectives/Product Specifications

- Set by Who?
- How are they set?
- Where do they come from?
- Close line between

FAIL | PASS | FAIL

1. On Target with Minimum Variation



1. On Target with Minimum Variation

Requirement reality

Commercial Objectives/Product Specifications

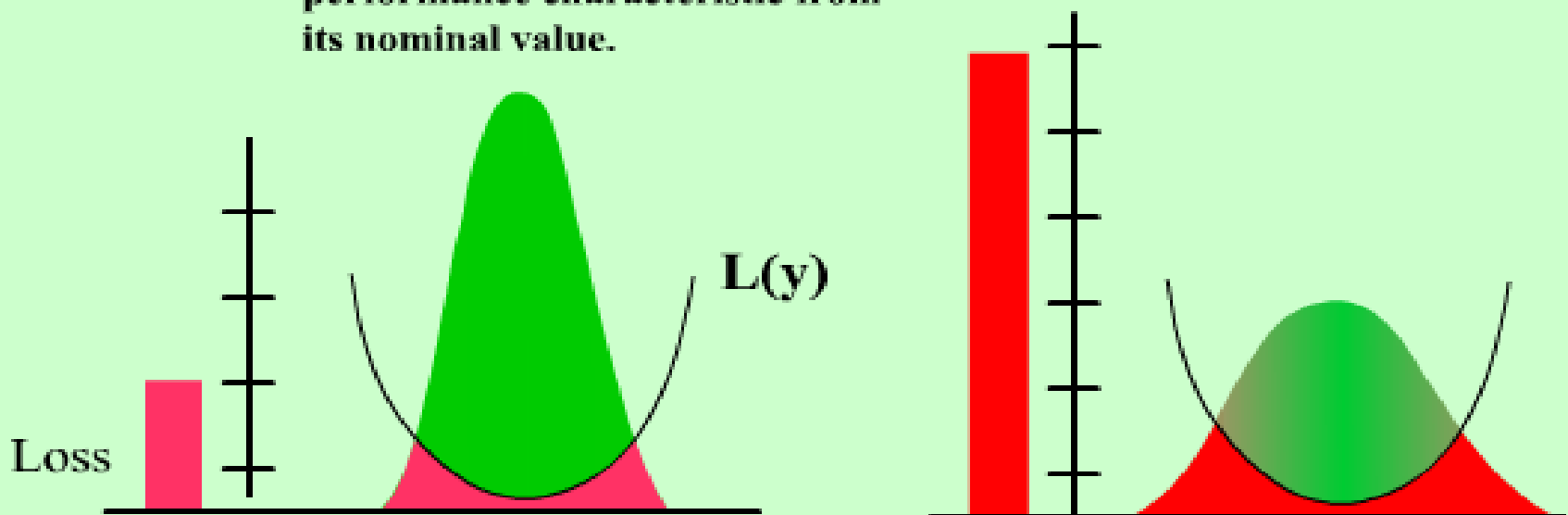
- Acceptance Criteria
- Satisfy: ‘Voice of the Customer’

1. On Target with Minimum Variation

TAGUCHI LOSS FUNCTION

$$L(y) = k(y-m)^2$$

The loss due to performance variation is proportional to the square of the deviation of the performance characteristic from its nominal value.



2. Let Your Process State Be Your Guide

David Chambers & Donald Wheeler

How Many Possible Voices?

2. Let Your Process State Be Your Guide

David Chambers & Donald Wheeler

How Many Possible Voices? - Two

Voice of Customer - requirements

&

Voice of Process - variation

2. Let Your Process State Be Your Guide

David Chambers & Donald Wheeler

How Many Possible Voice Levels?

Two for both

Voice of Customer: 100% Conforming / <100%

Voice of Process: Predictable / Unpredictable

2. Let Your Process State Be Your Guide

David Chambers & Donald Wheeler

How Many Possible Process States?

2. Let Your Process State Be Your Guide

David Chambers & Donald Wheeler

2 Voices x 2 Levels = 4 States

2. Let Your Process State Be Your Guide

Voice of the Process
(type of variation)

Predictable
Process

IDEAL STATE

THRESHOLD
STATE

Unpredictable
Process

BRINK of CHAOS

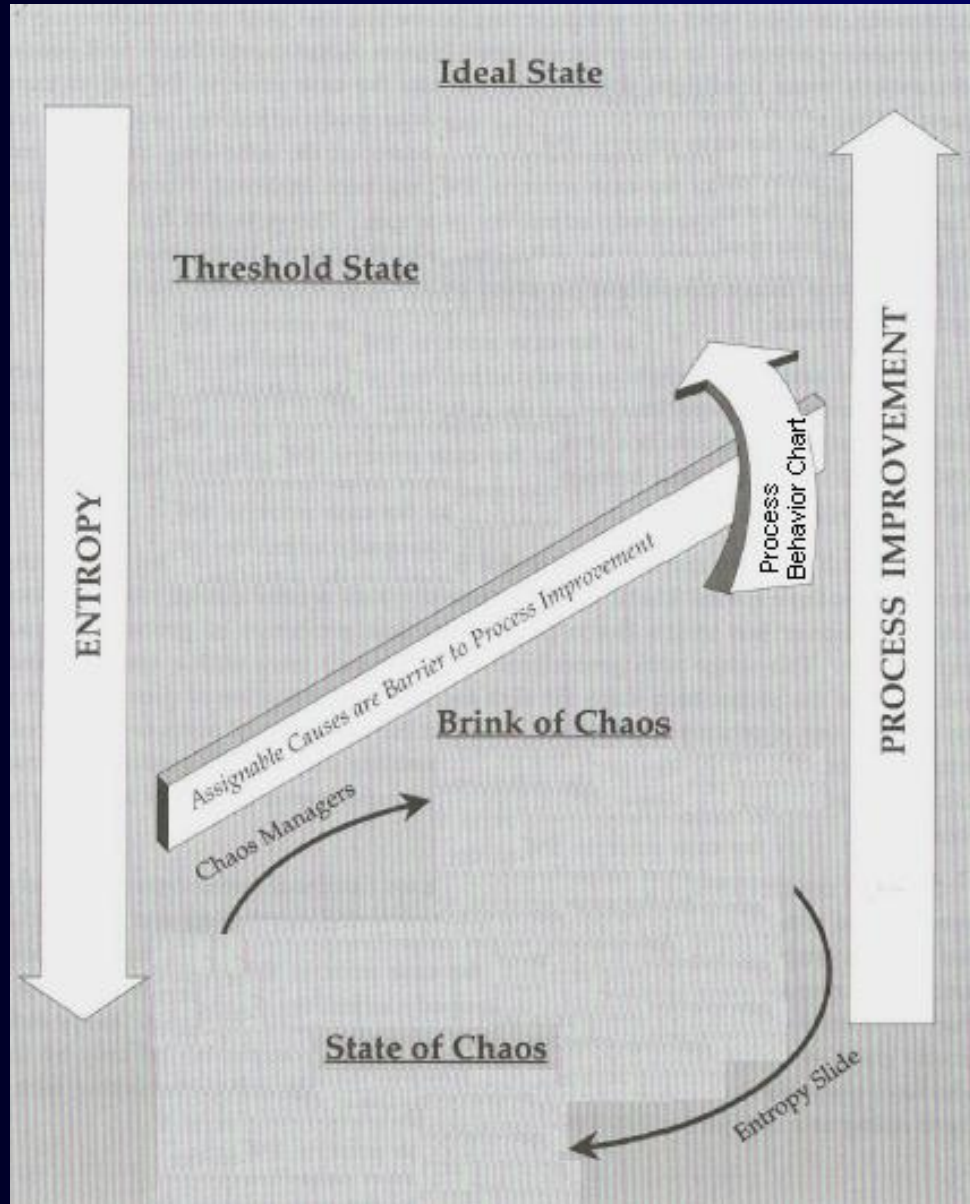
STATE of CHAOS

Voice of Customer
(requirements)

100% Conforming
Output

< 100% Conforming
Output

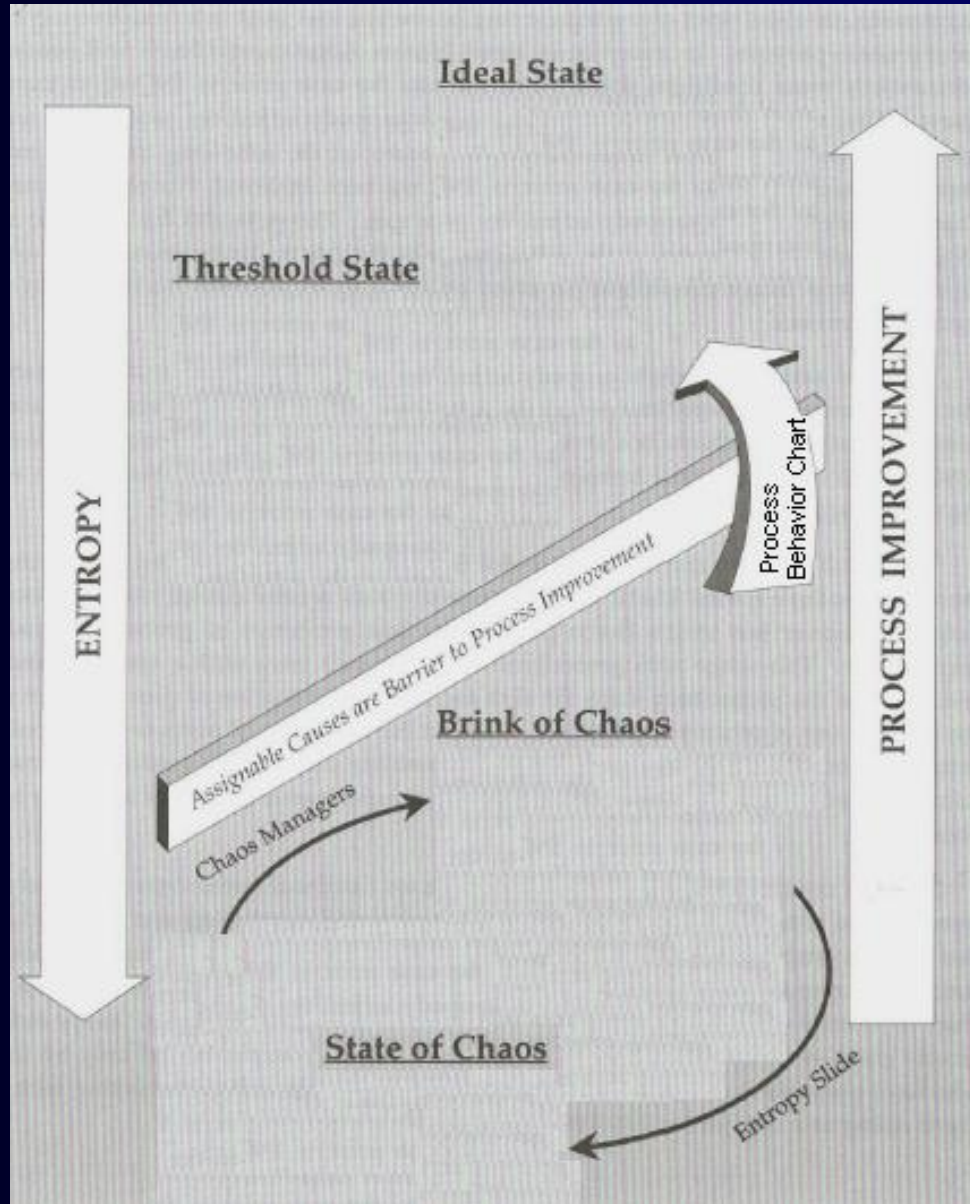
2. Let Your Process State Be Your Guide



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2. Let Your Process State Be Your Guide

Predictable
Process

IDEAL STATE

- An accomplishment vs. entropy
- Need timely warning of any issue
- VOC & VOP analysis constancy

THRESHOLD STATE

- Screening is temporary/costly fix
- Change process &/or requirements
- DOE/SS tools to center the process

Unpredictable
Process

BRINK of CHAOS

- All may seem OK but...
- Quality & Conformance can change in an instant
- ID/remove extreme variation

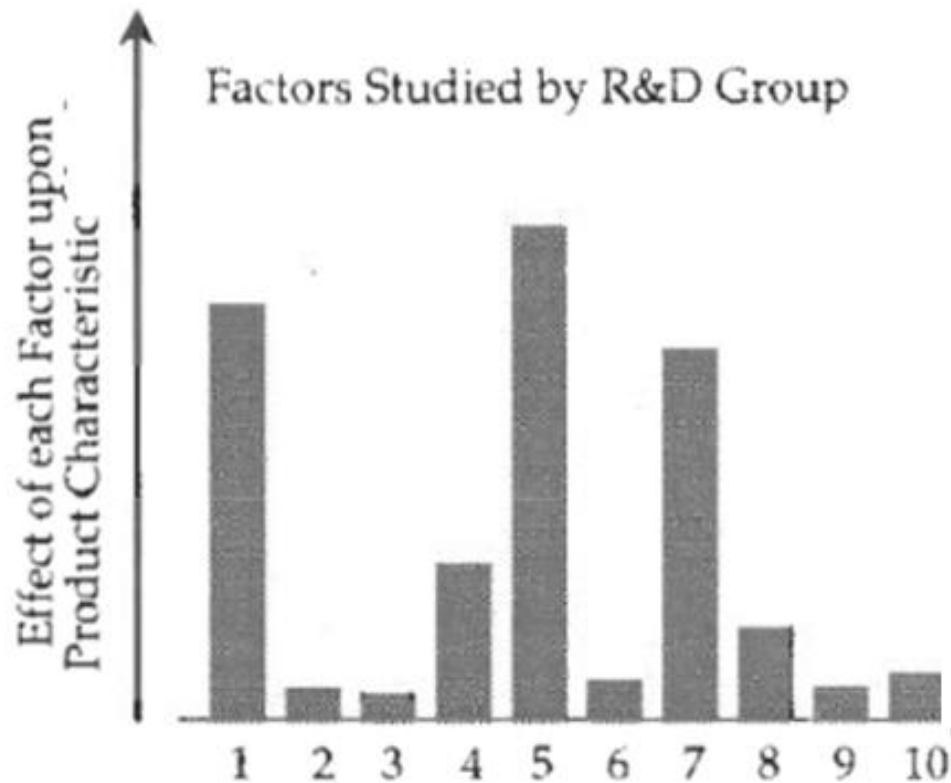
STATE of CHAOS

- Attack variation -> Threshold

100% Conforming
Output

Some
Non-Conforming
Output

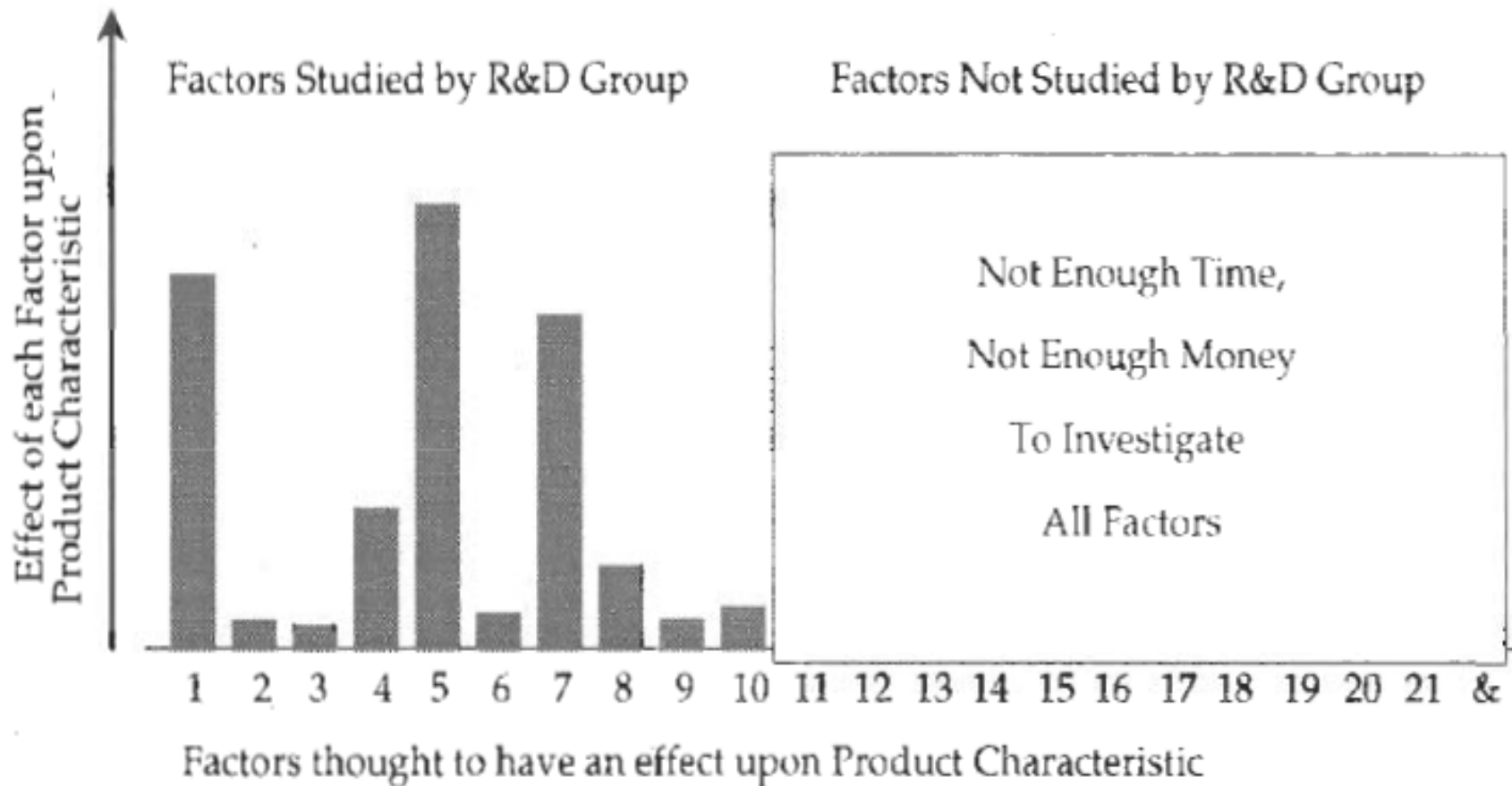
2. Let Your Process State Be Your Guide



Factors thought to have an effect upon Product Characteristic

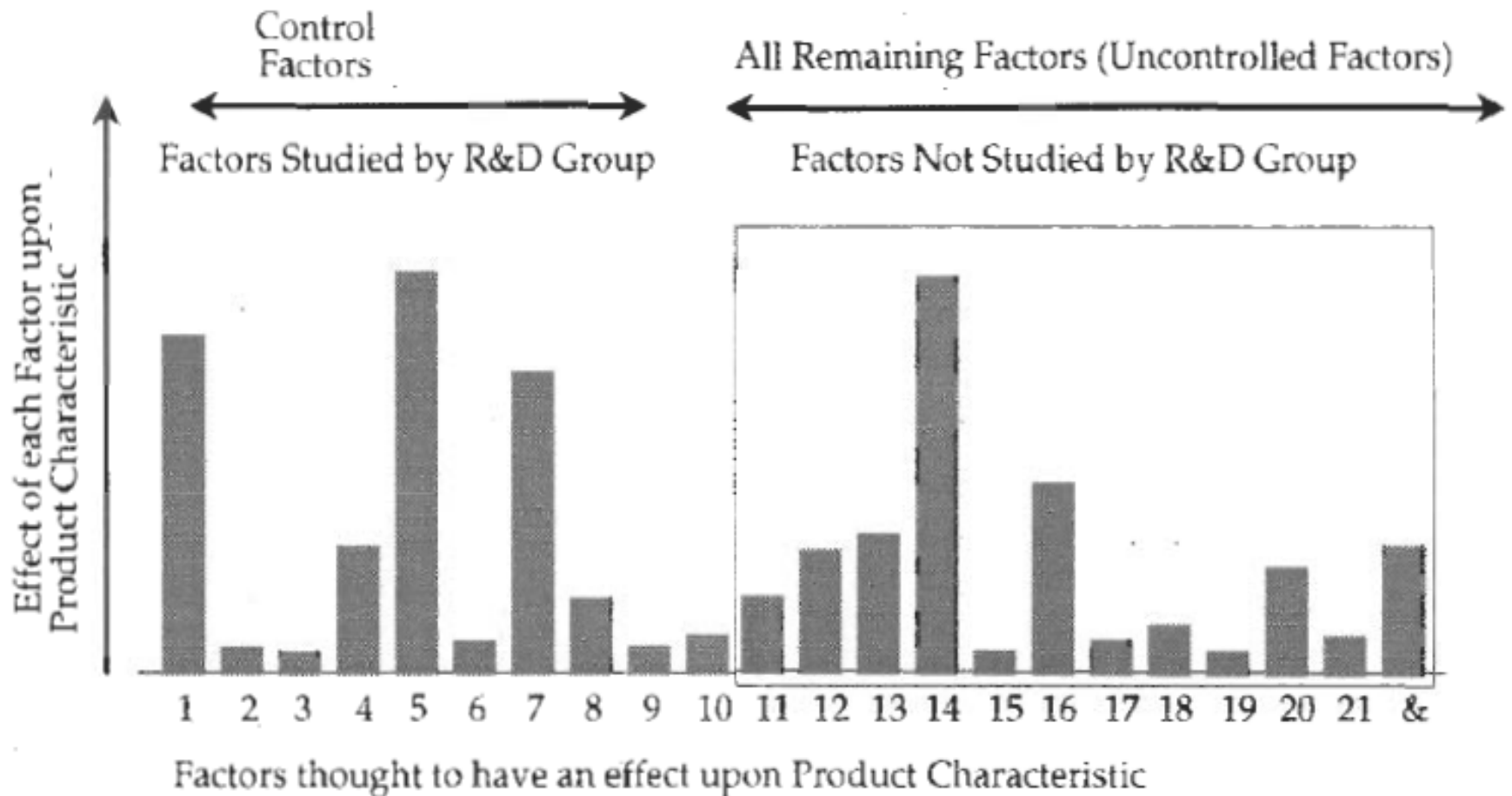
Cause and Effect Relationships Studied by R&D

2. Let Your Process State Be Your Guide



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STATE of CHAOS


- Attack variation -> Threshold

100% Conforming
Output

Some
Non-Conforming
Output

3. Always ... Plot the Data

Lynne Hare & Don Wheeler

- Case Study: HW Pharma Inc
- Business: pharmaceutical ingredient 
- Metric: quarterly sales (bigger the better)
- Source: three geographic regions—A, B & C

What does data say?

3. Always ... Plot the Data

Lynne Hare & Don Wheeler

(sales in thousands)	A	B	C
Q - Quota	\$500	\$500	\$400
2007 Q4	\$802	\$878	\$462
2008 Q1	\$749	\$939	\$420
Q2	\$762	\$834	\$454
Q3	\$807	\$688	\$447
Q4	\$781	\$806	\$359

3. Always ... Plot the Data

Reward vs. Reprimand

	Q4 '08 Sales	vs. Q3 '08 % change		vs. Q4 '07 % change		Index
A	\$781	\$807 -3%	bad	\$802 -3%	bad	-- = -2
B	\$806	\$688 +17%	very good	\$878 -8%	bad	++- = +1
C	\$359	\$447 -20%	very bad	\$462 -22%	very bad	---- = -4

3. Always, always, always Plot the Data

Lynne Hare & Don Wheeler

Process State Identification Tools

How many tools are needed?

3. Always, always, always Plot the Data

Lynne Hare & Don Wheeler

Process State Identification Tools

Voice of Customer:

Histogram

Voice of Process:

Process Behavior Chart

3. Always ... Plot the Data

Lynne Hare & Don Wheeler

Voice of Customer : Histogram

- Piles of observation frequencies
- Conformance limit(s)

3. Always ... Plot the Data

Regions A B & C : 2004 -> 2008

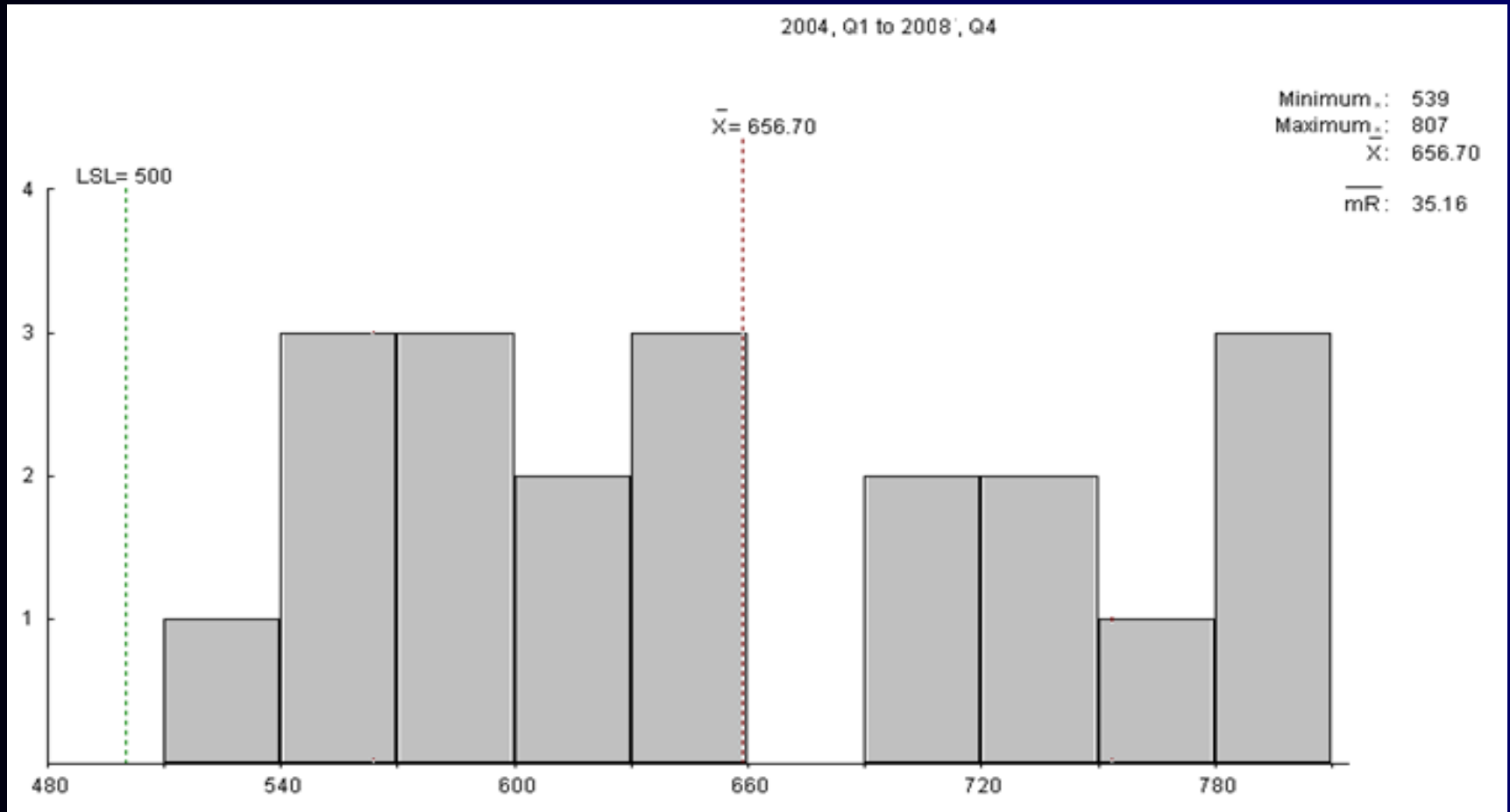
Region A				Region A			
		Loc	Disp			Loc	Disp
2004	Q1	\$539		2006	Q3	\$596	\$6
	Q2	\$558	\$19		Q4	\$640	\$44
	Q3	\$591	\$33	2007	Q1	\$691	\$51
	Q4	\$556	\$35		Q2	\$723	\$32
2005	Q1	\$540	\$16		Q3	\$701	\$22
	Q2	\$590	\$50		Q4	\$802	\$101
	Q3	\$606	\$16	2008	Q1	\$749	\$53
	Q4	\$643	\$37		Q2	\$762	\$13
2006	Q1	\$657	\$14		Q3	\$807	\$45
	Q2	\$602	\$55		Q4	\$781	\$26

Avg Location: \$657

Avg Dispersion: \$35

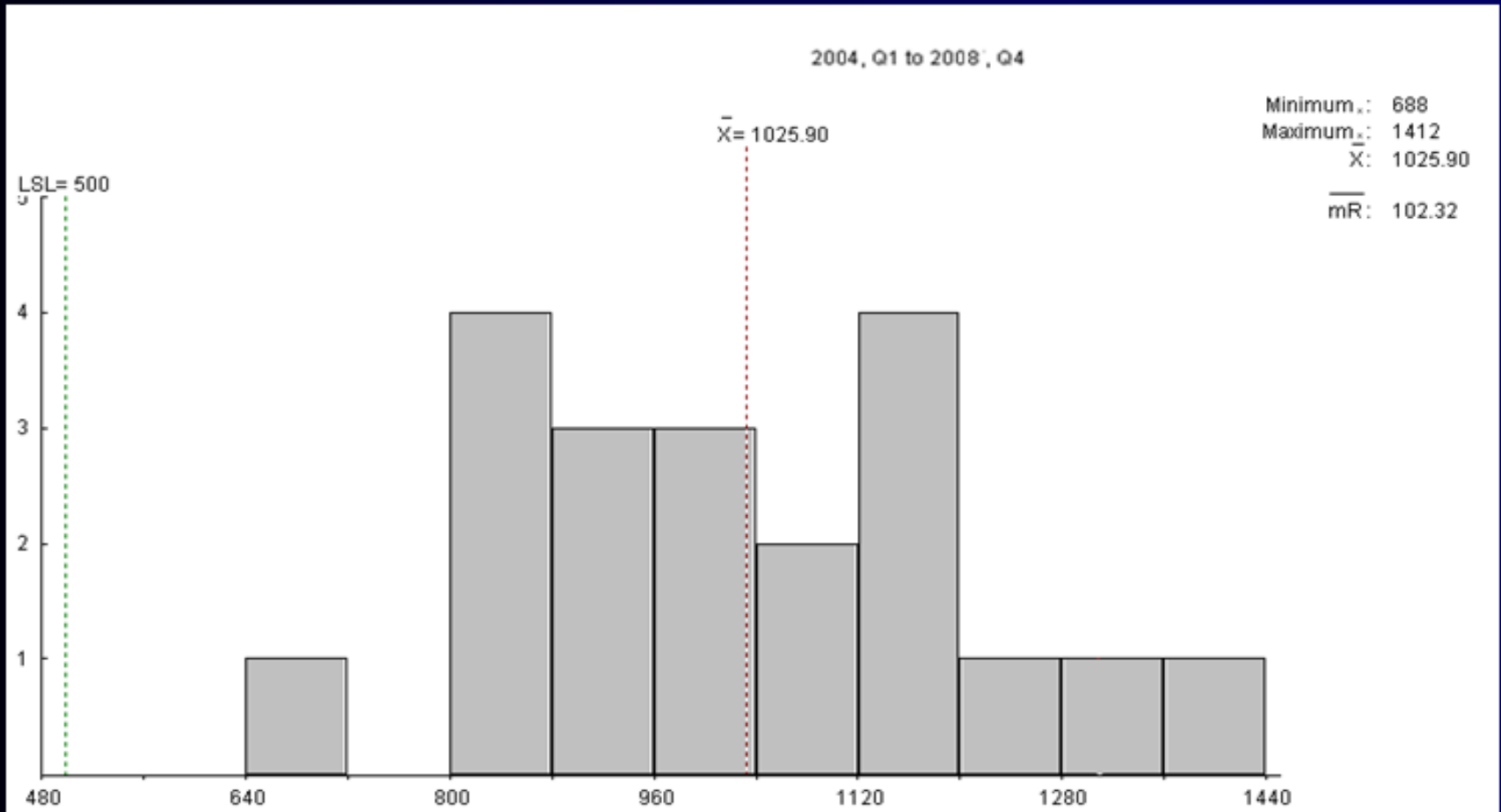
3. Always ... Plot the Data

Region A : quarterly quota \$500,000



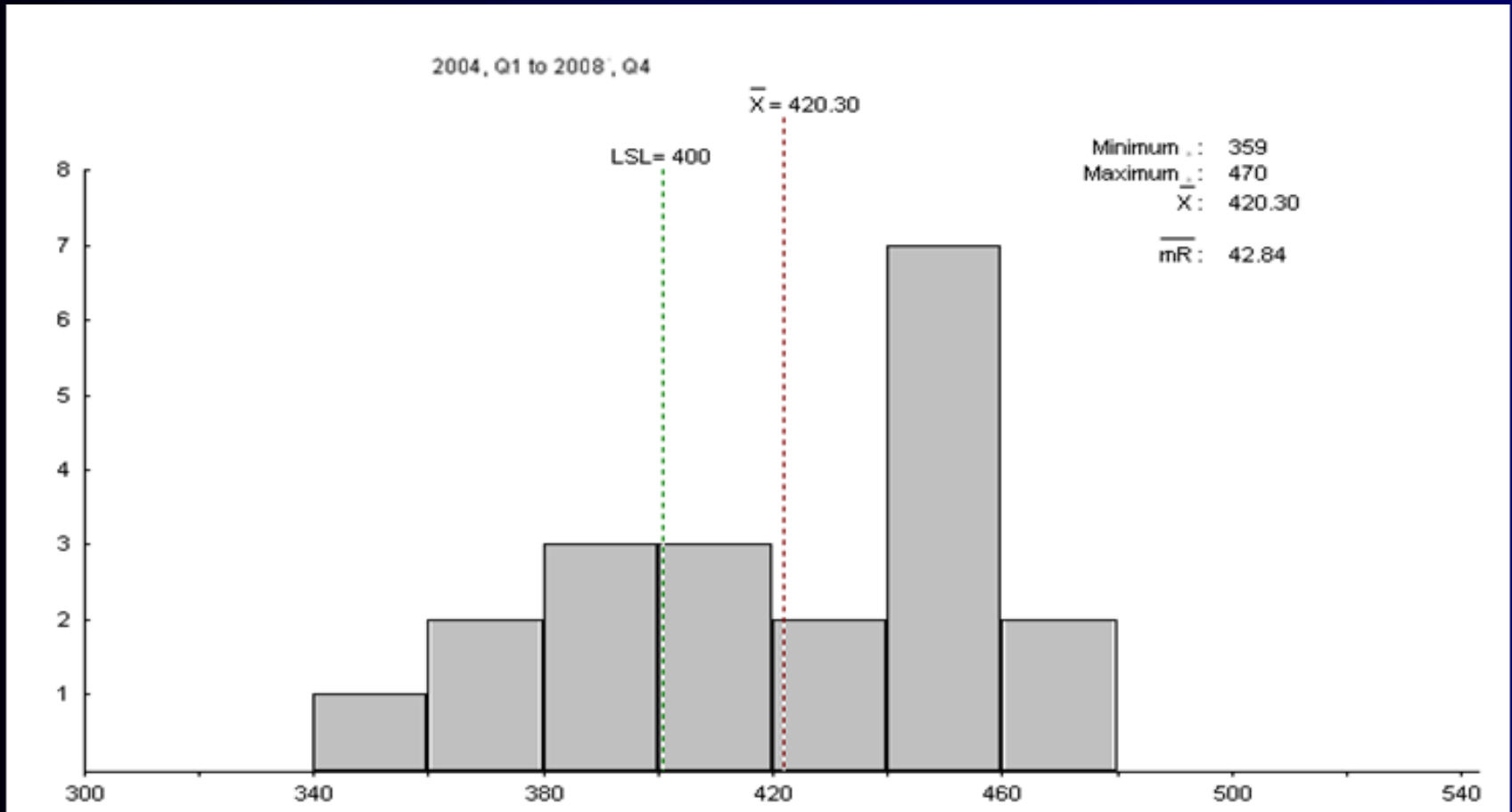
3. Always ... Plot the Data

Region B – quarterly quota: \$500,000



3. Always ... Plot the Data

Region C – quarterly quota: \$400,000



3. Always ... Plot the Data

Lynne Hare & Don Wheeler

Voice of Customer: 20 quarters 2004 -> 2008

- Region A & B – met quota 100%
- Region C - six quarters below quota

3. Always ... Plot the Data

Lynne Hare & Don Wheeler

Voice of Process - Process Behavior Chart:

Process Location & Dispersion

- Running record
- Natural process limits

3. Always ... Plot the Data

Region A: Location & Dispersion

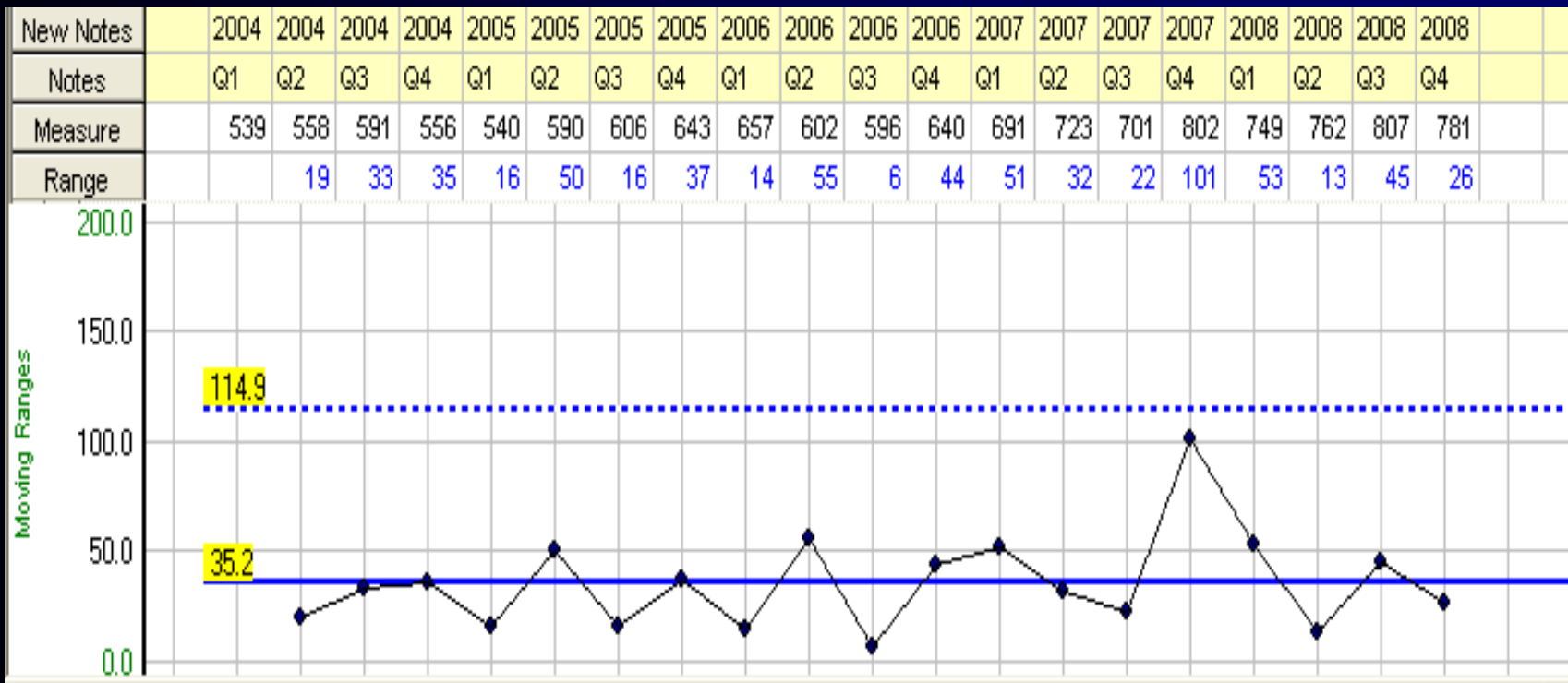
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		Loc	Disp			Loc	Disp
2004	Q1	\$539		2006	Q3	\$596	\$6
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Avg Location: \$657

Avg Dispersion: \$35

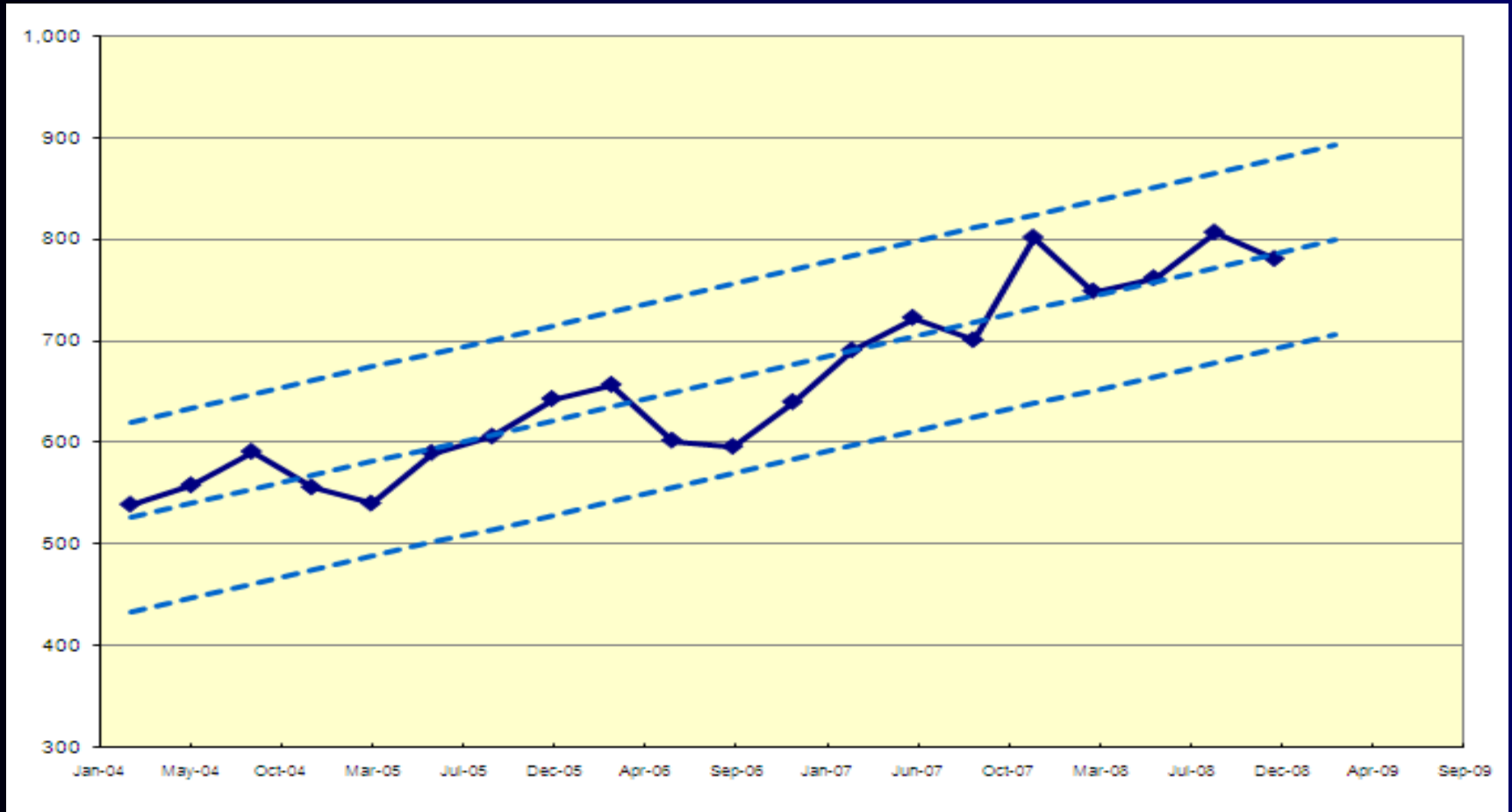
3. Always ... Plot the Data

Region A: predictable dispersion



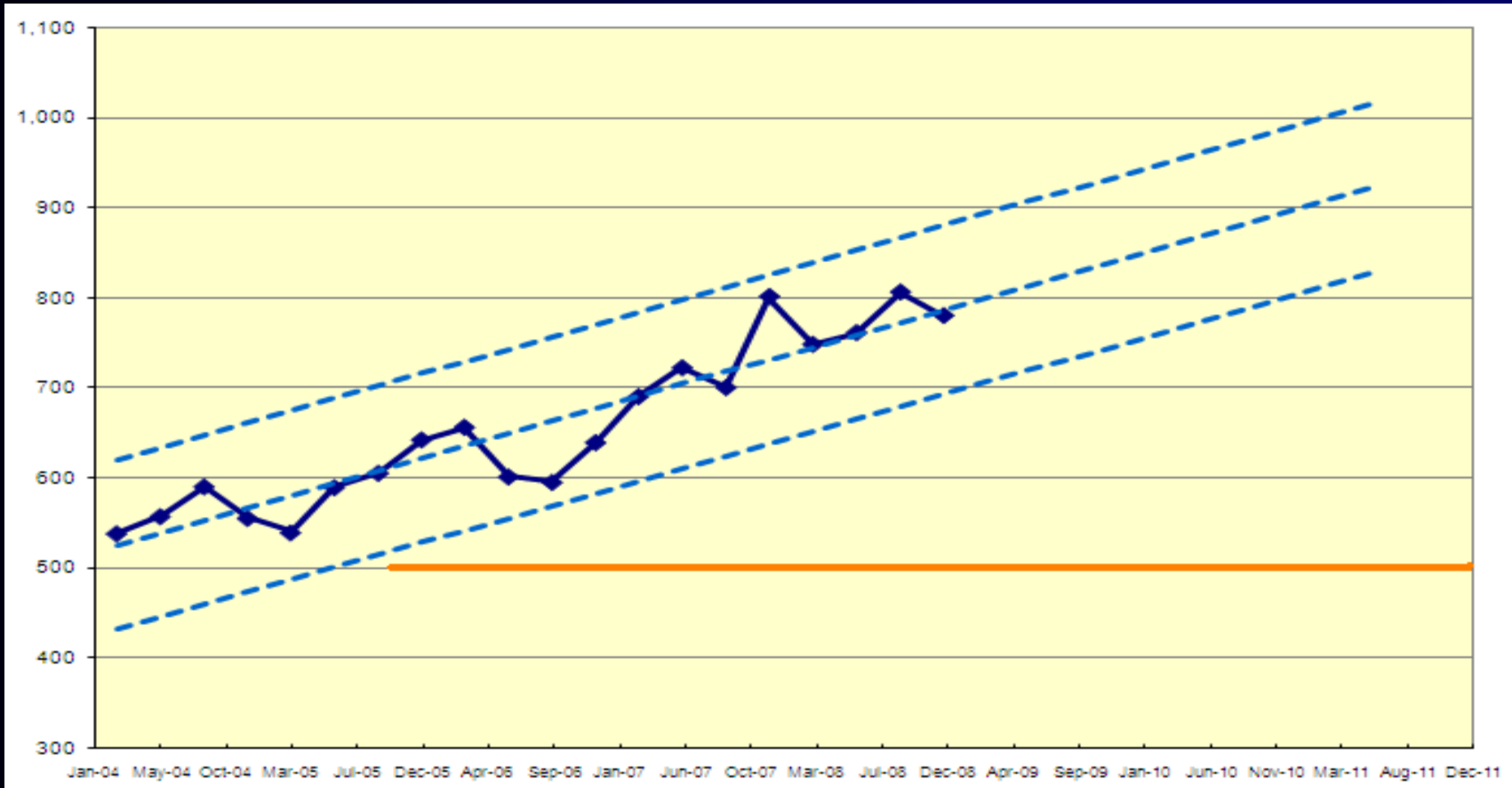
3. Always ... Plot the Data

A (- 2) avg. loc 656 / predictable growth



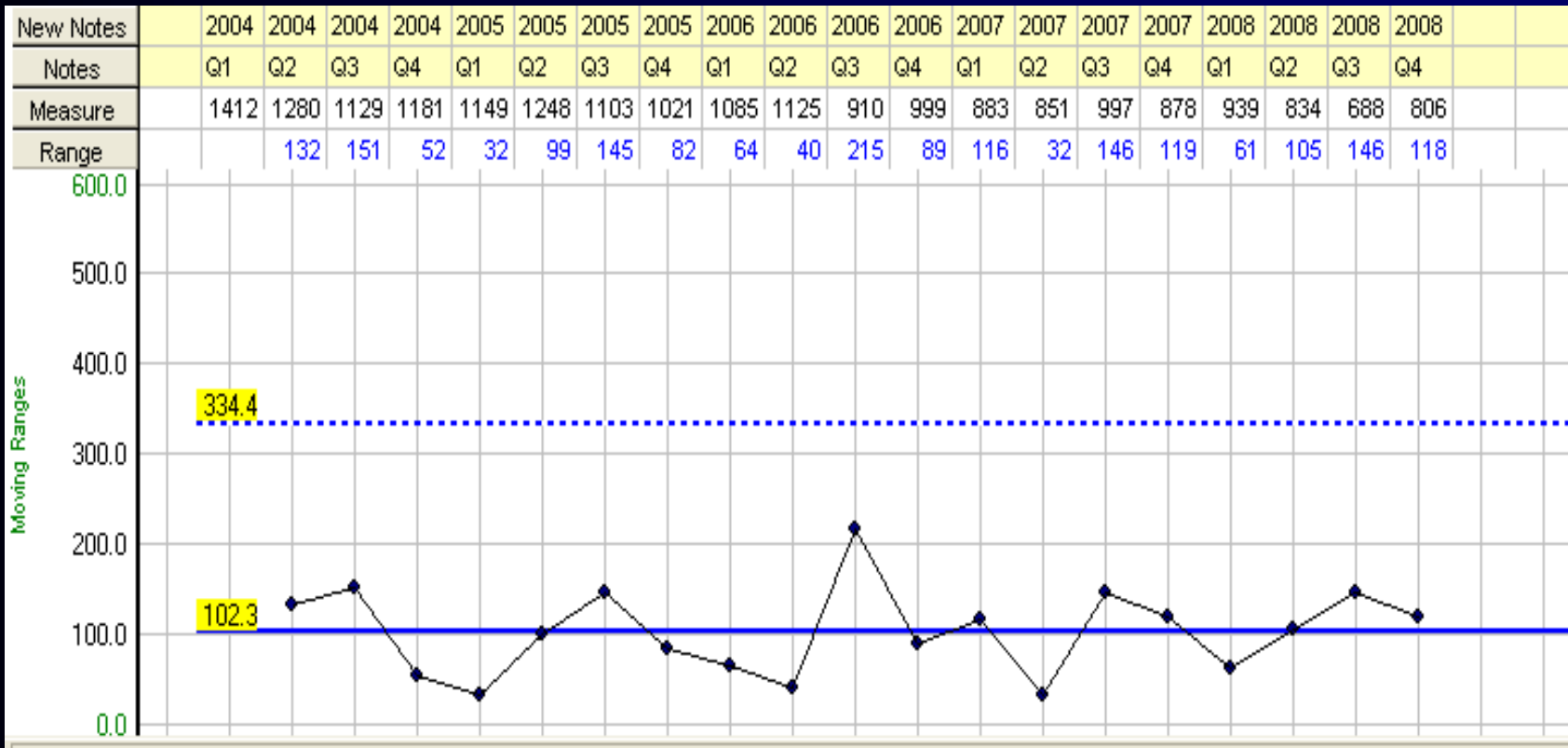
3. Always ... Plot the Data

A: +16%/yr growth - clear windshield



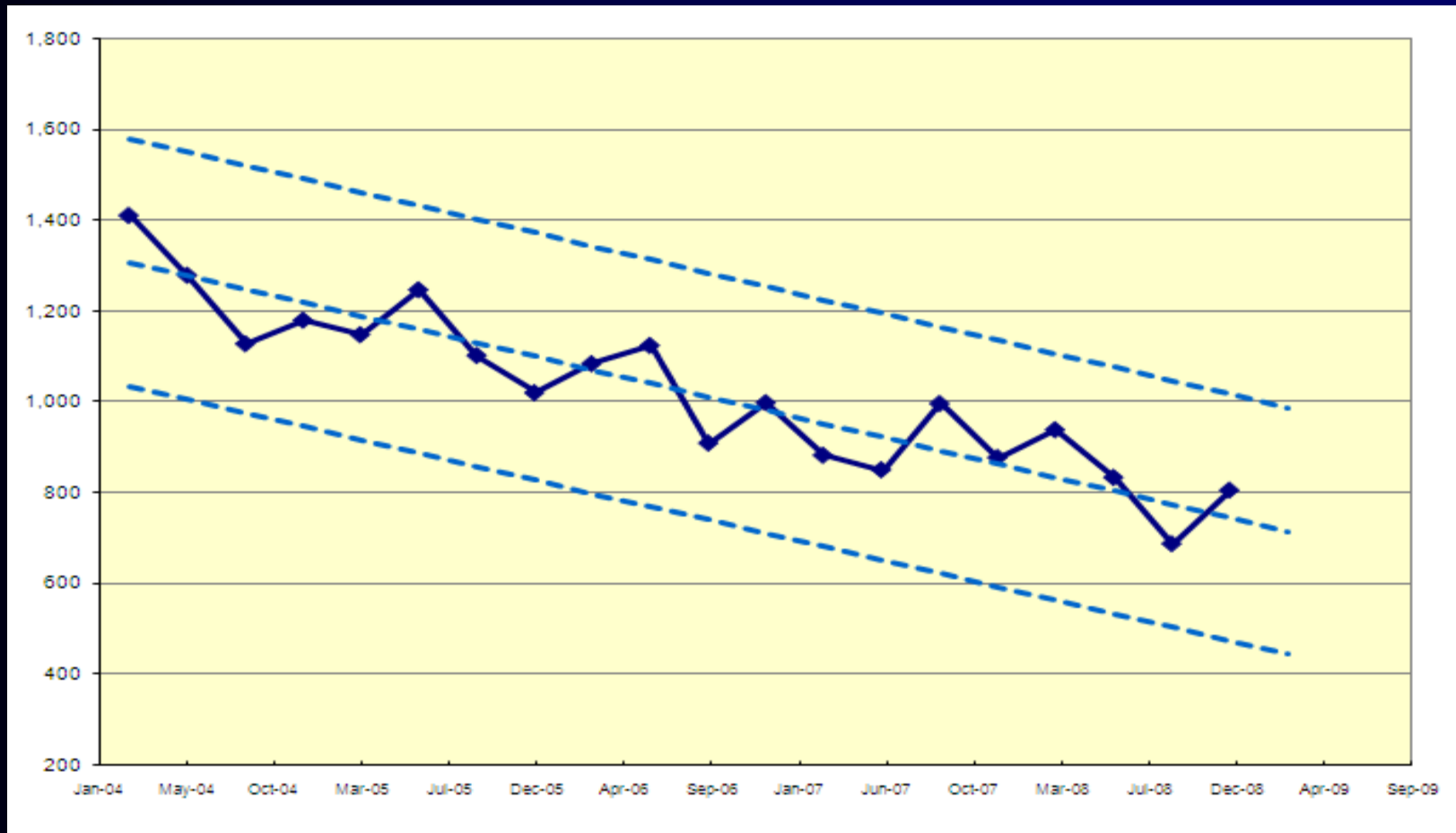
3. Always ... Plot the Data

Region B: predictable dispersion



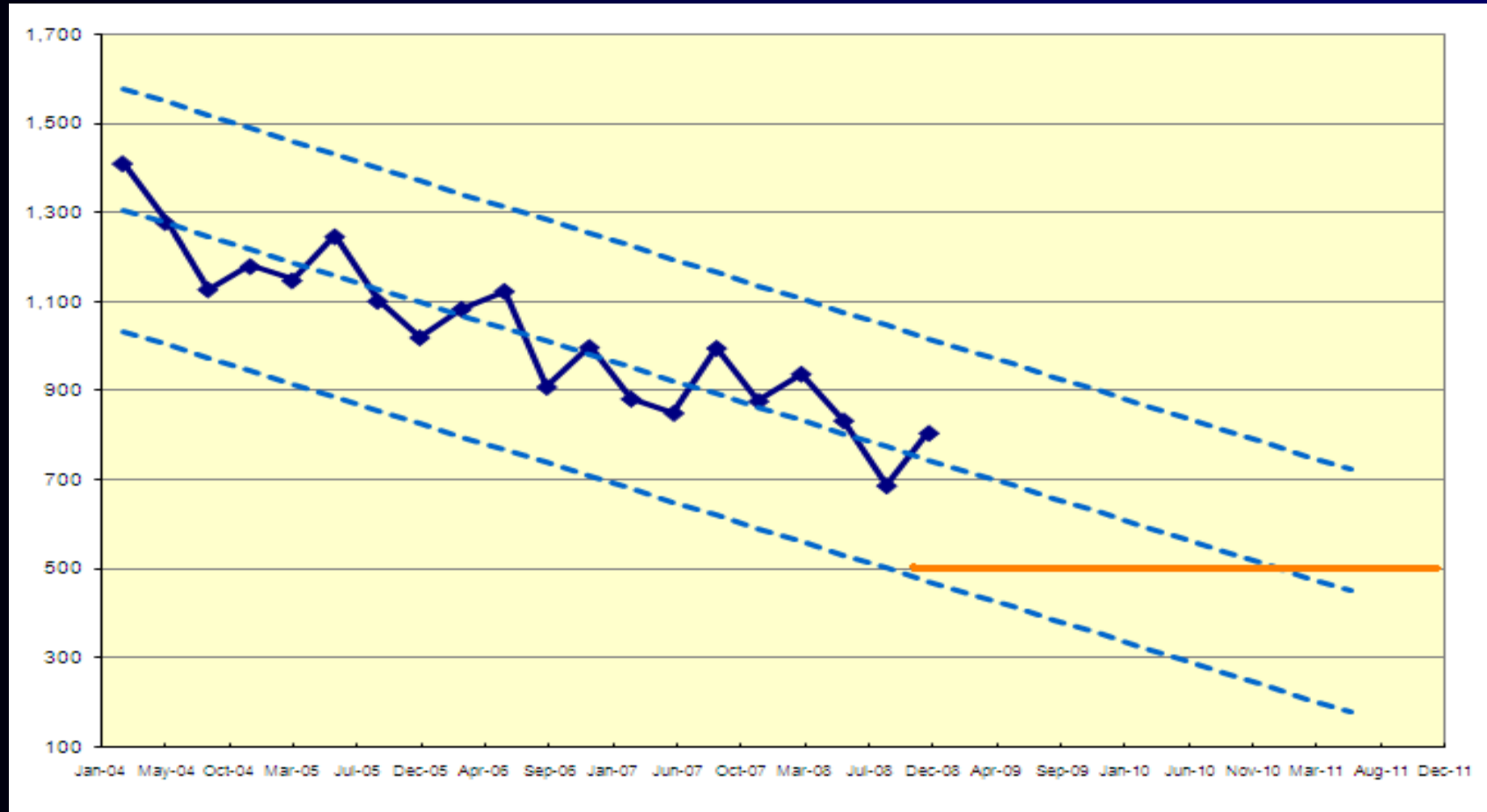
3. Always ... Plot the Data

B (+1) avg. loc 1026 /predictable downtrend



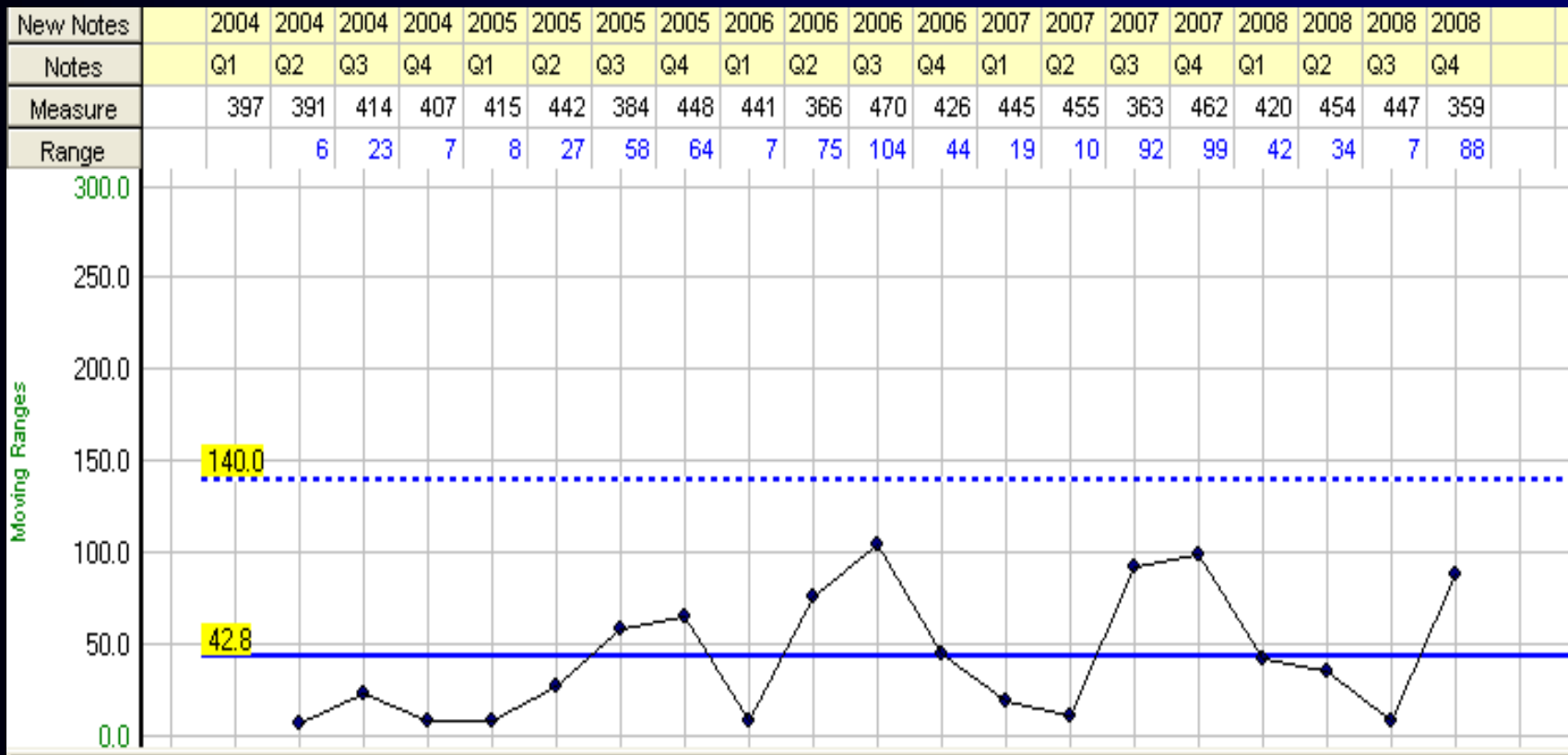
3. Always ... Plot the Data

B: -14%/yr downtrend - clear windshield



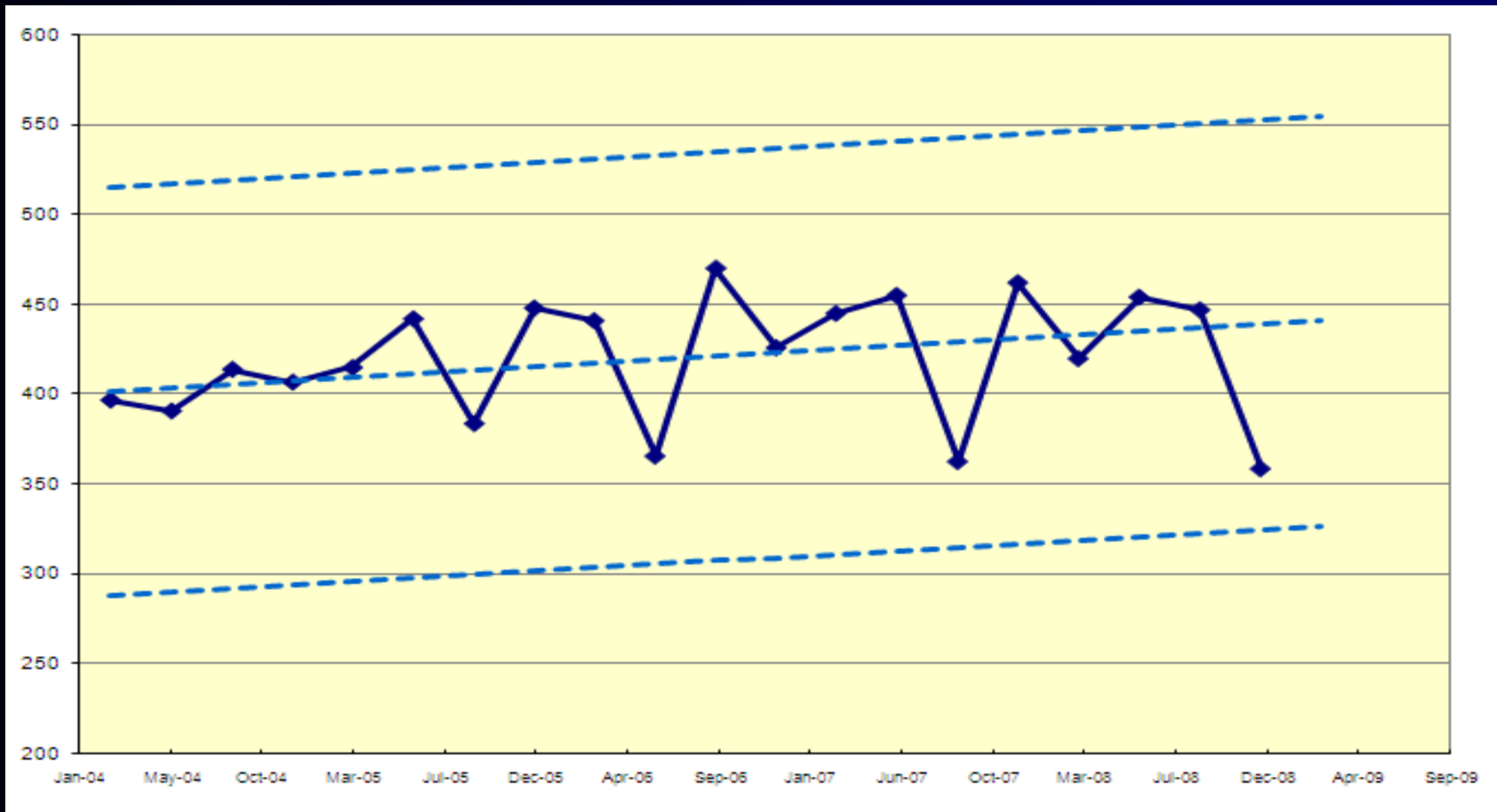
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Region C: predictable dispersion



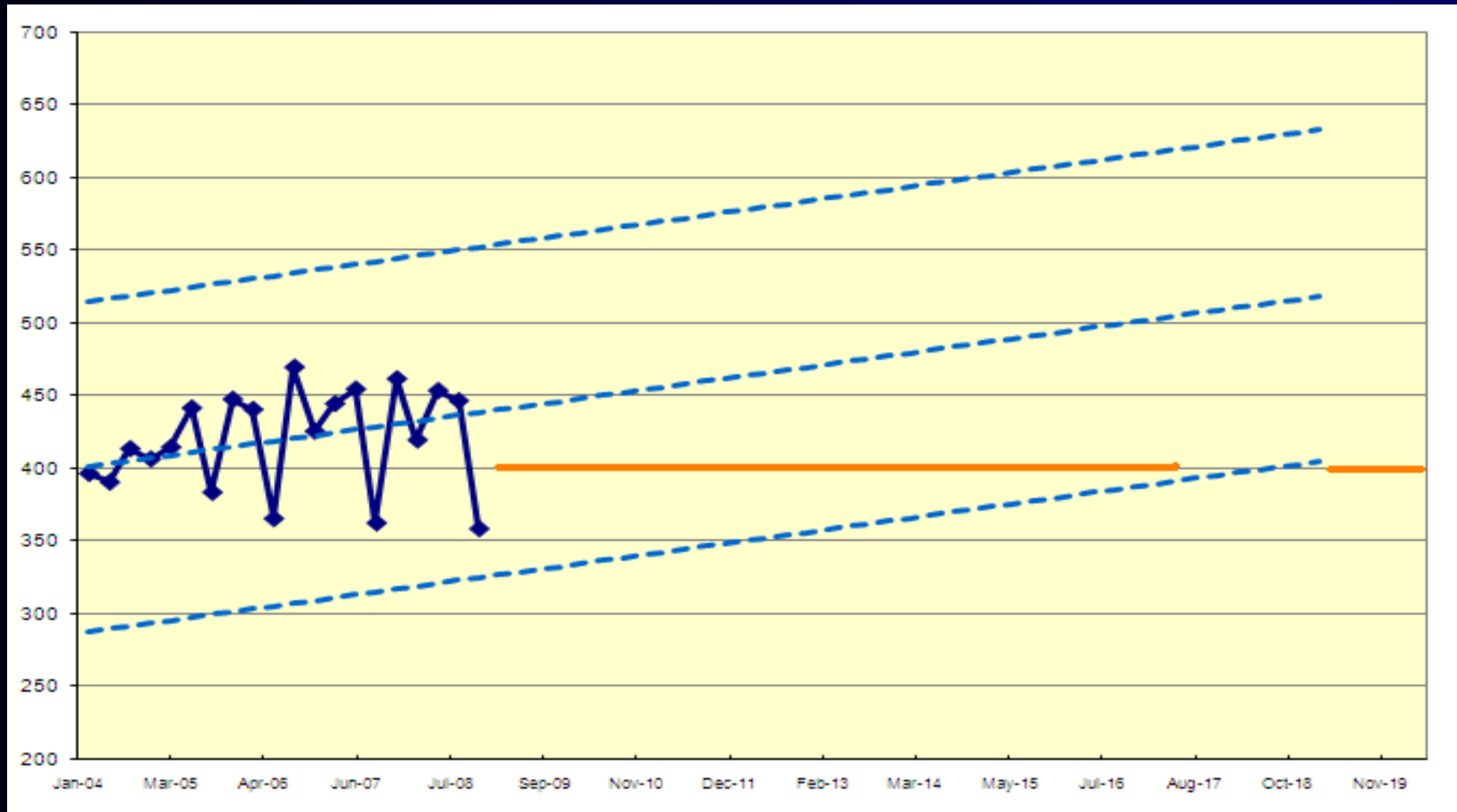
3. Always ... Plot the Data

C (- 4) avg. loc 420 / predictable growth



3. Always ... Plot the Data

C: 3.0%/yr growth - clear windshield



3. Always ... Plot the Data

Region	A	B	C
2008 Q4 Actual	-2	+1	-4
2008 Q4 PBA	\$781	\$806	\$359
2009 Q4 Trends	\$787	\$746	\$439
	\$842 +16%	\$628 -14%	\$447 +3%

3. Always ... Plot the Data

Trend vs. Quota?

Region B: 2008 Q4 LLL: \$474
2011 Q1 Mean: \$480

Region C: 2008 Q4 Mean: \$439
2018 Q3 LLL: \$401
2018 Q3 Mean: \$515

3. Always ... Plot the Data

Region	A	B	C
VOP	Predictable +16%	Predictable -14%	Predictable +3%
VOC	Quota certainty	Will miss quota 2010	Close to quota
Process State	Ideal	Threshold	Threshold to Q3 2017

4. Constancy of Purpose

W.E. Deming

Number 1 of 14 Points:

“Create constancy of purpose for continual improvement of products & service to society, allocating resources to provide for long range needs rather than short-term profitability, with a plan to become competitive, to stay in business, and to provide jobs.”

4. Constancy of Purpose

W.E. Deming & Chambers-Wheeler

Case Study: Tokai Rika

Process: fabrication of electronic dashboard socket

Metric: dimension in millimeters

Requirement: 15.90 ± 0.10 mm (nominal the best)

What is organizational approach?

4. Constancy of Purpose

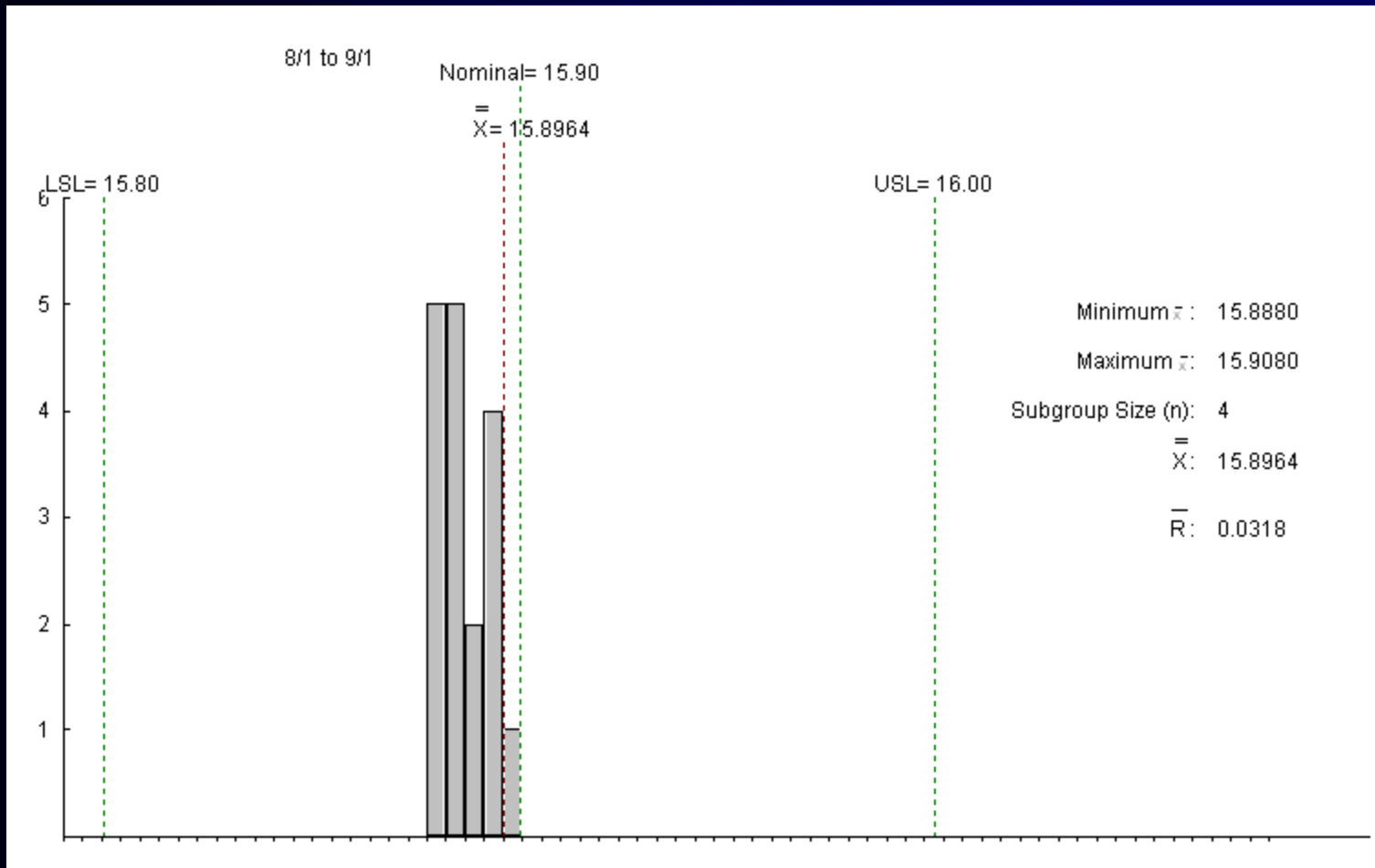
Deming & Chambers-Wheeler

Corporate Policy:

Investigate & eliminate all signals of extreme variation

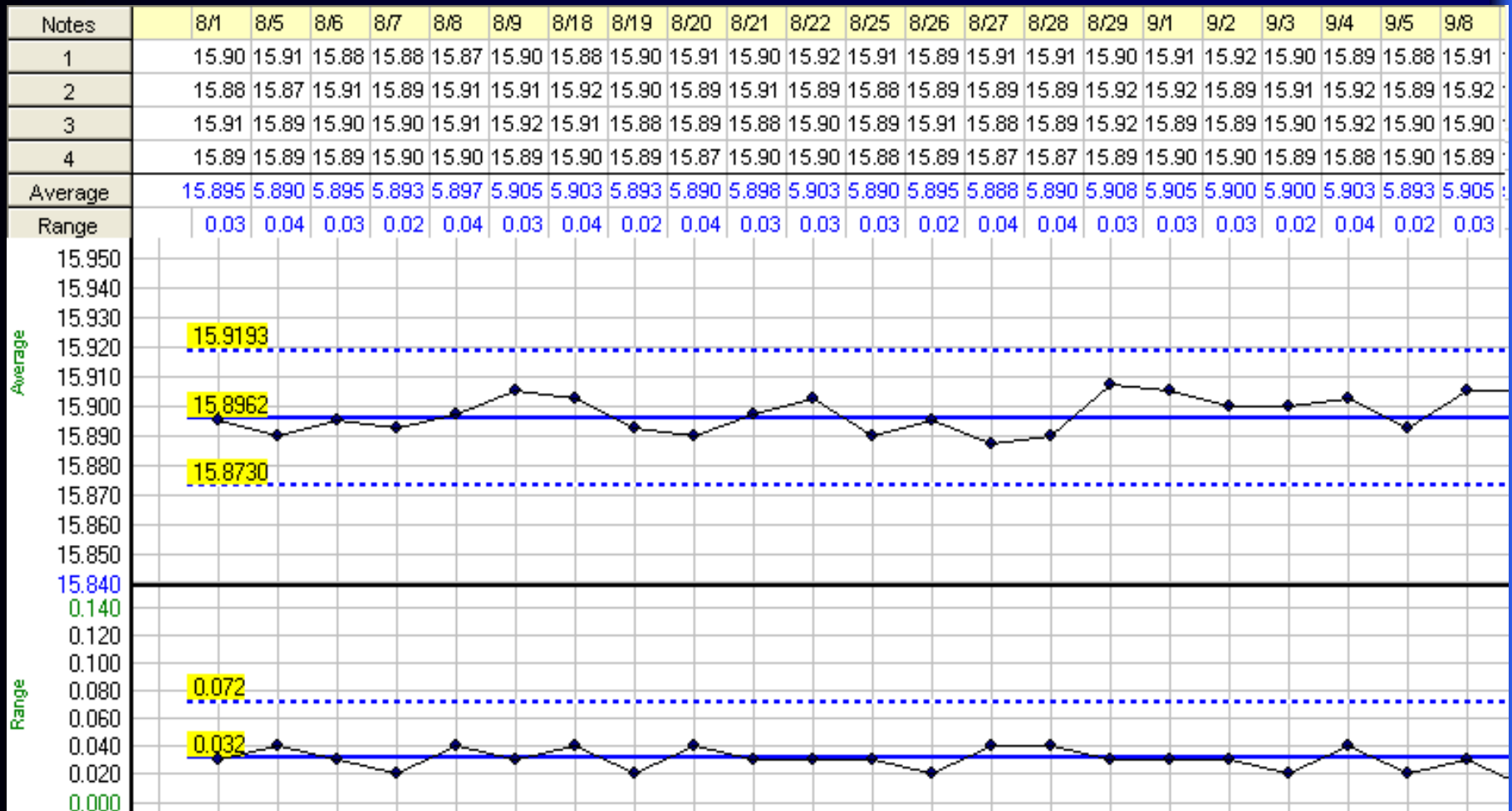
4. Constancy of Purpose

August/September: Ideal state



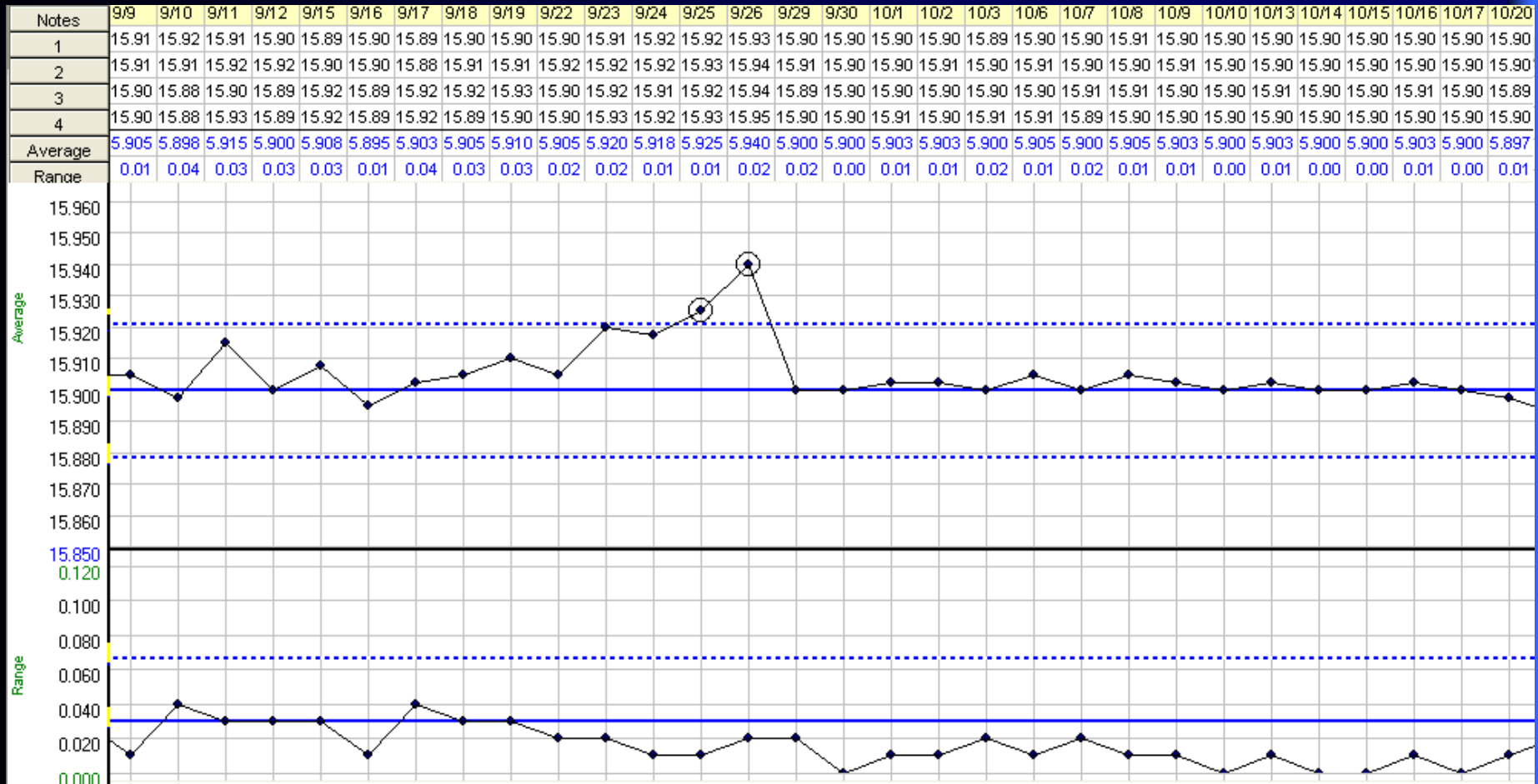
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August/September: Ideal state



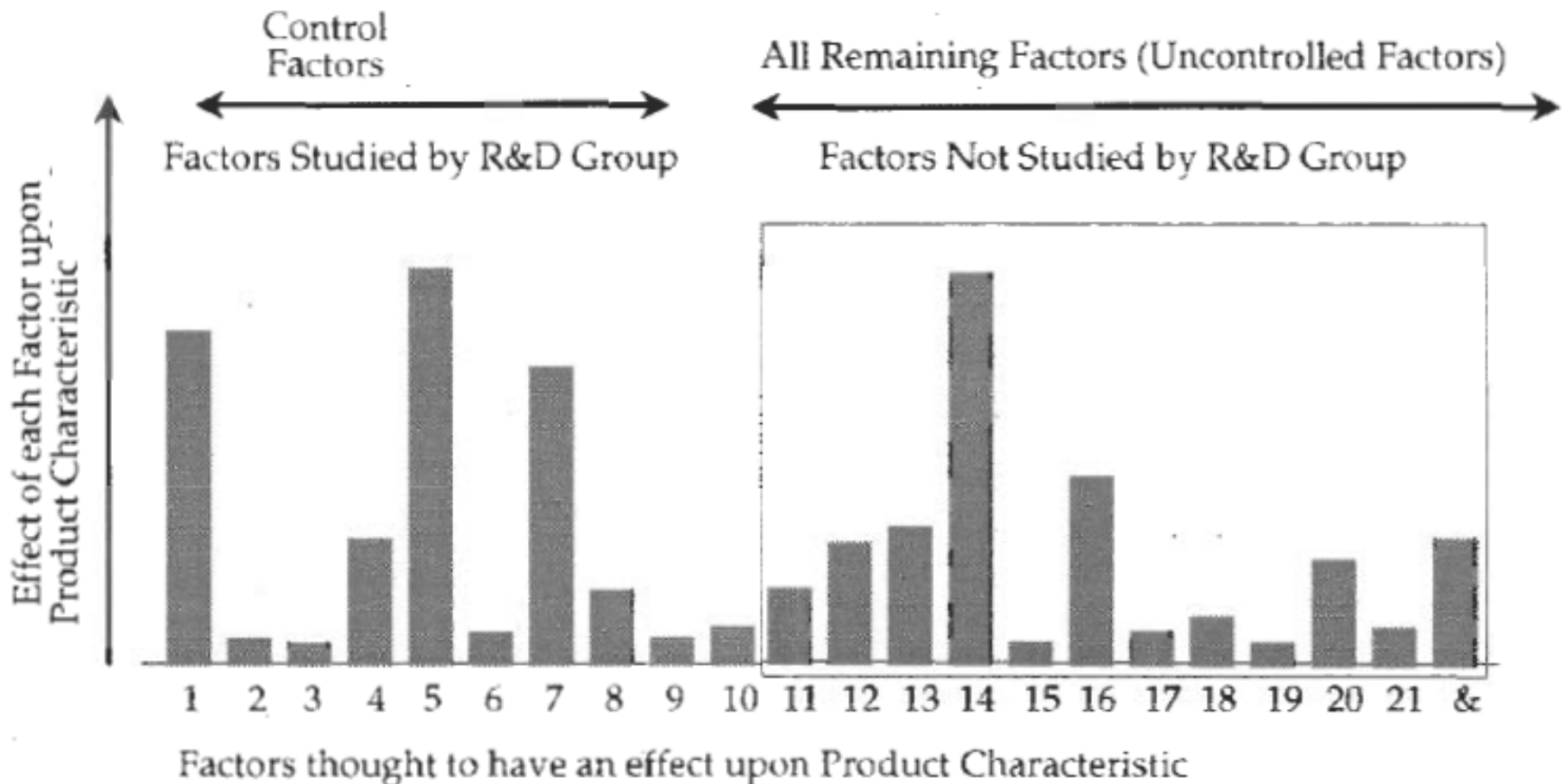
4. Constancy of Purpose

Sep 25 & 26: Extreme variation - **Brink of Chaos**



4. Constancy of Purpose

September 25 & 26: Extreme variation



Cause and Effect Relationships Studied by R&D

4. Constancy of Purpose

September 25 & 26: Extreme variation

Process team action:

Identify direct cause →

Positioning collar attrition

4. Constancy of Purpose

Process team extreme variation response

Implement immediate corrections:

Reposition old collar

Order new collar

4. Constancy of Purpose

Process team extreme variation response

Direct cause -> immediate corrections

Root cause -> permanent corrective action

4. Constancy of Purpose

Extreme variation response – find & remove root cause



Dandelion
Taraxacum officinale



4. Constancy of Purpose

Extreme variation

Process team root cause investigation results:

- Collar - inadequate design for high volume
- Mgmt system – lack of preventive maintenance

4. Constancy of Purpose

Extreme variation

Process team corrective & preventive actions/CAPA:

- Redesign collar – higher resistant material
- Implement preventive maintenance – replace collar every 4 months

4. Constancy of Purpose

Corporate Policy:

Investigate & eliminate all signals of extreme variation

Collar attrition signal -> process improvement action

Unknown factors still exist -> continue New Rules

4. Constancy of Purpose

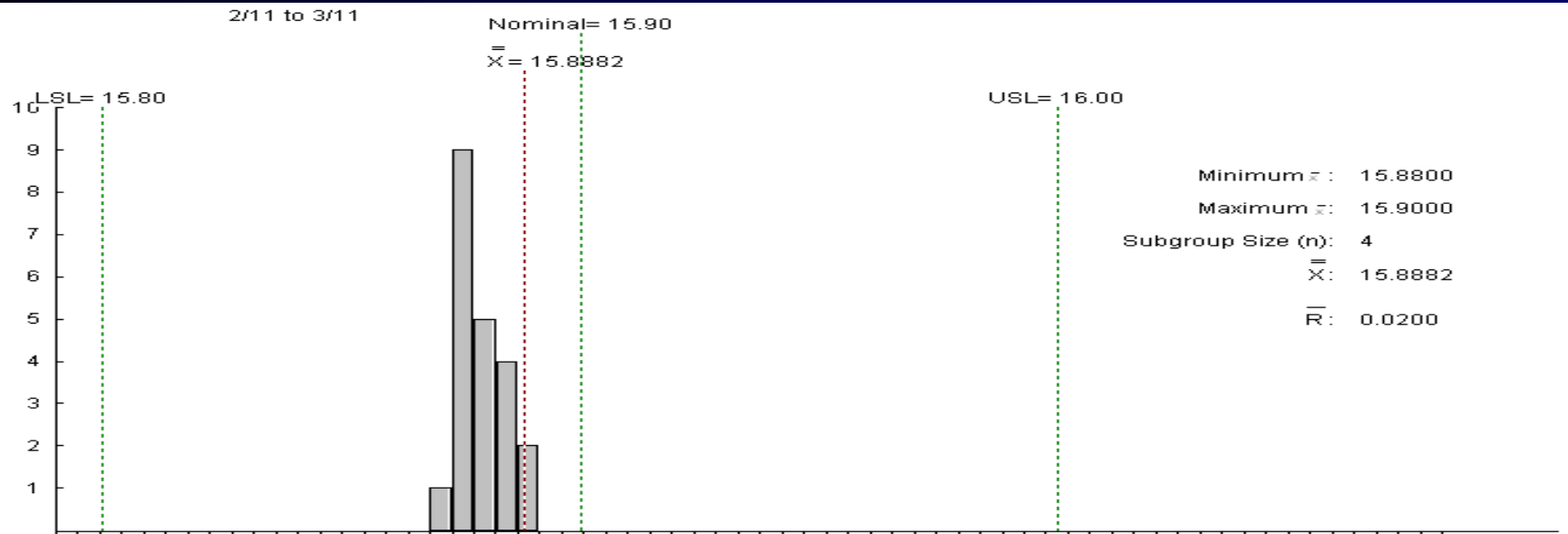
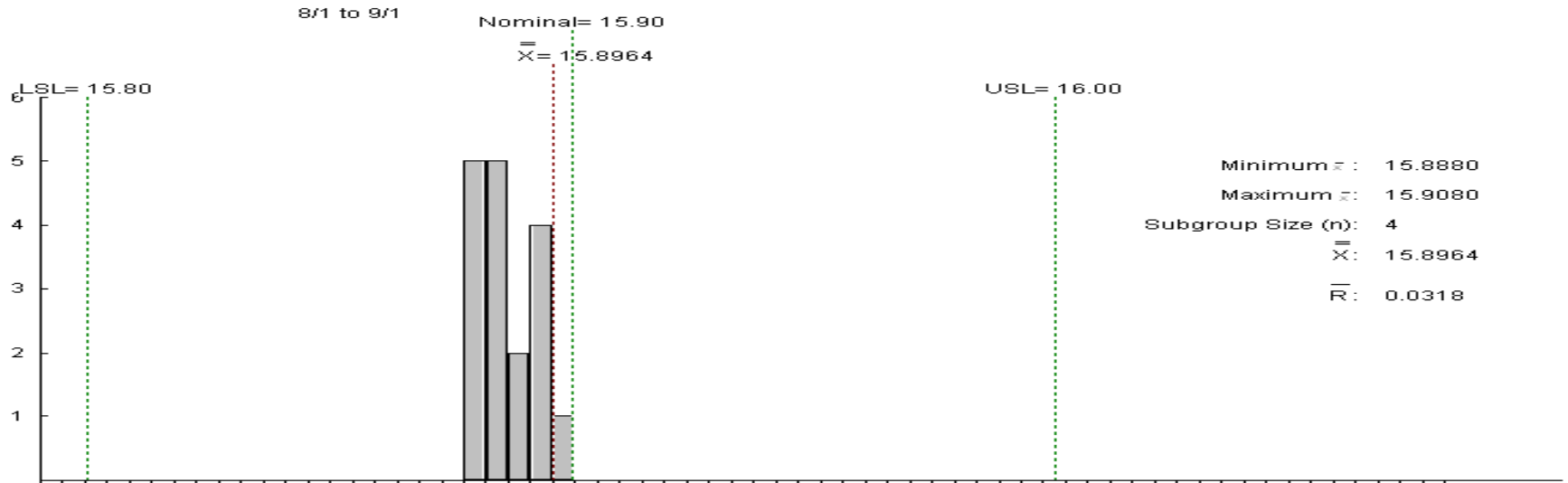
From 1-Aug to 12-March (2½ years later)

Extreme variation: 9

Root cause investigations: 9

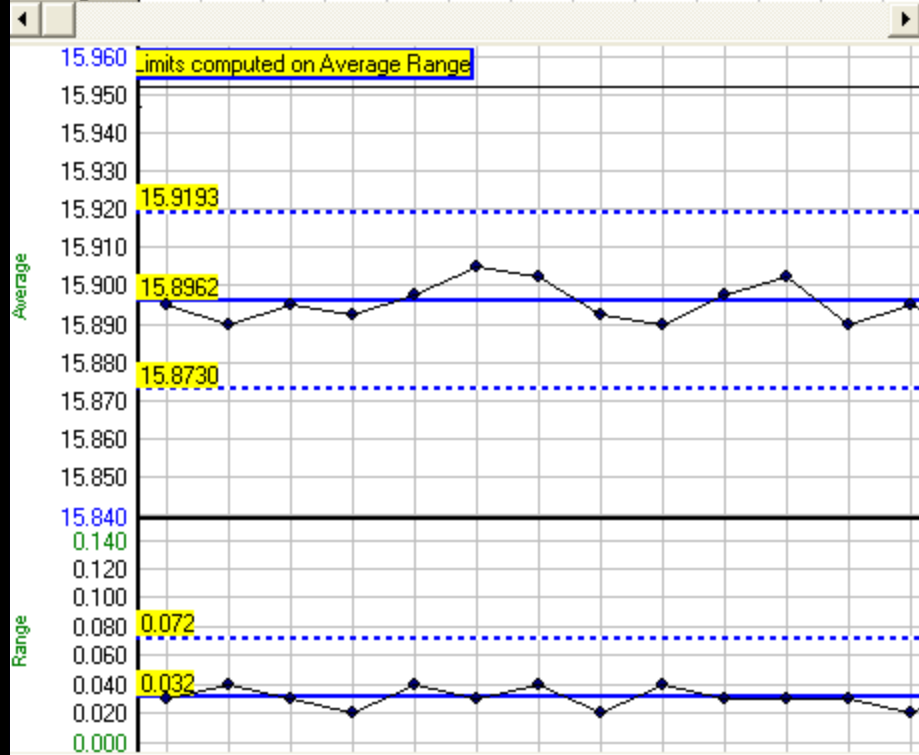
CAPA implementations: 9

4. Constancy of Purpose

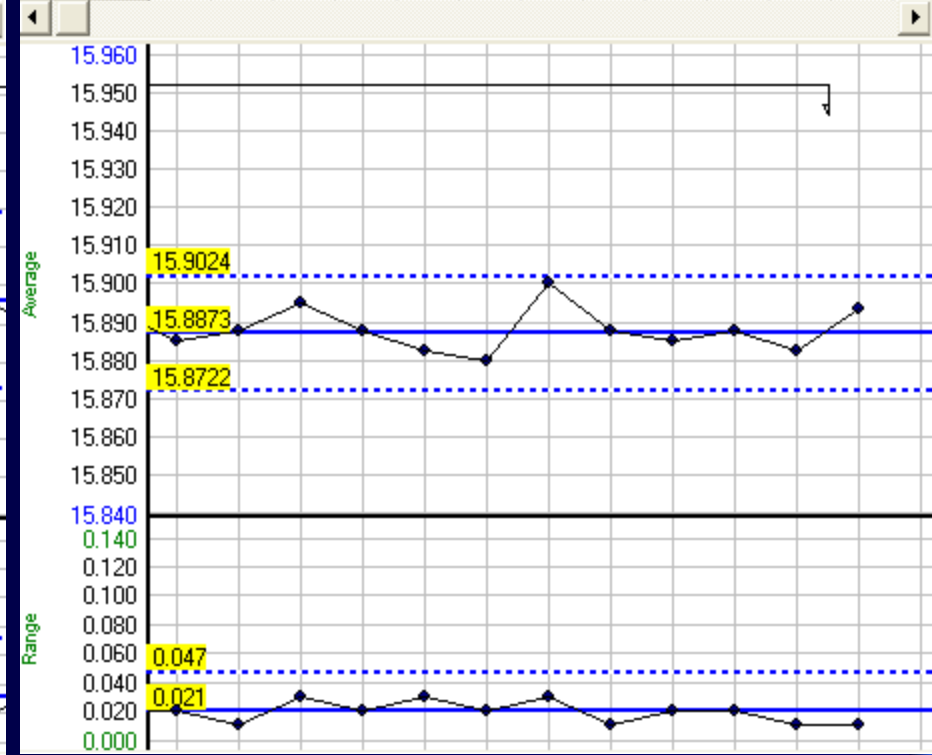


4. Constancy of Purpose

Notes	8/1	8/5	8/6	8/7	8/8	8/9	8/18	8/19	8/20	8/21	8/22	8/25	8/21
1	15.90	15.91	15.88	15.88	15.87	15.90	15.88	15.90	15.91	15.90	15.92	15.91	15.88
2	15.88	15.87	15.91	15.89	15.91	15.91	15.92	15.90	15.89	15.91	15.89	15.88	15.88
3	15.91	15.89	15.90	15.90	15.91	15.92	15.91	15.88	15.89	15.88	15.90	15.89	15.88
4	15.89	15.89	15.89	15.90	15.90	15.89	15.90	15.89	15.87	15.90	15.90	15.88	15.88
Average	5.895	5.890	5.895	5.893	5.897	5.905	5.903	5.893	5.890	5.898	5.903	5.890	5.895
Range	0.03	0.04	0.03	0.02	0.04	0.03	0.04	0.02	0.04	0.03	0.03	0.03	0.03



Notes	2/25	2/26	3/1	3/2	3/3	3/4	3/5	3/8	3/9	3/10	3/11	3/12
1	15.88	15.89	15.91	15.90	15.87	15.88	15.91	15.89	15.89	15.90	15.88	15.89
2	15.90	15.88	15.88	15.88	15.90	15.87	15.90	15.88	15.89	15.88	15.88	15.90
3	15.88	15.89	15.89	15.88	15.88	15.88	15.88	15.89	15.87	15.88	15.89	15.89
4	15.88	15.89	15.90	15.89	15.88	15.89	15.91	15.89	15.89	15.89	15.88	
Average	5.885	5.888	5.895	5.888	5.883	5.880	5.900	5.888	5.885	5.888	5.883	5.893
Range	0.02	0.01	0.03	0.02	0.03	0.02	0.03	0.01	0.02	0.02	0.01	0.01



4. Constancy of Purpose

Spec	Start	Today
15.80 – 16.00		Month 19
State	Ideal	Ideal
Location	15.873 – 15.919	15.872 – 15.902
Spread	0.046	0.030
Dispersion	0.072 max	0.047 max
		35% less variation

4. Constancy of Purpose

15-Dec (last corrective action) ->12-March
3 months of homogeneous & predictable behavior

Spread is 0.03 mm

Measurement unit is 0.01 mm

Variation partly obscured by low measurement accuracy

Time for a more sensitive dimensional gage

New Rules of Process Improvement

- Rule 1 '*On Target with Minimum Variation*' Taguchi
- Rule 2 '*Let your Process State be your Guide*'
Chambers & Wheeler
- Rule 3 '*Always, always, always, without exception:
Plot the Data*' Hare
- Rule 4 '*Constancy of Purpose*' Deming

New Rules of Process Improvement

<u>FDA/GMP</u>	<u>ISO</u>	<u>Lean</u>	<u>Six Sigma</u>
Validated process ✓	Quality Management Systems ✓	Eliminate waste ✓	Near zero defects ✓
Change control ✓	Process approach ✓	Reduce wait time ✓	DMAIC project ✓
Final inspection ≠ guarantee safety/efficacy ✓	Customer perception ✓	Increase productivity ✓	Minimum process variation ✓
	Continual improvement ✓	Reduce Costs ✓	✓✓✓

NEW RULES of PROCESS IMPROVEMENT

How to use GMP, ISO, Lean & Six
Sigma to Optimize Productivity and
Minimize Cost

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