Pakistan’s 9th International Convention on Quality Improvement
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SIX SIGMA
AND ITS INTEGRATION WITH ISO 9000

Mr. Kamran Moosa
CEO & Principal Consultant
Pakistan Institute of Quality Control
15-A-1, PECO Road, Township, Lahore
Ph: +92 42 5140001-02
Fax: +92 42 5140003
E-mail: kamranmoosa@piqc.com.pk
Six Sigma
and its Integration with ISO 9000

Kamran Moosa
Pakistan Institute of Quality Control

Contents
1. Fundamentals of Quality Management
2. Fundamentals of Six Sigma
3. Six Sigma Tools
Some Important aspects and evolution of Quality Management

Changing Scope of “Quality”

Product Quality

Organizational Performance
products, processes, Systems, departments

from

to

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Evolution of Quality Field

Six Sigma

TQM

QA/QMS

QC

SPC

Inspection/Testing
Mesology


Output of Quality Management

Quality Management

Conformance & Improvement
Two Dimensions of Quality

Improvement (CQI)

ISO 9000

Conformance (QA)

Six Sigma

Company A

Company D

Company C

Company D

Benchmark

Competitive

Targets

Improvement is part of every
Quality Management Program

TQM / TQC

ISO 9000

Business Excellence
Quality Awards

Six Sigma
Conformance is now an issue of series of standardization – Conformity Assessment

Quality Control vs Inspection
3rd Stage of QC

Part 2

Fundamentals of SIX SIGMA

1. A Business Strategy
2. Body of Knowledge
3. An Approach
4. A Metric
5. Programs
6. Structure
7. Methodologies
8. Six Sigma Company
9. Required Changes and Challenges
**Six Sigma Definitions**

1. A management-driven, scientific methodology for product and process improvement which creates breakthroughs in financial performance and customer satisfaction. *Source: Motorola*

2. A methodology that provides businesses with the tools to improve the capability of their business processes. This increase in performance and decrease in process variation lead to defect reduction and improvement in profits, employee morale, and quality of product. *Source: ASQ*

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**1: SS as a Business Strategy**

- **Increase Sales**
  - Profit
    - Indirect
    - Direct
  
  \[10-20\%\]

- **Increase Sigma**
  - Profit
    - PONC
    - POC
  
  \[30-40\%\]
2: SS Body of Knowledge

- Process Know-how
- Training Management
- TQM Tools
- Group Dynamics
- Statistical Tools
- Project Management
- Lean Management

3: SS Approach is Problem Solving

- Correction
- Corrective action
- Preventive action
- BPR

- Fixing mistakes
- Fixing Root-causes
- Fixing Systems & Processes
- Changing Systems & Processes
### Problem Solving Logic

**OK**

- dept’l performance

---

**Causes**

- Human Factor
- Ethics
- Competence
- Approach
- Machine
- Factor
- Variability
- Capability
- Conditions
- Methods/Tools
- Env’tmnt/Material

---

**Classification of Causes**

- C, B, A, D, F, B, A
- C, B, B, C, F, D, F, C, B
- C, B, F, D, F, C, B

---

**Solutions and Checking solutions**

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### Kaizen, Quality Circles and Six Sigma Problem Solving

- **Common Sense Suggestions, No stat tools**

- **Medium level problems Basic Analysis 7-SQC Tools**

- **High value, Complex problems Advance Statistical Analysis**

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**Kaizen**

**Quality Circles**

**Quality Teams**

**Six Sigma Projects**
SS is a high potency Capsule to solve quality related problem

Kaizen
For improving Day to day Quality issues

Q.Team/Circles
For improving Day to day Quality Issues
Require group efforts

Six Sigma Project Teams
Only for improving High value, deep rooted Quality issues

Not every problem is a Six Sigma Project

BB and Champions should screen through most beneficial projects to be handled through Six Sigma Methodologies.

Kaizen
By any person

Quality Circles
A little trained

Six Sigma
Specialists

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4: Six Sigma as a Metric

\( \sigma \)

What is Sigma

A Metric that indicate how well a process is performing. A higher sigma means higher performance. A statistical measure of the capability of a process.
Sigma Value and Process Rating

- **V.Poor**
  - 1 Sigma
  - CoQ > 40%
  - Non-Competitive

- **Ordinary**
  - 2 Sigma
  - CoQ > 25%
  - Non-Competitive

- **Excellent**
  - 4 Sigma
  - CoQ < 1%
  - World-Class

- **World-Class**
  - 5 Sigma
  - CoQ < 1%
  - World-Class

- **Process Oscillation - 1.5 Sigma Shift Theory**
  - 3 Sigma
    - Yield = 99.73% (OK)
    - 0.27%, 2700 ppm Defects
  - 3 Sigma
    - Yield = 93.32% OK
    - 6.68%, 66,807 ppm Rej

99.73% 93.32%
### Sigma Table (see Annex)

<table>
<thead>
<tr>
<th>Process Not Shifted</th>
<th>Process Shifted 1.5 $\sigma$</th>
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<tbody>
<tr>
<td><strong>Short Term</strong></td>
<td><strong>Long Term</strong></td>
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<tr>
<td>Yield (OK) %</td>
<td>Reject ppm</td>
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<tr>
<td>1$\sigma$</td>
<td>68.27</td>
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<tr>
<td>2$\sigma$</td>
<td>95.45</td>
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<tr>
<td>3$\sigma$</td>
<td>99.73</td>
</tr>
<tr>
<td>4$\sigma$</td>
<td>99.9937</td>
</tr>
<tr>
<td>5$\sigma$</td>
<td>99.999943</td>
</tr>
<tr>
<td>6$\sigma$</td>
<td>99.999998</td>
</tr>
</tbody>
</table>
### Increasing # of Parts or Processes reduces quality level

<table>
<thead>
<tr>
<th>Part 1 Defect Rate</th>
<th>Part 2 Defect Rate</th>
<th>Final Product Defect Rate</th>
<th>Final Product OK Rate (Yield)</th>
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<tbody>
<tr>
<td>50%</td>
<td>50%</td>
<td>75%</td>
<td>25%</td>
</tr>
<tr>
<td>40</td>
<td>40</td>
<td>64</td>
<td>36%</td>
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<tr>
<td>30</td>
<td>30</td>
<td>51</td>
<td>49%</td>
</tr>
<tr>
<td>20</td>
<td>20</td>
<td>36</td>
<td>64%</td>
</tr>
<tr>
<td>10</td>
<td>10</td>
<td>19</td>
<td>81%</td>
</tr>
<tr>
<td>5</td>
<td>5</td>
<td>10</td>
<td>90%</td>
</tr>
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</table>

### Defect Rate and Final Assembly

(Without 1.5 Sigma Shift)

<table>
<thead>
<tr>
<th>Yield %</th>
<th>Def Rate %</th>
<th>2 Parts</th>
<th>5 Parts</th>
<th>10 Parts</th>
<th>100 Parts</th>
<th>1000 Parts</th>
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<tbody>
<tr>
<td>80.0%</td>
<td>2.4%</td>
<td>64</td>
<td>33</td>
<td>11</td>
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<tr>
<td>85</td>
<td>2.6%</td>
<td>72</td>
<td>44</td>
<td>20</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>90</td>
<td>2.8%</td>
<td>72</td>
<td>44</td>
<td>20</td>
<td>0</td>
<td>0</td>
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<tr>
<td>95</td>
<td>3.2%</td>
<td>90</td>
<td>77</td>
<td>60</td>
<td>1.0%</td>
<td>0</td>
</tr>
<tr>
<td>96</td>
<td>3.3%</td>
<td>92</td>
<td>82</td>
<td>66</td>
<td>1.2%</td>
<td>0</td>
</tr>
<tr>
<td>97</td>
<td>3.4%</td>
<td>94</td>
<td>86</td>
<td>74</td>
<td>5%</td>
<td>0</td>
</tr>
<tr>
<td>98</td>
<td>3.6%</td>
<td>96</td>
<td>90</td>
<td>82</td>
<td>13%</td>
<td>0</td>
</tr>
<tr>
<td>99</td>
<td>3.9%</td>
<td>98</td>
<td>95</td>
<td>90</td>
<td>2.8%</td>
<td>37.1%</td>
</tr>
<tr>
<td>99.9</td>
<td>4.6%</td>
<td>99.8</td>
<td>99.5</td>
<td>99.0</td>
<td>96.2%</td>
<td>37.1%</td>
</tr>
<tr>
<td>99.99</td>
<td>5.2%</td>
<td>99.9</td>
<td>99.9</td>
<td>99.9</td>
<td>99.4%</td>
<td>90.2%</td>
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</tbody>
</table>

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Vendors AQL% effect on final quality

<table>
<thead>
<tr>
<th>Vendors (Def %)</th>
<th>5%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5%</td>
</tr>
<tr>
<td>2</td>
<td>5%</td>
</tr>
<tr>
<td>3</td>
<td>5%</td>
</tr>
<tr>
<td>4</td>
<td>5%</td>
</tr>
<tr>
<td>5</td>
<td>5%</td>
</tr>
<tr>
<td>6</td>
<td>5%</td>
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<tr>
<td>7</td>
<td>5%</td>
</tr>
<tr>
<td>8</td>
<td>5%</td>
</tr>
<tr>
<td>9</td>
<td>5%</td>
</tr>
<tr>
<td>10</td>
<td>5%</td>
</tr>
</tbody>
</table>

Assembly

Yield: 60%
40% Def

Or if you have 10 processes

\[ \text{Yield (RTY)} = (0.95 \times 0.95 \times 0.95 \times 0.95 \times 0.95 \times 0.95 \times 0.95 \times 0.95 \times 0.95 \times 0.95 = 0.6) \]
Sigma Calculations

**DPU**
(Defects/Unit)

Say
10 Defects, 100 pairs
DPU = 10/100 = 0.1 (10%)

**DPO**
(Defects/Opportunity)

Say
10 Defects, 100 pairs,
2 opportunities / carton
DPO = 10/100x2 = 0.05
Or 5% for each type

(cont.)

**DPMO**
(Defects/M. Opportunity)

DPO x 10^6

10 Defects, 100 pairs
2 types of defects
DPMO = 0.05 x 10^6 = 50,000

**Sigma**
Consult Table with DPMO

From Sigma Conversion Table
50,000 DPMO = 3.1 σ
And Yield = 94.7%

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Sigma, Yield, DPMO Table

<table>
<thead>
<tr>
<th>Yield %</th>
<th>Sigma</th>
<th>Defects Per Million Opportunities</th>
</tr>
</thead>
<tbody>
<tr>
<td>99.9997</td>
<td>6.00</td>
<td>3.4</td>
</tr>
<tr>
<td>99.9770</td>
<td>5.00</td>
<td>230</td>
</tr>
<tr>
<td>99.3790</td>
<td>4.00</td>
<td>6210</td>
</tr>
<tr>
<td>93.3200</td>
<td>3.00</td>
<td>66800</td>
</tr>
<tr>
<td>84.2000</td>
<td>2.50</td>
<td>158000</td>
</tr>
<tr>
<td>69.2000</td>
<td>2.00</td>
<td>306000</td>
</tr>
<tr>
<td>50.0000</td>
<td>1.50</td>
<td>500000</td>
</tr>
<tr>
<td>31.0000</td>
<td>1.00</td>
<td>690000</td>
</tr>
<tr>
<td>16.0000</td>
<td>0.51</td>
<td>840000</td>
</tr>
<tr>
<td>8.0000</td>
<td>0.09</td>
<td>920000</td>
</tr>
</tbody>
</table>

Calculating Sigma

- Company: IPP
- Product: Electricity
- CTQ: Up time / Down time
- CTQ Measure: minutes
- CTQ Specs: no downtime
- Defect measure: one min of no power
- Opportunity/unit: 1
- Total Defects in 2005: 500 min
- DPU = 500/525,000 = 0.00095
- Yield: \( \frac{525,000 - 500 \times 100}{525,000} = 99.90 \)
- DPMO = DPU / 0 x 10⁸ = 950
- Sigma (from table) = 4.6 Sigma
Calculating Sigma (2nd Example)

Company: PCB Manufacturing
Product: Printed Circuit Board
CTQ: Board Functionality
CTQ Measure: Non Functioning of Board
CTQ Specs: All boards function properly
Defect measure: Any non-functioning board
Opportunity: Total # of parts + solder points (58)
Defects in a lot of 1000 = 90
DPU = 90/1000 = 0.09
Yield: = 99.84 % (Y = e^-DPU)
DPMO = 0.09 / 58 x 10^6 = 1552
Sigma (from table) = 4.5 Sigma

5: Six Sigma Programs

SS (Six Sigma) → Elimination of Defects from Existing Products and processes

LSS (Lean Six Sigma) → Elimination of Wastes from Existing Products and processes

DFSS (Design for Six Sigma) → Elimination of Defects from New Products and processes
6: SS Structure

Quality Council/Steering Committee

Champions

Sponsors
Process Owner
Coach
Trainers

SS Project Managers
Team Leaders
Team Members

Master
Black Belt

Black Belt

Green Belt

Black Belt

Green Belt

Green Belt

Green Belt
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Project Based Hierarchy

CEO

HODs

Mgrs

Sup

SIX SIGMA PROJECT TEAMS

7: Six Sigma Methodologies

DMAIC

Define

Measure

Analysis

Improvement

Control

DMADV

Define

Measure

Analysis

Design

Verify

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Proper Use of Methodologies

- Reliable / Customer Focused
- (Design for Six Sigma - DMADV)
- Design (Product / Process)
- Efficiency
- (Lean Six Sigma - DMAIC)
- Transactional / Service
- Production
- (Six Sigma - DMAIC)
- Rejection / Errors

Six Sigma Frameworks

<table>
<thead>
<tr>
<th>Program</th>
<th>Six Sigma</th>
<th>Lean Six Sigma</th>
<th>DFSS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Focus / Theme</td>
<td>Variation</td>
<td>Waste / Speed</td>
<td>Reliability &amp; Robustness &amp; Design Features</td>
</tr>
<tr>
<td>Methodology</td>
<td>DMAIC</td>
<td>DMAIC</td>
<td></td>
</tr>
<tr>
<td>Tools</td>
<td>SIPOC, CTQ, SPC, FMEA, DOE, QFD, CoQ, ANOVA, Hypothesis, Regression, MSA (R &amp; R), QFD</td>
<td>5S Value Mapping, Time Study, TPM, Cellular Prod, Supply Chain, Takt Time, Poka Yoke</td>
<td>VOC, QFD, FMEA, CTQ, Gage R &amp; R, TRIZ, Pugh, Matrix, DOE, Reliability Analysis, SPC Systems Engineering</td>
</tr>
</tbody>
</table>

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Define

Define the project goals, business justification, and project outcome

- Customers and Critical to Quality (CTQs)
- Problem Statement, Goals and Benefits
- Identify Champion, Process Owner and Team
- Resources
- Evaluate Key Organizational Support
- Develop Project Plan and Milestones
- Develop Process Map

Tools

- Process Chart
- SIPOC Diagram
- WBS / Project Mgt
- CTQs
- Surveys

Measure

Measure the baseline - determine current performance and long term process capability

Activities

- Define Defect, Opportunity, Unit and Metrics
- Detailed Process Map of Appropriate Areas
- Develop Data Collection Plan
- Validate the Measurement System Analysis (MSA)
- Collect the Data and extensive study
- Begin Developing Y=f(x) Relationship
- Determine Process Capability and Sigma Baseline

Tools

- Process Flow Charting
- Data Collection Plan
- Benchmarking
- Measurement System Analysis (MSA), R&R
- Voice of Customer Gathering
- Process Sigma Calculations
**Analyse**

Extensive exercise to carry out root-cause analysis

**ACTIVITIES**

1. Define Performance Objectives
2. Identify Value/Non-Value Added Process Steps
3. Identify Sources of Variation
4. Determine Root Cause(s)
5. Determine Vital Few x’s, Y=f(x) Relationship

**TOOLS**

1. Pareto Analysis, Time Series/Run Charts
2. Scatter Plots, Regression Analysis
3. Cause and Effect Matrix and Diagrams
4. Test of Hypothesis
5. Data Analysis
6. Failure Mode and Effect Analysis

---

**Improve**

Improve the process with experimentations by eliminating defects and re-engineering.

**ACTIVITIES**

1. Perform Design of Experiments
2. Develop Potential Solutions
3. Define Operating Tolerances of Potential System
4. Assess Failure Modes of Potential Solutions
5. Validate Potential Improvement by Pilot Studies
6. Correct/Re-Evaluate Potential Solution

**TOOLS**

1. Mistake Proofing (Poke Yoke)
2. Design of Experiments (DOE)
3. House of Quality (Quality Function Deployment)
4. Failure Mode and Effect Analysis
5. Simulations
Control

Improve the process with experimentations by eliminating defects and re-engineering.

**ACTIVITIES**

1. Define and Validate Monitoring and Control System
2. Develop Standards and Procedures
3. Implement Statistical Process Control
4. Determine Process Capability and Cost of Quality
5. Develop Transfer Plan, Handoff to Process Owner
6. Verify Benefits, Cost Savings/Avoidance, Profit Growth
7. Close Project, Finalize Documentation, Reward/Award

**TOOLS**

1. Process Sigma Calculation
2. Control Charts
3. Cost of Quality Calculations
4. Control Plan
5. ISO 9001

8: What is a Six Sigma Company?

You don’t have to achieve the 6 Sigma performance level to qualify as Six Sigma...

An organization that is actively working to build the themes and practices of Six Sigma into its daily management activities, and is showing significant improvements in process performance and customer satisfaction.
9: Six Sigma Challenges

1. Sustaining Core competence & talent (BB,GB,Champ)  
   Challenge : HR Function
2. Lessons Learnt and Communication  
   Challenge : Knowledge Management Function
3. Six Sigma # of Projects per year  
   Challenge : Project Management
4. Senior Management Involvement and drive  
   Challenge : Strategic Management Function
5. Motivation / De-motivation  
   Challenge : Reward/Award Program
6. Involvement of Suppliers  
   Challenge : Suppliers Quality Assurance Function
Required Changes

from

- Just measuring the Quality in Products
- Just training Q. Mgrs on Quality
- Conducting normal Reviews on performance
- Culture of individual Performance appraisal

to

- Measuring the quality of all departments for their errors, mistakes & weaknesses
- Train all departmental Heads on Quality Management
- Conduct special reviews on Quality regularly
- Culture of Departmental (process) performance appraisal

from

- Just collecting data on incidences
- Losing historical data and trends of Quality performance
- Ignoring those who solve and improve Quality Issues
- Believe of individual Performance

to

- Also collect data on Root-causes of incidences
- Retain historical data and trends of Quality performance
- Reward and Award those who solve and improve Quality issues
- Believe of Team / Collective Performance
Part 3

Six Sigma Tools

1. Quality Tools
2. Statistical Tools
3. Management Tools

Every tool is a junk unless used appropriately
Six Sigma Tools

Quality Tools
- QFD
- FMEA
- SPC
- GC Tools
- New Mgt Tools
- Benchmarking
- BPR
- COQ
- MSA

Statistical Tools
- Probability Distribution
- Sampling
- Confidence Intervals
- Hypothesis Testing
- Control Charts
- Capability Analysis
- Correlations Analysis
- Regression Analysis
- Design of Experiments
- Analysis of Variance

Management Tools
- Project Management
- Organization Behavior
- Human Resource Management
- Knowledge Management
- SWOT
- MBO

Part 4
Integrating Six Sigma with ISO 9001:2000

1. Survey Findings and Lessons Learnt
2. Linking Six Sigma with 8 QM Principles
3. Integrating Six Sigma with ISO 9001:2000 Clauses
Human Resource Management

a. How Organized

- Unorganized: 80%
- Organized: 20%

b. Effectiveness

- Poor: 70%
- Satisfactory: 30%

A few root-causes

1. Weak External Quality Audits and Consulting Services
2. ISO 9000 for Marketing not for Quality
3. Weak Quality Structure
4. Weak Quality Leadership
5. Little Knowledge of Quality Management Tools
6. Negative Attitude
7. Little Motivation
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2: Linking SS with 8 Principles of ISO 9000 QMS

1. Customer Focused
2. Quality Leadership
3. Involvement of People
4. Process Approach
5. Systems Approach
6. Continual Improvement
7. Decision Making On Data/Facts
8. Beneficial Supplier Relationships
### 3: Integrating Six Sigma with ISO 9001

<table>
<thead>
<tr>
<th>Clause Description</th>
<th>Y</th>
<th>N</th>
<th>Nature of Change</th>
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<tbody>
<tr>
<td>4  General Requirements</td>
<td></td>
<td>✔</td>
<td></td>
</tr>
<tr>
<td>5  Management Responsibility</td>
<td></td>
<td></td>
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<tr>
<td>5.1 Mgt Commitment</td>
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<td>Role of Champions</td>
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<td>5.2 Customer Focus</td>
<td>✔</td>
<td></td>
<td>Critical to Quality</td>
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<tr>
<td>5.3 Quality Policy</td>
<td>✔</td>
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<td>5.5 Resp., Authority, Com</td>
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<td>BB, GB, Champions</td>
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<td></td>
<td>Training Resources</td>
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<td>6.2 Human Resources</td>
<td>✔</td>
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<td>6.3 Infrastructure</td>
<td></td>
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<td>6.4 Work Environment</td>
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<td>✗</td>
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<tr>
<td>7.2 Customer Processes</td>
<td></td>
<td>✗</td>
<td></td>
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<td>7.5 Production provision</td>
<td></td>
<td>✗</td>
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<td>7.5 Measuring Devices</td>
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### (cont.)

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<thead>
<tr>
<th>Clause Description</th>
<th>Y</th>
<th>N</th>
<th>Nature of Change</th>
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<tbody>
<tr>
<td><strong>8 Performance Measurement, Analysis &amp; Improvement</strong></td>
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<td>8.1 General</td>
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<td>8.2 Monitoring and measurement</td>
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<td>IQA to include Six Sigma Program Audit</td>
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<td>8.3 Nonconforming Product</td>
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<td>8.4 Analysis of data</td>
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<td>DMAIC, DMADV</td>
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<td>8.5 Improvement</td>
<td>✓</td>
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<td>Six Sigma Teams</td>
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</tbody>
</table>
Lastly, Two important points to remember...

1. **System Maturity Logic**

   - **An S-Curve**
   - **Six Sigma Implementation**

   - 1st Year: Embryonic
   - 2nd Year: Improvement
   - 3rd Year: Maturity
2. Leadership Drive from Champions

Role of Champions

Poor

Good

Six Sigma
ISO9000
The End

Let's Create together
WORLD-CLASS ORGANIZATIONS

Thank You