ISO 9001:2008, SIX SIGMA, CAPABILITY MATURITY MODEL INTEGRATION (CMMI)

PROCESS IMPROVEMENT INITIATIVES
Process management practices are the shared underlying component of a series of quality related initiatives, including total quality management (TQM), the Malcolm Baldrige Award criteria, ISO 9000, and Six Sigma programs.

The process management philosophy and associated procedures, focused on improving organization's efficiency by:

- rationalizing, coordinating, repeating
- problem solving, heuristic, fact based
- customer focused, comprehensive, participative throughout a firm
ISO's name

"INTERNATIONAL ORGANIZATION FOR STANDARDIZATION"

Whatever the country, whatever the language, the short form of the organization's name is always ISO.

The Founders chose "ISO", derived from the Greek *isos*, meaning "equal" - a short, all-purpose name.
» ISO – A nongovernmental organization
  > Network of the national standards bodies of some 160 countries, from all regions of the world

» ISO standards
  > Practical tools for tackling challenges in all three dimensions of sustainability: economic, environmental, and societal

» ISO has a current portfolio of over 18,600 standards supporting almost every sector of business, industry and technology
Two Key Family of Management Systems Standards are:

- ISO 9000 (quality)
- ISO 14000 (environment)

ISO 9001 as a part “ISO 9000 family” gives requirements for an organization’s quality management system (QMS).

Current Standard in effect is: ISO 9001:2008

- Based 8 Management Principles
- A Requirement Document
- Need to be complied with to qualify for ISO certification
Based on ISO Survey year 2011

- Total No. Countries: 180
- Total No. ISO 9001 Certifications: 1,111,698
- No. of Certifications USA: 25,811

| Year 2011 - Top 10 countries for ISO 9001 certificates |
|-------------|------------------|
| 1 | CHINA | 328,213 |
| 2 | ITALY | 171,947 |
| 3 | JAPAN | 56,912 |
| 4 | SPAIN | 53,057 |
| 5 | GERMANY | 49,540 |
| 6 | UNITED KINGDOM | 43,564 |
| 7 | INDIA | 29,574 |
| 8 | FRANCE | 29,215 |
| 9 | BRAZIL | 28,325 |
| 10 | REPUBLIC OF KOREA | 27,284 |

ISO – World Wide

LakSaNA LLC
Tsukiji (築地) is a district of Chūō, Tokyo, Japan, the site of the Tsukiji fish market:
ISO 9001 certification of a fish wholesaler in Tsukiji
During WWII, 100% Quality inspection; about 80% reliable.

From Dr. Demming, Dr. Juran and other QC experts, Japan manufacturers focused on Quality assurance management systems to prevent defects.

**BRIEF HISTORY OF ISO 9000**
Principle 1 – Customer focus
Principle 2 – Leadership
Principle 3 – Involvement of people
Principle 4 – Process approach
Principle 5 – System approach to management
Principle 6 – Continual improvement
Principle 7 – Factual approach to decision making
Principle 8 – Mutually beneficial supplier relationships

EIGHT MANAGEMENT PRINCIPLES

ISO 9001:2008
Continual Improvement of the Quality Management System

ISO 9001:2008 Process Model

Management Responsibility

Resource Management

Measurement, Analysis, Improvement

Product Realization

Inputs

Outputs

Product

CUSTOMER REQUIREMENTS

Satisfaction

LakSaNA LLC
» ISO 9001:2008 consists of 8 sections
» Sections 1 to 3 define Scope & Reference Documents
» Sections 4 thru 8 defines Requirements
Section 1: Scope
Talks about the standard and how it applies to organizations

Section 2: Normative Reference
References another document that should be used along with the standard, Quality Management Systems-Fundamentals and Vocabulary

Section 3: Terms and Definitions
Gives a few new definitions

Section 4: General Requirements
Gives requirements for the overall Quality Management System
» **Section 5: Management Responsibility**
States requirements for Management and their role in the Quality Management System

» **Section 6: Resource Management**
Provides requirements for resources including personnel, training, the facility and work environment

» **Section 7: Product Realization**
Gives requirements for the production of the product or service, including things like planning, customer related processes, design, purchasing and process control

» **Section 8: Measurement, Analysis and Improvement**
Addresses requirements on monitoring processes and improving those processes

ISO 9001:2008 REQUIREMENTS
<table>
<thead>
<tr>
<th>Business Model</th>
<th>ISO 9001:2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vision and Strategy</td>
<td>Quality Policy</td>
</tr>
<tr>
<td></td>
<td>Quality Objectives</td>
</tr>
<tr>
<td>Customer &amp; Market Focus</td>
<td>Customer focus</td>
</tr>
<tr>
<td>Customer Satisfaction</td>
<td>Customer related processes</td>
</tr>
<tr>
<td></td>
<td>Customer satisfaction</td>
</tr>
<tr>
<td>People Management</td>
<td>Human Resources</td>
</tr>
<tr>
<td>Business Processes</td>
<td>QMS General requirements</td>
</tr>
<tr>
<td></td>
<td>Product Realization</td>
</tr>
<tr>
<td>Organization’s Business Results</td>
<td>Not specifically addressed</td>
</tr>
</tbody>
</table>
EFFECTIVENESS

ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.

ISO 9001:2008

Extent to which planned activities are realized and planned results achieved.

ISO 9000:2008 3.2.14
» EFFECTIVENESS

> Top Management shall ensure that the quality policy includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system.

ISO 9001:2008 5.3

> The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

ISO 9001:2008 8.5.1
Six Sigma is more of a methodology or a philosophy

- Manage the Process Improvement Quantitatively

“Six Sigma is a disciplined, data-driven approach and methodology for eliminating defects (driving towards six standard deviations between the mean and the nearest specification limit) in any process -- from manufacturing to transactional and from product to service.” – isixsigma.com
Year 1979 – Art Sundry & Bill Smith Engineers in Motorola developed statistical method to analyze production problems – casually named as SIX sigma

Year 1995 – Jack Welch at GE adopted it

- Popularized with concepts such as Voice of the customer (VOC), Critical to Quality, DMAIC
- Motorola and GE publicly promoted without any ownership
- Like a Open Source Standard
» A Vision and Philosophical commitment to our consumers to offer the highest quality, lowest cost products

» A Metric that demonstrates quality levels at 99.9997% performance for products and process

» A Benchmark of our product and process capability for comparison to ‘best in class’

» A practical application of statistical Tools and Methods to help us measure, analyze, improve, and control our process
σ is a measure of how much variation exists in a process

**New Belief**
High Quality = Low Cost
3.4 Defects Per Million Opportunities (DPMO)

DPMO allows you take complexity of product/process into account

Refers to statistics. The +/-6 standard deviations (sigma) away from the standard mean

Most companies are within 3 standard deviations of the mean

The higher the sigma value, the better the process is capable of producing defect free results

To be in this six sigma range you must have a quality product 99.9999998% of the time
**Sigma** = **σ** = Deviation

(Square root of variance)

\[ \sigma = \sqrt{\frac{\sum (x_i - \bar{x})^2}{n-1}} \]

---

<table>
<thead>
<tr>
<th>Interval</th>
<th>Percentage</th>
<th>Result (deviation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>between + / - 1σ</td>
<td>68.27 %</td>
<td></td>
</tr>
<tr>
<td>between + / - 2σ</td>
<td>95.45 %</td>
<td>45500 ppm</td>
</tr>
<tr>
<td>between + / - 3σ</td>
<td>99.73 %</td>
<td>2700 ppm</td>
</tr>
<tr>
<td>between + / - 4σ</td>
<td>99.9937 %</td>
<td>63 ppm</td>
</tr>
<tr>
<td>between + / - 5σ</td>
<td>99.999943 %</td>
<td>0.57 ppm</td>
</tr>
<tr>
<td>between + / - 6σ</td>
<td>99.9999998%</td>
<td>0.002 ppm</td>
</tr>
</tbody>
</table>
» Structured problem solving techniques and roadmap

» To improve existing processes
  > Two primary sub-methodologies in Six Sigma
    + DMAIC - **Define-Measure-Analyze-Improve-Control**
    + DMADV - **Define-Measure-Analyze-Design-Verify**

» To design/introduce a new process
  > DFSS (Design for Six Sigma)
    + Using models or prototypes to create designs and ensure they are effective in meeting goals
Define
> Define the problem or process to improve upon related to the customer and goals

Measure
> How can you measure this process in a systematic way?

Analyze
> Analyze the process or problem and identify the way in which it can be improved – way to eliminate the gap between current performance to desired goal(s)
> What are the root causes of problems within the process?

Improve
> Once you know the causes of the problems, present solutions for them and implement them

Control
> Utilize Statistical Process Control to continuously measure your results and ensure you are improving
> Several Software Packages available to assist in measuring yield, defects per million opportunities, etc.
DMAIC

**DEFINE**
- Define Project Scope
- Define Process
- Select Team Members
- Black Belt Sponsor
- Obtain Charter Approval
- Train Team

**MEASURE**
- Identify Needed Data
- Obtain Data Set
- Evaluate Data Quality
- Summarize Data

**ANALYZE**
- Explore Data
- Determine Process Drivers
- Characterize Process & Problem
- Analyze Value Stream
- Update Scope as needed

**IMPROVE**
- Prioritize Opportunities
- Select Solution(s)
- Define New Process/Design
- Implement (pilot if needed)
- Evaluate Risks & Failure Modes

**CONTROL**
- Validate New Process/Design
- Develop & Implement Control Plan
- Document
- Obtain Sponsor Approval

**USING DMAIC on Six Sigma Project**
Define-Measure-Analyze-Design-Verify

Methodology for producing new processes that meet the Six Sigma Quality levels desired.

Similar to DMAIC, however, Improve and Control stages are replaced by design and Verify.
<table>
<thead>
<tr>
<th>DEFINE</th>
<th>MEASURE</th>
<th>ANALYZE</th>
<th>IMPROVE</th>
<th>CONTROL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Charter</td>
<td>Measurement System Analysis</td>
<td>Cause and-Effect Diagram</td>
<td>Force Field Diagrams</td>
<td>SPC</td>
</tr>
<tr>
<td>VOC tools</td>
<td>Process Behavior Chart (SPC)</td>
<td>Tree Diagram</td>
<td>FMEA</td>
<td>FMEA</td>
</tr>
<tr>
<td>(surveys, focus</td>
<td>Exploratory Data Analysis</td>
<td>Brain Storming</td>
<td>7M tools</td>
<td>ISO 900X</td>
</tr>
<tr>
<td>groups, letters,</td>
<td>Descriptive Statistics</td>
<td>Process Behavior Chart</td>
<td>Project Planning &amp;</td>
<td>Change budgets, bid</td>
</tr>
<tr>
<td>comment cards</td>
<td>Data Mining</td>
<td>(SPC)</td>
<td>Management Tools</td>
<td>models, EVMS, Ciost</td>
</tr>
<tr>
<td>Process Maps</td>
<td>Run Charts</td>
<td>Process Maps</td>
<td>Prototype &amp; Pilot Studies</td>
<td>Models</td>
</tr>
<tr>
<td>QFD</td>
<td>Pareto Analysis</td>
<td>Design Experiments</td>
<td>Simulations</td>
<td></td>
</tr>
<tr>
<td>SIPOC</td>
<td></td>
<td>Enumerative Statistics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benchmarking</td>
<td></td>
<td>(Hypothesis Testing)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Project Planning &amp;</td>
<td></td>
<td>Inferential Statistics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Management Tools</td>
<td>Pareto Analysis</td>
<td>(Xs and Ys)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Six Sigma Commonly Used Tools in Each Phase

DMAIC TOOLS
» Champion
  > Manager/Director/Executive who makes sure the resources are in place for a Six Sigma project

» Master Black Belts
  > Quality experts in an organization
  > Responsible for strategic implementation
  > Teach/Mentor other Black and Green Belts

» Black Belts
  > Six Sigma team leaders responsible for implementing process improvement projects within the business

» Green Belts
  > Employee of an organization that has some training in Six Sigma and may lead a Six Sigma project, but only as part of their job
» CMMI is acronym for Capability Maturity Model Integration

» A Capability Maturity Model® (CMM®), including CMMI, is a simplified representation of the world.

» CMMs contain the essential elements of effective processes.

» These elements are based on the concepts developed by Crosby, Deming, Juran, and Humphrey.
The SEI created the first CMM designed for software organizations and published it in a book, *The Capability Maturity Model: Guidelines for Improving the Software Process* [SEI 1995].

CMM model had to change to become CMMI for Development and the concept of constellations was created.

A “constellation” is defined as a collection of CMMI components that are used to construct models, training materials, and appraisal related documents for an area of interest.
Provides guidance for delivering services within organizations and to external customer
Total PAs: 24
Core: 16
Shared with: 1
SVC Specific: 6
Added: 1

Provides guidance for managing, measuring, and monitoring development process
Total PAs: 22

Provides guidance to enable informed and decisive acquisition leadership
Total PAs: 22

CMMI 3 Constellations
» CMMI is a collection of best practices
  > Over 100 organizations formally assisted in its development, including NASA
» There is a wide range of freedom in how an organization decides to embrace the CMMI.
» The CMMI documents best practices from many organizations.
» The CMMI describes WHAT to do, not HOW to do it.

**CMMI WHAT IS IT?**
The CMMI is structured as follows:

> Maturity Levels: staged representation
  + layer in the foundation for continuous process improvement
  + Staged representation is the approach used in the Software CMM
  + It is predefined sets of process areas to define an improvement path
    – Single rating for the organization – facilitates comparison among the Organizations

> Capability Levels: continuous representation
  + Characterize improvement relative to an individual process area.
  + Make improvements to selected specific process areas
    – Enables comparisons across and among organizations on a process-area-by-process-area basis.
<table>
<thead>
<tr>
<th>Level</th>
<th>Capability</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Continuous Process Improvement</td>
<td>Organizational Innovation &amp; Deployment Causal Analysis &amp; Resolution</td>
</tr>
<tr>
<td>4</td>
<td>Quantitative Management</td>
<td>Quantitative Process Management Software Quality Management</td>
</tr>
<tr>
<td>3</td>
<td>Process Standardization</td>
<td>Requirements Development Technical Solution Product Integration Verification Validation Organizational Process Focus Organizational Process Definition Organizational Training Integrated Product Management Risk Management Integrated Teaming Integrated Supplier Management Decision Analysis &amp; Resolution Organizational Environment for Integration</td>
</tr>
<tr>
<td>1</td>
<td>Heroic Efforts</td>
<td>Design Develop Integrate Test</td>
</tr>
</tbody>
</table>

**Process improvement**

Process measured and controlled

Process characterized for the organization and is proactive

Process characterized for projects and is often reactive and poorly controlled

Process unpredictable and poorly controlled

**CMMI LEVELS**
The CMMI is structured as follows:

> Process Areas (PA)
  + A Process Area is a cluster of related practices in an area
  + Each process area is defined by a set of goals and practices
  + All CMMI process areas are common to both continuous and staged representations

> Goals: Generic and Specific
  + There are two categories of goals and practices:
    - **Generic goals and practices**: They are a part of every process area.
    - **Specific goals and practices**: They are specific to a given process area.
    - A process area is satisfied when the processes of a company cover all of the generic and specific goals and practices for that PA.

> Common Features

> Practices: Generic and Specific
» Focused on Concept of Process Areas (PA)
  > Collection of Best Practices
» Each PA has Goals to be achieved
» Each goal is supported by Best Practices
» Goals are defined in high level terms
» practices are in ‘actionable terms’
» Specific Practices for Specific Goals
» Generic Practices for Generic Goals
» Improved schedule predictability
» Improved Cycle time
» Increased productivity
» Improved quality
» Enhanced customer satisfaction
» Decreased cost of quality

CMMI BENEFITS
Appraiser collect evidence to verify goals are achieved

Implementation Scheme:

- Continuous Representation – Focus on capability of the PAs
  + Focus on chosen process areas and implement Best Practices
  + Auditor will measure the progress on 6 tier capability scale
  + Higher-up the scale means more capable

- Staged Representation - Focus on Organizational Maturity
  + Focus on pre-defined set of PAs
  + Auditor will measure the progress on 6 tier capability scale of the whole organization
  + More ordered way of integrating suite of process improvement
CMMI Appraisal

> An examination of one or more processes by a trained team of professionals
> To assess strengths and weaknesses of an organization
> using an appraisal reference model as the basis for assessment
> categories of model components as defined in the CMMI:
  + **Required** : specific and generic goals only.
  + **Expected** : specific and generic practices only.
  + **Informative** : includes sub-practices and typical work products.

CMMI Appraisals
The SEI has released two guiding documents for CMMI assessments:

- **Appraisal Requirements for CMMI (ARC)**: It contains the requirements for three classes of appraisal methods Class A, Class B, and Class C.
- **Standard CMMI Appraisal Method for Process Improvement (SCAMPI)**: Method Description Document (MDD) is currently the only approved Class A appraisal method.
ISO 9001:2008, CMMI and CMMI share many similar characteristics.

ISO 9001:2008 is a generic Quality Standard well suited to any production environment crossing many functional areas including customers.

Six Sigma well suited in a transaction heavy stable environment.

Six Sigma is based on statistical analysis focused on shaping process to reflect Voice Of the Customer (VOC).

The CMMI is well suited in a technology development environment.

In a multimodal environment:

- For successful implementation, requires an understanding of these process plans and their relationships – interoperability characteristics.
- To be most effective, all selected improvement initiatives should be unified, integrated - not layered or stove piped.
- Develop their strategy keeping in mind that multiple initiatives are interoperable.

SUMMARY
<table>
<thead>
<tr>
<th>Adoption Attributes</th>
<th>ISO 9001</th>
<th>Six Sigma</th>
<th>CMMI</th>
</tr>
</thead>
</table>
| Acceptance & Recognition by Industry | • Widely recognized and accepted in the International community  
• Independent Registrars/Certifying body  
• Legislated support by Member countries | • More like an Open Source Process Improvement Program  
• No Legislated support – not an official program | • Fairly recognized and accepted in the International community  
• CMMI institute is the only Certifying body  
• Funded largely by DoD and Carnegie Melon University through CMMI institute. |
| Focus | • Satisfying Customer Requirements  
• Implemented across the entire enterprise  
• Checking for compliance against a definition or model | • Focus on problems and opportunities  
• Implemented across the entire enterprise, areas such as engineering, sales, marketing, and research. | • Typically Domain Specific such as Systems Engineering, Software Engineering  
• Checking for compliance against a definition or model |
| Application | • A generic quality standard  
• Can be adopted to any business | • Well suited for heavy transaction environment. Such as Manufacturing or business | • Well suited for technology development environment  
• It encompasses best practices for systems engineering, software engineering, , supply sourcing, integrated process and product development. |
<table>
<thead>
<tr>
<th>Adoption Attributes</th>
<th>ISO 9001</th>
<th>Six Sigma</th>
<th>CMMI</th>
</tr>
</thead>
</table>
| **ADOP**TION **DEPTH** | • When Implemented, it covers all department/segments of the business.  
• Need to implement all stated requirements.  
• Certification issued to the specific business facility. | • Implemented by Six Sigma team.  
• Scope is defined by the team’s charter.  
• Depth could be very shallow. | • It is collection of process Areas (PA)  
• Organization can choose the PAs to suit their needs.  
• In staged Representation need to follow fixed adoption path |
| **REQUIRED KNOWLEDGE & SKILLS** | • Good understanding of how process can help the current business.  
• Does not require large degree of specialized skills | • Need to have formal analytical and design experience  
• Require knowledge of statistical and quantitative analysis, Design of experiments, Control Charting, etc. | • Need to have experience/knowledge with execution and management of technology projects and its life-cycle |
| **PROVEN EFFECTIVENESS** | • Has long track record  
• It is mandatory for business transactions in most of the countries outside United States | • Has solid track record for proven performance. | • DoD and other U. S Government agencies either require or favor CMMI certifications for issuing contracts.  
• Other foreign Governments are also started adopting this approach |
| **ROI*** | 2.1 to 24.1 | **Motorola & GE show large savings.  
GE cited $320 Million in 1997, $740 Million in 1998 & 1.5 Billion in 1999 | 1.85 to 45.1 |
» PROCESSES AND PEOPLE
» PROCESS MANAGEMENT AND INNOVATION
» Processes are as good as the people

”Peter Drucker wrote that “neither technology or people determines the other, but each shapes the other.” —that success stems from having the right people and the right processes in place.

» Emphasizing people over process sets up a solid foundation for success

» Building a right team

> getting that blend of disparate talents and qualities which mix together to make a functioning unit.
DOES PROCESS MANAGEMENT ENHANCE OR HINDER INNOVATION?

EXPLOITATION AT THE COST OF EXPLORATION?
  > Exploitation - builds on a firm's existing technological capabilities
  > Exploration - More distant search for new capabilities

“Process management and its associated technologies and philosophies are conservative and resistant to anything but incremental or competence-enhancing innovation. . . It is the promise of ambidextrous organizational forms and heterogeneous senior teams that provide the possibility of building organizations capable of both celebrating process activities as well as limiting their damage.”

By MARY I. BENNER, University of Pennsylvania & MICHAEL L. TUSHMAN, Harvard Business School”

PROCESS MANAGEMENT AND INNOVATION
Albert Einstein said, "The significant problems we face today cannot be solved at the same level of thinking we were at when we created them."

“We hypothesized that the greater the extent of process management, the smaller the number of exploratory innovations.”

» MAJOR SOURCES USED FOR THIS PRESENTATION:
  > http://www.sei.cmu.edu
  > http://cmmiinstitute.com/
  > ISO’s Website: www.iso.org
  > “Process Improvement Essentials by James R. Persse
  > CMMI and Six Sigma: Partners in Process Improvement by Jennine M. Siviy, M. Lynn Penn and Robert W. Stoddard
    + Authors: David I. Levine, Haas School of Business, University of California, Berkeley, CA 94720, levine@haas.berkeley.edu & Michael W. Toffel, Harvard Business School, Boston, MA 02163, mtoffel@hbs.edu, January 18, 2010.
MAJOR SOURCES USED FOR THIS PRESENTATION:


> Is CMMI an Applicable Framework That Can be Used to Improve New Technology Venture Processes? By Zella Jackson Hannum and Dr. David Lyth, Western Michigan University


> Perspectives on the productivity dilemma Paul S. Adler a, Mary Benner b, David James Brunner c,*, John Paul MacDuffie b, Emi Osono d, Bradley R. Staats c, Hirotaka Takeuchi d, Michael L. Tushman c, Sidney G. Winter