Quality Management Systems
Topics to cover:

- Elements of TQM
- ISO 9000 family of standards (then and now)
- QS 9000
- The Baldrige and Deming Awards
- Quality Management in Service Industries
Evolution of QA Methods...

- SPC
- DOE
- Taguchi
- Quality Mgmt Systems
- Six Sigma...

What does the term Quality really mean?

Quality is the ability of a product or service to consistently meet or exceed customer expectations.
Historical Summary

• Quality Assurance
  – Artisanship
    • One person / common purpose among tasks
    • Closeness of producer and consumer
  – Industrial revolution
    • Long supply chains
    • Unskilled labor (division of labor)
      – Mass production
      – Uniform quality
      – Loss of understanding of purpose
    • Eli Whitney and Henry Ford
  – Consumerism: a response

• Quality has emerged now as a business strategy
Total Quality

Total Quality Management

– What does *total* mean?
  • Entire organization
  • All products and processes
  • All aspects (management, design, control)

– Not a *flavor of the month* (i.e., typical management fad)
  • Long term perspectives
  • Consider the Japanese

– Checklist in Summary
Costs of Quality

- Failure Costs - costs incurred by defective parts/products or faulty services.
- Internal Failure Costs
  - Costs incurred to fix problems that are detected before the product/service is delivered to the customer.
- External Failure Costs
  - All costs incurred to fix problems that are detected after the product/service is delivered to the customer.
Costs of Quality (contd)

- Appraisal Costs
  - All product and/or service inspection costs.
- Prevention Costs
  - All TQ training, TQ planning, customer assessment, process control, and quality improvement costs to prevent defects from occurring.
Quality Cost: Traditional View

Cost per good unit of product

Quality level (q)

Internal and external failure costs

Prevention and appraisal costs

Total quality costs

Minimum total cost

Optimum quality level

100%
Quality and Competitiveness

Continuous Quality Improvement

- Increased revenue
- Increased market share
- Higher prices
- Improved competitive position
- Increased defects-free output
- Reduced cost of operations
- Increased profits

Market-Route Benefits

Cost-Route Benefits
Quality Cost Minimized at Zero Defects

Cost per good unit of product

Internal and external failure costs

Total quality costs

Minimum total cost

Prevention and appraisal costs

Quality level (q)

Optimum quality level

100%
Taguchi's Quality Loss Function

Any deviation from target causes a loss to society
Quality and Competitiveness

• Value of Quality
  – Impacts of quality efforts on performance
    • Market share and profitability
    • Customer satisfaction
    • Quality
    • Costs
    • Employee relations
  – Directly related to ROI
  – Six Sigma programs have proven the value of quality
Total Quality Management Principles

1. Customer-focused Organization
2. Leadership
3. Involvement of People
4. Process Approach
5. System Approach to Management
6. Continual Improvement
7. Factual Approach to Decision Making
8. Mutually Beneficial Supplier Relationships
How do Customers see Quality

- **Performance** - main characteristics of the product/service
- **Aesthetics** - appearance, feel, smell, taste
- **Special features** - extra characteristics
- **Conformance** - how well product/service conforms to customer’s expectations
- **Safety** - Risk of injury
- **Reliability** - consistency of performance
Dimensions of Quality (Cont’d)

• *Durability* - useful life of the product/service

• *Perceived Quality* - indirect evaluation of quality (e.g. reputation)

• *Service after sale* - handling of customer complaints or checking on customer satisfaction
Determinants of Quality

- Design
- Ease of use
- Conformance to design
- Service
Consequences of Poor Quality

Recall that Quality is…

The ability of a product or service to consistently meet or exceed customer expectations

Not meeting Quality is…

**Loss of business:**

Poor designs or defective products or services can result in loss of business

**Liability:**

Damage or injures resulting from faulty design

**Productivity:**

Productivity and quality are often closely related

**Costs:**

Poor quality increases certain costs incurred by the organization
Responsibility for Quality

• Top management
• Design
• Procurement
• Production/operations
• Quality assurance
• Packaging and shipping
• Marketing and sales
• Customer service
Ethics and Quality

• Substandard work
  – Defective products
  – Substandard service
  – Poor designs
  – Shoddy workmanship
  – Substandard parts and materials

Having knowledge of this and failing to correct and report it in a timely manner is unethical.
Quality Gurus

- Edward Deming
  - Plan - Do - Check - Act; statistical methods
  - Fourteen Points for Transformation Management
  - Design of Experiments

- J. M. Juran
  - Managerial Practices; Training; Cost of Quality
  - Total Quality Control, “hidden plant”
  - Fourteen Points for Transformation Management

- Armand Feigenbaum
  - Total Quality Control, “hidden plant”
  - Managerial Practices; Training; Cost of Quality

- Kaoru Ishikawa
  - Total Quality Control, “hidden plant”
  - Managerial Practices; Training; Cost of Quality

- Philip Crosby
  - Quality Circles, 7 Tools
  - Zero Defects and Quality is Free

- Genichi Taguchi
  - Robust Design
  - Quality Loss Function
  - Design of Experiments
  - Quality Circles, 7 Tools

- J. M. Juran
  - Fourteen Points for Transformation Management
  - Plan - Do - Check - Act; statistical methods
  - Quality Gurus
Quality Certification

• ISO 9000, QS 9000

• Set of international standards on quality management and Quality assurance, critical to international Business

• ISO 9000 series standards, briefly, require firms to document their quality-control systems at every step (incoming raw materials, product design, in-process monitoring and so forth) so that they’ll be able to identify those areas that are causing quality problems and correct them.
The ISO 9000 Series Standards

- ISO 9000 requires companies to document everything they do that affects the quality of goods and services.
  - Hierarchical approach to documentation of the Quality Management System
Why International Standards?

✓ They promote trade and cooperation

✓ Product standards allow consumers to purchase items from different manufacturers and know those items will perform equally

✓ Management system standards promote common approaches to managing quality and the environment. They promote dependability and a consistent use of statistics
ISO 9000 Consensus Process

New Work Item Proposal

Formal Ballot

Working Draft

Committee Draft

Draft International Std

Formal Ballot

Final Draft Int’l Standard

Formal Ballot

Published Standard

Vote to Release
ISO 9000 Series

| ISO 9000 | Helps companies determine which standard of ISO 9001, 9002, and 9003 applies |
| ISO 9001 | Outlines guidelines for companies that engaged in design, development, production, installation, and servicing of products or service |
| ISO 9002 | Similar to 9001, but excludes companies engaged in design and development |
| ISO 9003 | Covers companies engaged in final inspection and testing |
| ISO 9004 | The guidelines for applying the elements of the Quality Management System |
ISO 10000 Series

ISO 10011  Quality system auditing guide
ISO 10013  Quality manual development guide
The ISO 9001:1994 Clauses
New ISO 9001:2000

• Quality management system
  – Put structure in what you do

• Management responsibility
  – Put someone in charge

• Resource management
  – Provide the resources to achieve goals

• Product realization
  – Design and make it to requirements

• Measurement, analysis and improvement
  – Know where you are and get better

9000    Fundamentals And Vocabulary
9001    Requirements
9004    Guidelines For Performance Improvements
10012   Measurement Control
19011   QMS/EMS Auditing

☑️ Technical Reports on Everything Else
☑️ Greater Compatibility with Environmental Management
Third party registration

Registrar Accreditation Board

Registrar

Company

Customers

Auditors

Course Providers

accredit

certify

accredit

hire

train

assess
Registration steps

The Registrar will:

• Request information from you
• Review your documents (mostly QA manual)
• Review your application
• Audit your facility
• Issue your certificate
• Conduct periodic surveillance
• Renew certificate after three years
ISO 9000 Registration Process

• The final audit begins with a review of the company's Quality Manual, which the accredited registrar or third party audit team typically uses as its guide.

• The audit team checks to see that the documented quality system meets the requirement of ISO 9000 and that the organization is practicing what is documented.
ISO 9000 Registration Process

• When an organization feels that its quality system is good enough, it may ask an accredited registrar or other third party audit team for pre-assessment.
Timeline for registration

0.0 Decide to go for registration
   Form a steering committee
0.5 Write your QA Manual
   Write process procedures
1.0 Conduct internal reviews
   Refine your processes
1.5 Conduct system audits
   Undergo a “mock” audit
2.0 Receive registration
Where to Inspect the Process

- Raw materials and purchased parts
- Finished products
- Before a costly operation
- Before an irreversible process
- Before a covering process
# Examples of Inspection Points

<table>
<thead>
<tr>
<th>Type of business</th>
<th>Inspection points</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fast Food</td>
<td>Cashier</td>
<td>Accuracy</td>
</tr>
<tr>
<td></td>
<td>Counter area</td>
<td>Appearance, productivity</td>
</tr>
<tr>
<td></td>
<td>Eating area</td>
<td>Cleanliness</td>
</tr>
<tr>
<td></td>
<td>Building</td>
<td>Appearance</td>
</tr>
<tr>
<td></td>
<td>Kitchen</td>
<td>Health regulations</td>
</tr>
<tr>
<td>Hotel/motel</td>
<td>Parking lot</td>
<td>Safe, well lighted</td>
</tr>
<tr>
<td></td>
<td>Accounting</td>
<td>Accuracy, timeliness</td>
</tr>
<tr>
<td></td>
<td>Building</td>
<td>Appearance, safety</td>
</tr>
<tr>
<td></td>
<td>Main desk</td>
<td>Waiting times</td>
</tr>
<tr>
<td>Supermarket</td>
<td>Cashiers</td>
<td>Accuracy, courtesy</td>
</tr>
<tr>
<td></td>
<td>Deliveries</td>
<td>Quality, quantity</td>
</tr>
</tbody>
</table>
ISO 9000 Registration Process

• When the registrar is satisfied with the favorable recommendation of the audit team, it grants registration and issues a registration document to the company.
International issues

• Environmental management systems
• Occupational health & safety
• Regulated industries
  – medical devices
  – pharmaceutical
  – health care
• Sector-specific applications
  – automotive (QS-9000 and TS-16949)
  – aerospace (AS-9000 / AS-9100)
  – telecommunications (TL-9000)
ISO 14000

• ISO 14000 - A set of international standards for assessing a company’s environmental performance

• Standards in three major areas
  – Management systems
  – Operations
  – Environmental systems
ISO 14000

• Management systems
  – Systems development and integration of environmental responsibilities into business planning

• Operations
  – Consumption of natural resources and energy

• Environmental systems
  – Measuring, assessing and managing emissions, effluents, and other waste
QS 9000

- Common Supplier Quality Standard established by the Big Three automakers: Chrysler, Ford, GM.
- First introduced in North America in Aug 1994
- Consists of:
  - Section I  ISO 9000 based requirements
  - Section II  Customer-specific requirements
- Meeting mandatory requirements for the auto industry
- Emphasis on Continuous Improvement and Defect Prevention
- Moving closer to TQM
* Implement Failure Mode and Effect Analysis (FMEA)

* Advance Product Quality Planning (APQP)
  Control Plan (CP)
  APQP is required for new and changed products.
  CP covers Prototype, Pre-launch & Production

* Feasibility Review
  Confirm manufacturing feasibility

* Production Part Approval Process (PPAP)
  Compilation of data for new or changed product
  (Cpk, FMEA, Test Results etc)
QS 9000 in Summary

- QS 9000 emphasizes on meeting customer requirements. In long run, this will improve competitiveness.

- QS 9000 put focus on
  - Continuous Improvement
  - Defect Prevention
  - Reduction of variation and waste

The standard possesses tremendous potential in term of Business Excellent.
Recognizing Quality

• Benchmarking
  – Definition: Identifying and documenting *best* practices
    • Competitors (OM Principle 4)
    • Other industries
  – Start by selecting and benchmarking *own* process
    • Metrics: comparisons (e.g., LT:Content ratio)
    • Practices: steps, errors, delays, etc.
  – Typical steps summarized in the next slide
  – Concept and methods are evolving
The Benchmarking Process: Common Steps

GETTING STARTED
Planning, Organizing, and Managing for benchmarking

CONDUCTING RESEARCH
Collect information: Who's the best? What to ask?

COLLECTING AND SHARING INFORMATION
Surveys Site visits Determine any third parties

Continuous Improvement

PREPARING TO BENCHMARK
Identify key process. Form team. Understand your own processes.

SELECTING WHOM TO BENCHMARK
Establish relationship. Plan to collect and share information.

ANALYZING ADAPTING AND IMPROVING
Compare data. Plan to surpass. Implement and monitor. Improve.
Recognizing Quality

• Quality Awards
  – Include:
    • Deming Prize (first major award)
    • Baldrige Award (established by Congress)
    • Statewide awards
  – Provide
    • Recognition (shouldn’t be primary goal)
    • Path to improved quality
  – Baldrige Award criteria
    • Juran: criteria summarize TQM
Quality Awards

Baldrige Award

Deming Prize
Malcolm Baldrige National Quality Award

1.0 Leadership
2.0 Strategic Planning
3.0 Customer and Market Focus
4.0 Information and Analysis
5.0 Human Resource Development and Management
6.0 Process Management
7.0 Business Results
Baldrige Award details

✓ A US National Quality Award
✓ Started in 1987
✓ Awards in three categories – manufacturing, service, small business – no more than two awards per category per year
✓ Stresses ‘management by fact’
✓ Consists of a three level judging process
✓ Is a seven-category, 1000-point scoring system
  • Leadership, information and analysis, strategic quality planning, human resource utilization, quality assurance of products and services, quality results, customer satisfaction
Leadership

• Contributes 100 points
  – Senior executive leadership
  – Quality values
  – Management for quality
  – Public responsibility
• Symbolism and Active involvement
• Intimate knowledge of how the work actually gets done
• Impressive listening skills
  – Skip-level communication
Information and analysis

• Contributes 70 points
  – Scope and management of quality data and information
  – Competitive comparisons and benchmarks
  – Analysis of quality data and information
• Must demonstrate fact-based management
• Information base must be comprehensive, accessible, and well validated.
• Use benchmarking as a enabler of change, a learning process
Strategic Quality Planning

- Contributes 60 points
  - Strategic quality planning process
  - Quality goals and plans
Human Resource Utilization

• Contributes 150 points
  – Human resource management
  – Employee involvement
  – Quality education and training
  – Employee recognition and performance measurement
  – Employee well-being and morale
• Empower the employees and unleash the full potential of the work force
• Quality training involves increased awareness, problem-solving tools, group process skills, and job-specific skills
• “Empowerment is in the eyes of the empowered.”
Quality Assurance of Products & Services

• Contributes 140 points
  – Design and introduction of quality products and services
  – Process quality control
  – Continuous improvement of processes
  – Quality assessment
  – Documentation
  – Business process and support service quality
  – Supplier quality
• Instead of functional lines, emphasize on process
Quality Results

• Contributes 180 points
  – Product and Service Quality results
  – Business process, operational, and support service quality results
  – Supplier quality results
• Look for ‘meaning trends’
• Sustained improvements on critical measures over a period of at least three years
• Use statistical methods to correlate objective quality results with measures of customer satisfaction
Customer Satisfaction

- Contributes 300 points
  - Determining customer requirements and expectations
  - Customer relationship management
  - Customer service standards
  - Commitment to customers
  - Complaint resolution for quality improvement
  - Determining customer satisfaction
  - Customer satisfaction results
  - Customer satisfaction comparison

- Customer information from a wide range of sources – focus groups, surveys, one-to-one meetings, sales visits etc.
- Measures are objective and validated, not anecdotal
The Deming Prize

• Honoring W. Edwards Deming
• Japan’s highly coveted award
• Main focus on statistical quality control
Employee-Driven Quality

• Training (and education)
  – Involves
    • Basic job skills
    • Tools for continuous improvement, SPC, etc.
    • Cross-training (OM Principle 7)
  – Must be considered as *investment*, not expense!
  – Old (and still prevalent) approach
    • Exploit division of labor (hire unskilled)
    • Inhibits pride in workmanship
  – Cross-training can build better understanding
Employee-Driven Quality

• Organization
  – Involves
    • Close supplier/customer (next process) contact
    • Multi-functional teams, etc.
  – Uniting workers for constancy of purpose
    • Typical formats
      – Quality circles
      – Cells and teams (pioneered in manufacturing)
      – Project teams: when work flows are separated
    • Gangs versus teams
  – Team training: team dynamics; problem-solving; quality tools
Deming’s 14 Points (I)

• Focus On Management
  – Quality problems lie with the system
  – The system is under the control of management

• The 14 Points -- Not a Menu!
  – Constancy of purpose
  – New philosophy
  – Mass inspection
  – Price tag
  – Continuous improvement
  – Training
Deming’s 14 Points (II)

• The 14 Points (Continued)
  – Supervision (leadership)
  – Fear
  – Barriers
  – Slogans
  – Quotas
  – Pride in workmanship
    • Management
    • Front-line
  – Education
  – Organizational structure/culture; top management
Software Quality

• Process Quality
  – Ensuring conformance with user requirements
  – Identifying defects
  – Monitoring the product through its phases of development

• Product Quality
  – Identifying user specified quality needs
  – Prioritizing quality needs
  – Resolving quality conflicts, if any
  – Building them into the development process
  – Allocating effort and time for them
A Step in Assuring Software Quality

- Analyze need for quality
- Convert quality needs to requirements
- Document SW Quality requirements

Quality factors
- Needs data base
- Quality conflicts
  - Cost of quality
  - Criteria for good requirements
- Traceability matrix
- Quality specification guideline

User opinions
- Req spec
- Derived req’s
- Level of quality matrix
- Quality needs data base
- Engineering criteria
- Factor and criteria definitions

Software qrs

OPRE 6364
Approaches to Attain Quality

Traditional Approach to Quality

- Control the quality of the product by inspection.
- Acceptable quality levels (AQL).
- Some defects will slip through.

World-Class Approach to Quality

- The product is only the result of the process which makes it.
- If the process is correct, the product will be good.
- No need to inspect.
Quality Control Modes a Company can be in

**Detection Mode**
- Heavy use of inspection
- Manufacturing & QC are adversaries
- Firefighting
- Management by crisis
- High costs
- Lost sales
- Loss of competitive position

**Prevention Mode**
- Very little inspection
- QC is a resource of Manufacturing - teamwork
- Problem elimination
- Smooth operations - continual improvement
- Decreasing costs
- Increased sales
- More competitive
Operations are a Transformation Process

Inputs:
- People
- Capital
- Energy
- Materials
- Technology
- Market and Environmental Forces

Transformation Processes

Outputs:
- Goods
- Services
The *Process* Focus

• Operation = Transformation Process
  – Process inputs
    • Management
    • Methods
    • Materials
    • Machines
    • Maintenance
    • Personnel
    • Information
    • Energy
  – Transformation (macro/micro views)
  – Outputs (components / finished goods / services)
The Process Focus: Contributing Variables

Process: 3-inch machine bolt

Distribution of bolt lengths

Process performance: Quality characteristics

Materials

Machines

Methods

Manpower

Measurement

Maintenance

Management
Managing the Process

• Problems
  – Result from series of activities (process)
  – Not from single aspect (e.g., physician)
  – Therefore, for each product, entire process needs study for improvement

• Process
  – Recall Input/Process/Output model:
  – Input components change over time
    → instability
Process Improvement and Control in a nutshell

- Apply Scientific Method
- Incorporate Tools
  - General tools
  - Coarse grained tools
  - Fine grained tools
Scientific Method for Process Improvement

1. Identify and define the problem.
2. Study the existing situation; collect necessary data.
3. Generate possible solution alternatives.
4. Evaluate alternatives and choose the preferred one.
5. Implement the improvement and measure results.
6. Evaluate and revise if required.
7. Otherwise, return to step 1 and start again with a new problem.
Tools for Process Improvement

General Tools
1. Team-building and group-interaction tools.
2. Specific process/technology tools.

Coarse-grained Tools
4. Check sheets and histograms.
5. Pareto analysis.
6. Fishbone charts.

Fine-grained Tools
7. Fail-safing (Pokayoke).
8. Design of Experiments (DOE)
10. Run diagram.
The Six Sigma Methodology

A 4-Step Methodology for Process Improvement

**Process Characterization**

1) **Measure**
   - Identify Project Scope / Goal
   - Define Key Process Elements
   - Establish Process Capability
   - Validate Measurement System

2) **Evaluate**
   - Benchmark Process Entitlement
   - Data Analysis
   - Determine Critical Factors

**Process Optimization**

3) **Improvement**
   - Develop Improvement Plan
   - Understand/Optimize Vital Process Elements
   - Reduce Variation / Defects
   - Verify Impact

4) **Control**
   - Implement Long Term Control Plan
   - Leverage to Similar Products/Processes
   - Document & Standardize
TQM

• Top management’s direct involvement
• Strong customer orientation
• Companywide participation to meet or exceed customer expectations; empowerment
• Systematic problem solving
• A philosophy of Continuous Improvement: Never-ending push to improve
Obstacles to Implementing TQM

Lack of

– Companywide definition of quality
– Strategic plan for change
– Customer focus
– Real employee empowerment
– Strong motivation
– Time to devote to quality initiatives
– Leadership
Obstacles to Implementing TQM

- Poor intraorganizational communication
- View of quality as a “quick fix”
- Emphasis on short-term financial results
- Internal political and “turf” wars
Summary

TQM requires

- Top management’s direct involvement
- Strong customer orientation
- Everyone participates: empowerment
- Systematic problem solving
- Continuous improvement

- TQM is a great foundation, but TQM does not directly relate to business results
- Six Sigma is the latest quality management innovation: It is a *focused method + a philosophy*
Useful links

- SWOT analysis for strategy development: http://www.mindtools.com/swot.html
- Overview of QS 9000: http://www.iqs.com/Presentations/SALE6108_files/frame.htm
- An overview of TQM: http://home.att.net/~iso9k1/tqm/tqm.html