Quality Management
Quality Systems

Quality Systems: ISO 9000:2000

What is ISO? Simply stated…

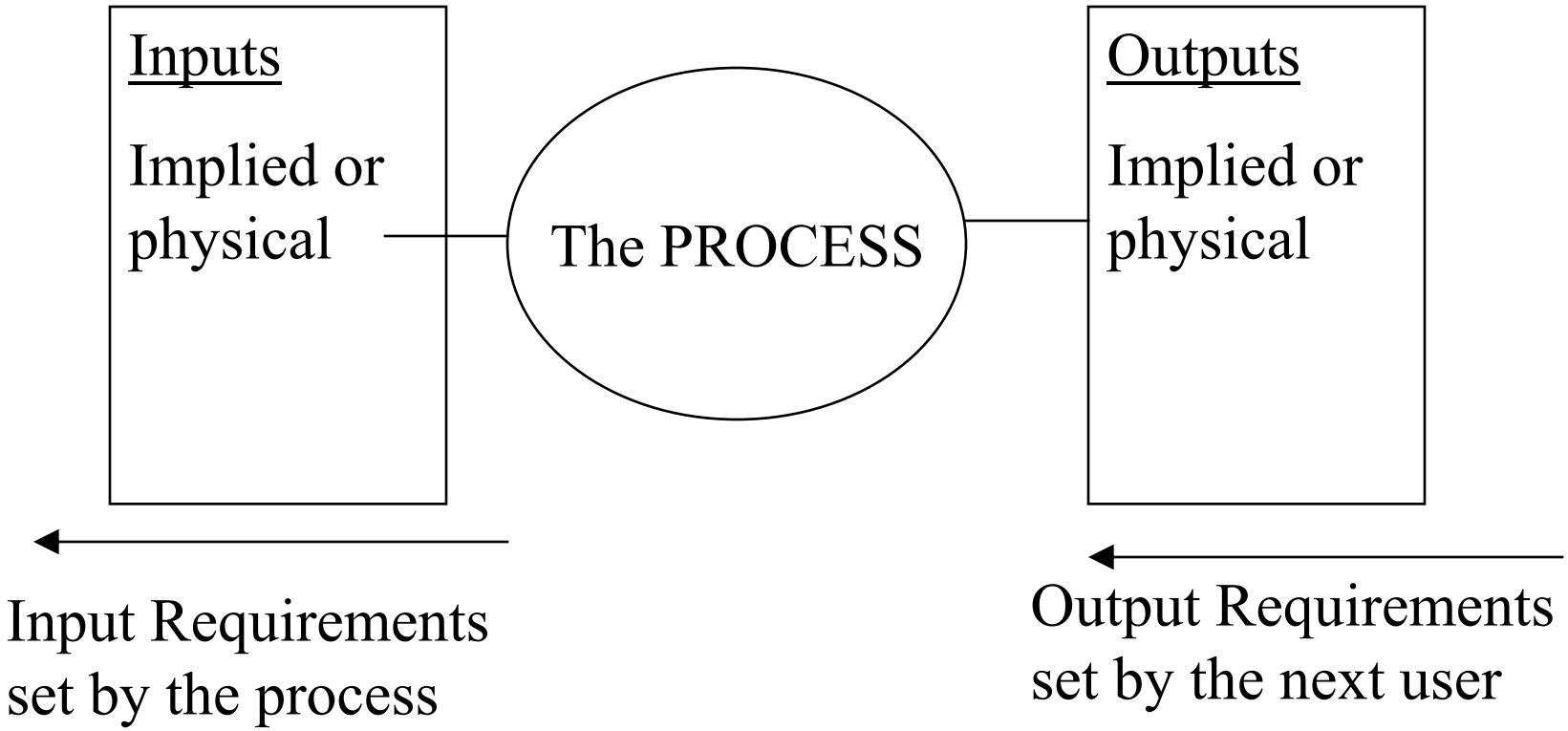
1) **Say what you do.**	(Document your processes.)
2) **Do what you say**.	(Follow your documents.)
3) **Do it well.**	(Be consistent.)
4) **Provide evidence that you did it well.**	(Audit your results and improve your processes.)

Quality Systems: ISO 9000:2000

- ISO 9001:2000 takes a process-oriented approach.
  - ISO 9000 requirements describe ‘what’ a company must accomplish in order to meet customer expectations.
  - ‘How’ these things are accomplished is left up to the particular company.

Quality Systems: ISO 9000:2000

Inputs and Outputs? …



Should be able to line up the processes in a row!!!

Quality Systems: ISO 9000:2000

The clauses of ISO 9001

Quality Systems: ISO 9000:2000

- Eight key principles have been integrated into the ISO 9000:2000 standards:
  - Customer Focused Organization
  - Leadership
  - Involvement of People
  - Process Approach
  - System Approach to Management
  - Continual Improvement
  - Factual Approach to Decision-Making
  - Mutually Beneficial Supplier Relationships

Sort of looks like the Baldrige criteria, doesn't it?

Quality Systems: ISO 9000:2000

- The ISO 9000 series consists of 3 standards:
  - ISO **9000**:2000 Quality Management Systems Fundamentals and Vocabulary
    - is referenced in ISO 9001:2000, can be used by companies and auditors to support their interpretations of ISO 9001 requirements
  - ISO **9001**:2000 Quality Management Systems
    - provides the requirements that must be met in order to achieve certification.
    - Designed to be used by any organization
  - ISO **9004**:2000 Quality Management Systems
    - guidance for performance improvement beyond 9001:2000
    - is Not referenced in ISO 9001, can not be used by auditors

Quality Systems: ISO 9000:2000

- ISO **9001**:2000
  - This is the actual specification for a company's quality management system.
  - This standard defines the criteria for an audit.
  - Organized into 4 sections:
    - Section 5: Management Responsibility
    - Section 6: Resource Management
    - Section 7: Product and/or Service Realization
    - Section 8: Measurement, Analysis and Improvement

Quality Systems: ISO 9000:2000

- ISO 9001:2000
  - Section 5: Management Responsibility
    - focuses on:
      - How does the analysis of data affects the performance of the organization's QM system?
      - How does management establish quality policies, make plans, achieve objectives and communicate customer requirements?

Quality Systems: ISO 9000:2000

- ISO 9001:2000
  - Section 6: Resource Management
    - Asks for details on resource availability and deployment
    - Resources include: information, facilities, communication, people and work environment.

Quality Systems: ISO 9000:2000

- ISO 9001:2000
  - Section 7: Product and/or Service Realization
    - How do customer requirements and organizational self-assessments lead to continued improvement of processes and work methods?

Quality Systems: ISO 9000:2000

- ISO 9001:2000
  - Section 8: Measurement, Analysis and Improvement
    - What methods are used to measure systems, processes, products or services?

Quality Systems: ISO 9000:2000

- ISO 9001:2000 requires:
  - a greater focus on identifying customer requirements, needs and expectations
  - the establishment of procedures for customer communication
  - making employees aware of the importance of meeting customer requirements

Quality Systems: ISO 9000:2000

- ISO 9001:2000 requires:
  - a greater focus on continuous improvement
    - establishing quality policies
    - establishing quality objectives
    - doing quality planning
    - gathering quality performance data
    - performing management reviews

Quality Systems: ISO 9000:2000

- After all that, how many different ISO documents are REQUIRED for 9001?

Quality Systems: ISO 9000:2000

- After all that, how many different ISO documents are REQUIRED for 9001?

  – ONLY Six **procedures** required by the standard;

  - Control of Documents (4.2.3)
  - Control of Quality Records (4.2.4)
  - Internal Audit (8.2.2)
  - Nonconforming Control (8.3)
  - Corrective Action (8.5.2)
  - Preventive Action (8.5.3)

Sometimes called "Level 3" or "Work Instructions "

LEVEL III WORK INSTRUCTION: How to use the ISO 9001 Documentation		MAINTENANCE RESPONSIBILITY: Director of Quality and Reliability
Clause: 7	**Product Realization**	**DATE OF ISSUE: 03/19/03**
7.5 Production Services		
Location:	Miamisburg	

REVIEWED AND ACCEPTED FOR USE BY:	TITLE:	DATE:
By on master copy		03/19/03

HOW TO READ

1. start with first letter on left
2. go to the letter to the right
3. repeat steps 1. and 2. until blank space appears
4. look up word(s) in dictionary
5. go to step 1.

example:

C->A->T

c+a+t=cat

cat = 

If you have this level of documentation, you are doing TOO MUCH!

Quality Systems: ISO 9000:2000

- Anything else absolutely required?

Quality Systems: ISO 9000:2000

- Anything else absolutely required?

1. Quality Manual (Level 1 Document)
   (signed by management)

2. Quality Policy and Quality Objective Statements

OUR QUALITY POLICY and Objective statement

Grizco is committed to meeting our Customers needs for training and consulting products and services, and to continually improve upon them by establishing quality objectives driven by our Customers, which are reviewed and then pursued by our Team!

Quality Systems: ISO 9000:2000

- Anything else absolutely required?

  What about any measured data ?

Quality Systems: ISO 9000:2000

- Data Records as required by the standard;
  - Management Reviews (5.6.1)
  - Education & Training (6.2.2 e)
  - Evidence of Requirements Fulfilled (7.1 d)
  - Design & Development Input (7.3.2)
  - Design Reviews (7.3.4)
  - Design Verification (7.3.5)
  - Design Change Review (7.3.7)
  - Results of Supplier Evaluations (7.4.1)

Quality Systems: ISO 9000:2000

- Data Records as required by the standard;con't
  - Process Validation (7.5.2 d)
  - Unique Identification (7.5.3)
  - Nonconforming Customer Property (7.5.4)
  - Local Standards for Calibration (7.6)
  - Validity of Previous Results (7.6)
  - Results of calibration (7.6)
  - Internal Audit Results (8.2.2)
  - Record of Product Conformity (8.2.4)
  - Product Nonconformity (8.3)
  - Corrective & Preventive Actions (8.5.2 and 8.5.3)

Quality Systems: TS 16949

- TS 16949
  - TS 16949 defines automotive industry standards world-wide

Quality Systems: TS 16949

- TS 16949 has two components:
  - ISO 9001 **AND**
  - Customer Specific Requirements
    - PPAP Production Part Approval Process
    - FMEA Failure Modes and Effects Analysis
    - MSA Measurement Systems Analysis
    - APQP Advanced Product Quality Planning and Control
    - QSA Quality System Assessment

Quality Systems: Six Sigma

- Bill Smith, Reliability Engineer, Motorola Corporation
  - The increasing complexity of systems and products used by consumers created higher than desired system failure rates.
  - Holistic approach to reliability and quality and developed a strategy for improving both (1988).

Quality Systems: Six Sigma

- Six Sigma is a structured, data driven methodology for eliminating waste from processes, products, and other business activities while having a positive impact on financial performance.

Quality Systems: Six Sigma

- Six Sigma Perceptions
  - Perceived to be a business system that improves the bottom line.
  - Perceived as fitting naturally into the business systems of most companies.

Quality Systems: Six Sigma

- Six Sigma Perceptions
  - Perceived as being more easily and more successfully launched than traditional Total Quality Management programs.
    - TQM perceived as technical system owned by technical specialists.

Quality Systems: Six Sigma

Six Sigma	**Quality Systems**
Highly focused problem-solving system DMAIC	Highly focused problem-solving system PDSA
Focus on profits	Focus on improving organizational performance including profit
Tools include SPC, DOE, FMEA Project management, Benchmarking.	Tools include SPC, DOE, FMEA, capability studies, benchmarking, Theory of constraints
3.4 defects/million	Process capability
Focus on metrics	Measures of Performance

Quality Systems: Six Sigma

- Benefits of adopting the Six Sigma methodology
  - Enhanced ability to provide value to customer
  - Enhanced understanding of key business processes
  - Reduction of waste
  - Improved profit performance

Quality Systems: Six Sigma

- Six Sigma Methodology focuses on:
  - Customer knowledge
    - *Critical to Quality* information
  - Core processes
    - Key business processes that deliver value directly to the customer
  - Accurate performance measures of both

Quality Systems: Six Sigma

- Six Sigma Methodology is based on:
  - Statistical Process Control Techniques
  - Data Analysis Methods
  - Project Management Techniques
  - Systematic Training of Participants

Quality Systems: Six Sigma

- Six Sigma is *data driven and profit focused*.

Quality Systems: Six Sigma

- The goal of Six Sigma is to reach 3.4 defects per million opportunities over the long term.

Quality Systems: Six Sigma

- Six Sigma seeks to reduce the *variability* present in processes.

Quality Systems: Six Sigma

Sigma	Defects per million opportunities	Yield
1	690,000	30.90%
2	308,000	69.20%
3	66,800	93.30%
4	6,210	99.40%
5	320	99.98%
6	3.4	99.9997%

Quality Systems: Six Sigma

- An improvement of just 1 sigma can result in a ten-fold reduction in the number of defects
  - At three sigma, 66,800 defects per million costing $10/piece to fix = $668,000
  - At four sigma, 6,210 defects per million costing $10/piece to fix = $62,100

Quality Systems: Six Sigma

- Six Sigma projects are selected based on their ability to contribute to and enhance an organization’s financial performance.

Quality Systems: Six Sigma

- Six Sigma projects seek out sources of waste (overtime, warranty claims, production backlogs, customer issues).

Quality Systems: Six Sigma

- Six Sigma projects have five phases:
  - Define
  - Measure
  - Analyze
  - Improve
  - Control (note similarity to PDSA)

Quality Systems: Six Sigma

- Define
  - Identify the problem/project
  - Define the requirements
  - Establish the goals to be achieved

Quality Systems: Six Sigma

- Measure
  - Gather information about the current process
    - Define and measure key process steps and inputs
  - Refine the problem statement and goals

Quality Systems: Six Sigma

- Analyze
  - Identify potential root causes of the problem
  - Validate the cause and effect relationship
  - Identify the vital few root causes

Quality Systems: Six Sigma

- Improve
  - Implement solution to address root causes of problem
  - Test solutions
  - Measure results

Quality Systems: Six Sigma

- Control
  - Evaluate and monitor improvements
    - Make adjustments as needed
  - Establish standard procedures

Quality Systems: Six Sigma

- Eight essential tools of Six Sigma Methodology
  - Used within DMAIC process
    - Process Maps
    - Cause and Effect Diagrams
    - Failure Modes and Effects Analysis
    - Measurement System Analysis
    - Process Capability Studies
    - Multi-variate studies
    - Design of Experiments
    - Process Control Plans

Quality Systems: Six Sigma

- Six Sigma Project Participants
  - Green Belts
    - training
    - complete a cost-savings project ($10,000+)
  - Black Belts
    - training (more advanced)
    - complete cost-savings projects ($100,000+)
  - Master Black Belts
    - extensive training
    - complete cost-savings projects ($1,000,000+)

Quality Systems: Six Sigma

Category ASQ Certified Quality Engineer (CQE)		**Black Belt**
Leadership	Management and Leadership in Quality Engineering	Enterprise-Wide Deployment
Business Processes	Not covered	Business Process Processes Management
Quality Systems	Quality Systems Development, Implementation, and Verification	Not Covered
Quality Assurance	Planning, Controlling, and Assuring Product and Process Quality	Not Covered
Reliability	Reliability and Risk Management	Not Covered
Problem-Solving	Problem-Solving and Quality Improvement	Define-Measure-Analyze-Improve-Control
Quality Tools	Problem-Solving and Quality Improvement	DMAIC
Project Management	Not Covered	Project Management
Team Concepts	Not Covered	Team Leadership
Statistical Methods	Probability and Statistics Collecting and Summarizing Data	Probability and Statistics Collecting and Summarizing Data
Design of Experiments	Designing Experiments	Design of Experiments
Process Capability	Analyzing Process Capability	Analyzing Process Capability
Statistical Process Control	Statistical Process Control	Statistical Process Control
Measurement Systems (metrology/calibration)	Measurement Systems Metrology	Measurement Systems Metrology
Lean Manufacturing	Not Covered	Lean Enterprise
Other Techniques	FMEA, FMECA, FT	FMEA, QFD Multi-Variate Studies

Body of Knowledge Comparison of CQE and Black Belt Certification

Quality Systems: Six Sigma

- **Six Sigma Acronyms**
- APQP Advanced Product Quality Planning
- CTQ Critical to Quality
- DFSS Design for Six Sigma
- DMAIC Define, measure, analyze, improve, control
- DPMO Defects per million opportunities
- DPU Defect per unit
- FMEA Failure Modes and Effects Analysis
- KPIV Key process input variable
- KPOV Key process output variable
- Process Owners The individual responsible for the process and what it produces
- Reliability measured as mean-time-to-failure
- Quality measured as process variability and defect rates

Quality Systems: Six Sigma

- In order to successfully adopt the Six Sigma methodology, an organization must have:
  - Visible management commitment
  - Visible management involvement
  - Clear definition of customer requirements
  - Understanding of key business processes
  - Sound measures of performance
  - Discipline
  - Rewards

Quality Systems: Six Sigma

- Who is doing it?
  - Motorola
  - G.E.
  - DuPont
  - Ford
  - AlliedSignal
  - Texas Instruments
  - Honeywell

Quality Systems: Six Sigma

- Six Sigma for the smaller company
  - Six Sigma Methodology is scaleable.
    - Ideas and concepts are viable regardless of size or type of industry.
  - Six Sigma Methodology requires participation and training of Black Belts
    - Time-consuming (4-12 months)
    - Expensive ($10-15K)

Quality Systems: Six Sigma

- A point to consider:
  - Six Sigma focuses on ***defects*** while other quality improvement methodologies emphasize ***non-conformances.***
    - A subtle, yet important distinction, especially in the legal sense.

Quality Systems: Six Sigma

- Another point to consider:
  - When the organization say no more improvement is possible.
    - Remember Six Sigma has a two pronged approach:
      - Fix the existing problems
      - Design Six Sigma into processes, products and services.

Quality Systems: Six Sigma

- Six Sigma is about results
  - Enhancing profitability through improved quality and efficiency.

Quality Systems: Six Sigma

Many companies operate at about three sigma, conforming to the US Governmental quality standards of 99% as established during World War II. Working at 99% defect-free, however, means:

- At least 200,000 wrong drug prescriptions each year
- Two short or long landings at major airports each day
- 5,000 incorrect surgical procedures every week
- 20,000 lost articles of mail per hour
- Unsafe drinking water for almost 15 minutes each day
- No electricity for almost 7 hours each month
- 50 dropped newborn babies each day

3 sigma is NOT good enough!

Quality Systems:
Malcolm Baldrige National Quality Award

Malcolm Baldrige was Secretary of Commerce from 1981 until July 1987.

Baldrige was a proponent of quality management as a key to this country's prosperity and long-term strength. He took a personal interest in the quality improvement act that was eventually named after him and helped draft one of the early versions. In recognition of his contributions, Congress named the award in his honor.

Quality Systems:
Malcolm Baldrige National Quality Award

Given by the President of the United States to businesses : manufacturing, non-profit, service, education and health care organizations

Judged to be outstanding in seven criteria areas:

1) Leadership,

2) Strategic Planning,

3) Customer and Market focus,

4) Information, Knowledge Management and Analysis,

5) Workforce Focus

6) Process Management

7) Results

LESS than 7 winners in the USA every year!