

# Quality Systems Frameworks



# What is a Quality System?

- An organization uses quality systems to control and improve the effectiveness of the processes used to deliver a quality product or service
- A Quality System is a set of formal and informal practices and processes that focus on ...
  - Customer needs
  - Leadership vision
  - Employee involvement
  - Continual improvement
  - Informed decision making based on real-time data
  - Mutually beneficial relationships with external business partners

... to achieve organizational outcomes

[Adapted from US Food and Drug Administration Staff Manual Guide 2020 [http://www.fda.gov/smg/vol3/2000/SMG\\_2020.pdf](http://www.fda.gov/smg/vol3/2000/SMG_2020.pdf)]



# What is a Quality System Framework?

- A quality system framework is a coherent set of objectives, policies, and practices for managing quality in an organization
- As a framework, it provides the essential elements of a quality system
  - The elements are expected to be tailored and expanded for a given organization and situation
  - The framework emphasizes what needs to be done and why, without prescribing how



# Using a Quality System Framework

- Use a quality system framework as guidance
  - A quality system framework can help an organization to ...
    - Review their current quality activities
    - Identify quality system elements that may already exist
    - Identify additional elements needed to implement a quality system
- Use a quality system framework for external assessment and validation
  - Objective criteria for assessing quality processes
  - Often required to be “in business”
    - Cannot bid on a contract if you are not certified
    - Use as a marketing tool—Certified Seal of Approval



# Some Major Quality Frameworks (1 of 3)

- ISO 9000 Family of Standards
  - A general international standard for organizational quality systems
  - Specializations for specific types of products and services (including software)
  - Oriented towards assessment and certification
- Malcolm Baldrige National Quality Award
  - Developed by the US Department of Commerce to encourage and recognize excellence
  - Created in 1987 in response to foreign competition eroding US productivity growth by having better product and process quality



# Some Major Quality Frameworks (2 of 3)

- Software Engineering Institute Capability Maturity Models (SEI CMM)
  - Created in response to US Department of Defense needs to improve software development capabilities for large, complex defense and other government systems
  - Originally a software-specific model for assessing the maturity of software development practices
  - Oriented towards both internal self-assessment and improvement and external certification assessment
  - CMM-Integrated includes software engineering, systems engineering, outsourcing (acquisition), services, etc.



# Some Major Quality Frameworks (3 of 3)

- Total Quality Management (TQM)
  - A philosophy and practices for improving quality
  - Build an organization-wide quality culture, focusing on providing customers with the products and services that satisfy their needs
  - Do it right the first time; eliminate defects and waste
- Six Sigma
  - Created by Motorola in the 1970's as a response to a perception of bad quality
  - Focuses on people rather than roles as the solution
  - Has metrics and measured improvement as core principles



# All the Frameworks Define Principles That Embrace a Philosophy and Practice of Quality





# Some Key Principles from W. Edwards Deming

- Continuously improve product, service, and process
  - Result: continuously decreasing cost
- Don't depend on detecting defects; Prevent them
- Don't focus on initial cost, instead minimize total cost in a long-term relationship of loyalty and trust
- Drive out fear, so that everyone may work effectively for the company
- Break down barriers between departments, roles, and disciplines
- Eliminate defect and productivity targets – management by numbers
  - Substitute leadership
  - Enable pride of workmanship

[Paraphrased and adapted from Deming, W. E. (1986) *Out of the Crisis*]



# Some TQM Principles

- Quality can and must be managed
- Customer focus; Everyone has a customer and is a supplier
- Processes, not people are the problem
- Every employee is responsible for quality
- Problems must be prevented, not just fixed
- Quality must be measured
- Quality improvements must be continuous
- The quality standard is defect free
- Goals are based on requirements, not negotiated
- Life cycle costs, not front end costs
- Management must be involved and lead
- Plan and organize for quality improvement



# Quality vs. Quality Frameworks

- A major point to note is that all these are about Quality Systems and not directly about the actual quality of the product
  - The difference between excellence in quality control for an assembly line car and producing a handmade Rolls-Royce (work of art) is significantly different!
- The principle is that an organization with a culture of focusing on quality and on continuous improvement will consistently produce good product output and achieve customer delight
  - Remember also “continually optimize achievement of multiple objectives”
  - The systems help find the optimal balance



# Quality System Frameworks Identify Areas of Importance



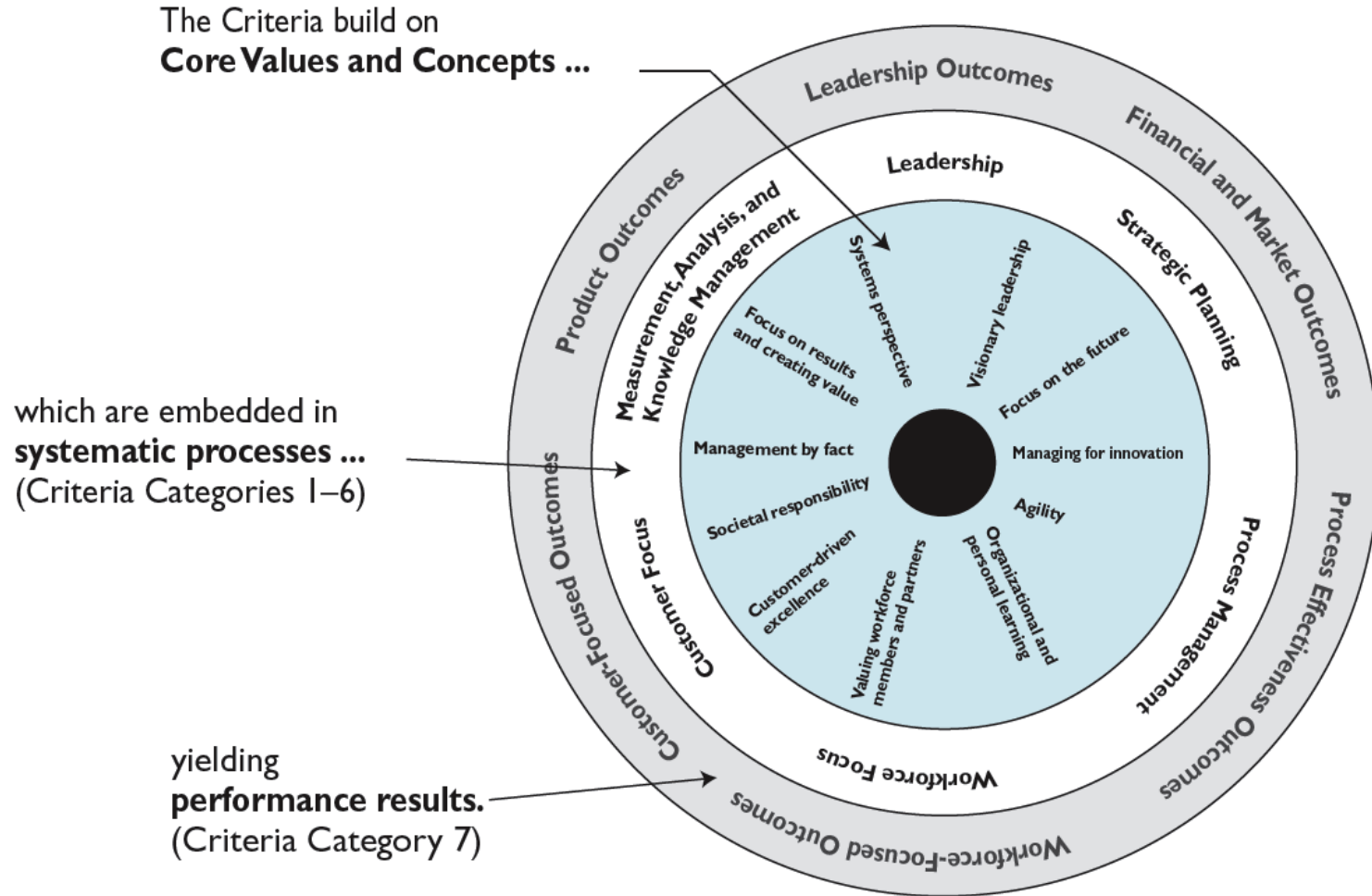
# Key Process Areas from SEI CMMI

Category	Process Area
Project Management	Project Planning Project Monitoring and Control Supplier Agreement Management Integrated Project Management Integrated Supplier Management Integrated Teaming Risk Management Quantitative Project Management
Support	Configuration Management Process and Product Quality Assurance Measurement and Analysis Causal Analysis and Resolution Decision Analysis and Resolution Organizational Environment for Integration
Engineering	Requirements Management Requirements Development Technical Solution Product Integration Verification Validation
Process Management	Organizational Process Focus Organizational Process Definition Organizational Training Organizational Process Performance Organizational Innovation and Deployment

The SEI CMMI details the expectations of a software engineering process definition in each of these key areas



# Core Values and Concepts of the Baldrige Criteria for Performance Excellence

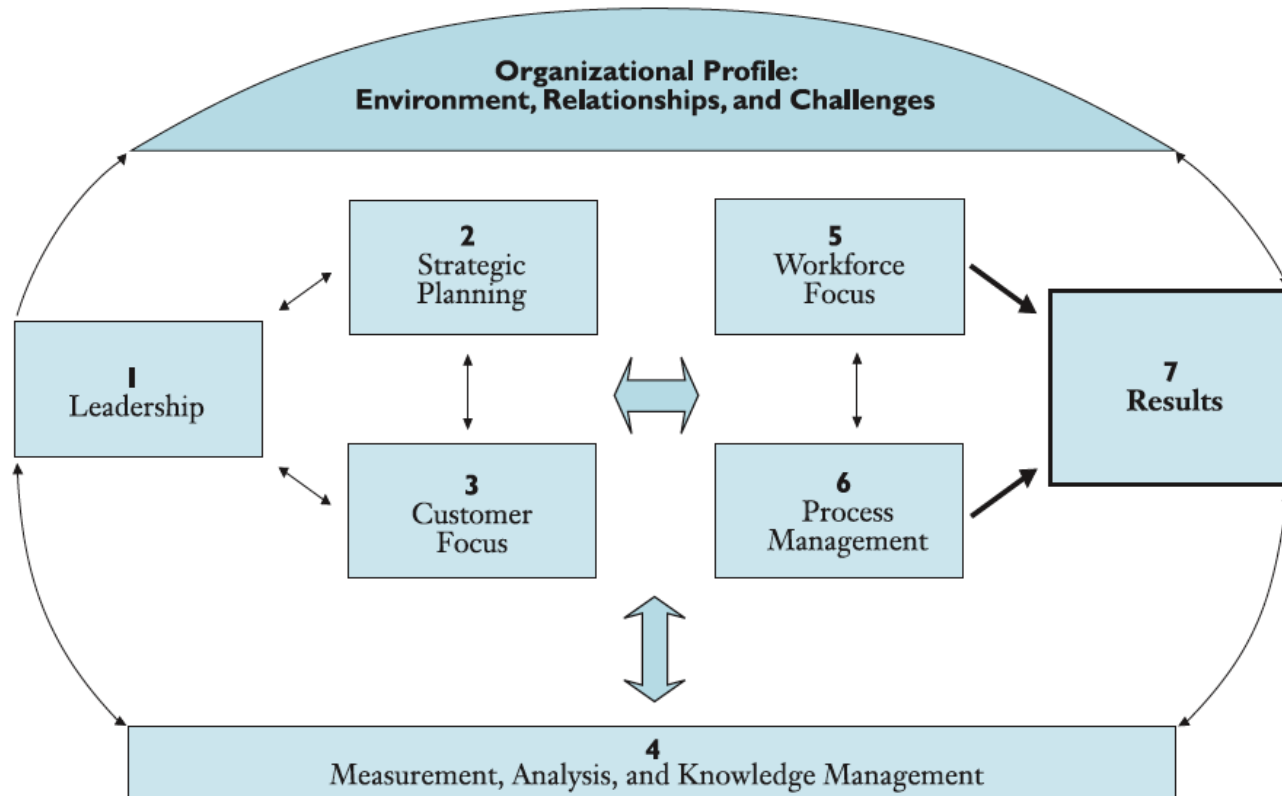


[http://www.quality.nist.gov/PDF\\_files/2009\\_2010\\_Business\\_Nonprofit\\_Criteria.pdf](http://www.quality.nist.gov/PDF_files/2009_2010_Business_Nonprofit_Criteria.pdf)



# Categories for the Baldrige Criteria

## Baldrige Criteria for Performance Excellence Framework A Systems Perspective



[http://www.quality.nist.gov/PDF\\_files/2009\\_2010\\_Business\\_Nonprofit\\_Criteria.pdf](http://www.quality.nist.gov/PDF_files/2009_2010_Business_Nonprofit_Criteria.pdf)



# ISO 9000

- “Say what you do, do what you say, and prove it”
- A standard for certifying that organizations follow procedures for ensuring quality
- Heavy focus on processes and evidence of compliance (documentation)
- Some focus on statistical techniques and processes for improvement
- ISO 9000 focuses on procedures for ensuring quality:
  - “assure minimum standards of operation”
  - “existence of quality systems and commitment to them”
- Complementary to other quality management frameworks – limited value in itself – Does not directly address quality results or customer satisfaction directly





# Value of the Frameworks

- “Optimize across all project and organizational objectives” is too open-ended
  - Frameworks provide models of what needs to be addressed
- Primary value from these frameworks includes:
  - Defining the specific set of areas to address
  - Defining specific criteria for determining whether the areas are being addressed well
  - Providing basic structures to ensure continuing focus
    - Defining appropriate processes and metrics
    - Mechanisms for continuous improvement, so that processes keep improving and evolving as needs change
    - Assessment mechanisms, to check that all this is happening



# Which Framework to Use?

- Different frameworks address different needs
  - Also, there are many other frameworks, and many additions/variations to each
- Organizations design their own quality management approaches (or it just evolves without design!), possibly using one or more frameworks as a starting point
  - Frameworks only supply goals, and suggest some ways to achieve goals
  - Each organization needs to adapt the framework(s) to their needs, and decide how to achieve their specific goals
- If used well, any of the frameworks are helpful
- If used poorly, none of them will help (In fact, they will hurt!)



# Why This “Big Picture” Now?

- Understanding the big picture helps, before we start to focus on specific quality metrics and practices
- Understanding the philosophy and limitations helps you to get a more balanced picture of the quality area
- General knowledge
  - As a software engineer, people will expect you to know about these models
  - As a software quality engineer or software process engineer, these models provide a wealth of wisdom
- Quality and Software process improvement pay for themselves (see next slide)



# Results from CMMI Improvements in 2005

Performance Category	Median	Number of Data Points		Low	High
Cost	20%	21		3%	87%
Schedule	37%	19		2%	90%
Productivity	62%	17		9%	255%
Quality	50%	20		7%	132%
Customer Satisfaction	14%	6		-4%	55%
Return on Investment	4.7 : 1	16		2 : 1	27.7 : 1

<http://www.sei.cmu.edu/cmmi/2005results.html>



# Frameworks as Knowledge Bases

- The quality system frameworks are a knowledge base to guide your quality system:
  - What areas do we need to address if we want projects to be successful?
  - How do we keep everyone aware of good ways to accomplish tasks?
  - What are common sources of problems?
  - What structures can we put in place to reduce the chance that problems will occur?
  - What structures do we need to ensure that the organization will keep trying to improve its processes and practices?
  - How do we ensure that good processes lead to good results?
  - How we can we figure out when things aren't working and how to fix them?
- An organization's quality management system is its own knowledge base of the best answers to these questions!



# Capability and Compliance Assessments

- Assessments are massive exercises
  - Value: Feedback on what's working, opportunities for improvement
  - Cross-fertilization of ideas
- Problems
  - Easy to “create evidence for the assessment”
  - Passing means at best that systems are in place, not that results are superior
  - Assessments easily become exercises in PR (public relations)
  - Over-focus on “avoiding mistakes” can take energy away from excellence
- It would be a mistake to read too much into the results
  - Being assessed at high maturity levels or receiving a quality award does NOT guarantee that the organization will be more successful or produce better products
    - It just means that they have structures in place to keep trying to do better



# Some Thoughts About Quality Frameworks

- Culture is always the best approach
- Systems have their place and value
- “Less is more”
  - Small organizations may not need very much formal quality management
  - Know the theory. As problems are perceived, incrementally put in only what is obviously useful
  - When designing a quality system, think carefully about what the needs of the organization are and what is appropriate
  - Processes tend to grow with time, so quality people should spend as much energy “deleting” unnecessary process as adding process



# Conclusion

- There are many quality systems frameworks, appropriate to different needs
- The quality system frameworks provide a good starting point for creating quality systems for your organization
  - Understand the underlying quality system philosophy and supporting activities and incorporate them throughout the organization
- Most organizations use a combination of quality systems
  - Assemble a quality system from the principles and practices that are most appropriate to your situation

