



INTEGRATING ISO 9000 METHODOLOGIES WITH PROJECT QUALITY MANAGEMENT

March 2015

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DIRECSYS INC

OBJECTIVE

ISO and Project Quality Management Process

Are they different or the same?

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ISO 9000 QMS FAMILY

ISO 9000:2005
Vocabulary

QMS - Fundamentals and

ISO 9001:2008

QMS - Requirements

ISO 9004:2009

Managing for the
sustained success of an organization. A
quality management approach (guidelines)

ISO 19011:2002

Guidelines on Quality
and/or Environmental Management Systems
Auditing



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WHAT IS ISO?

- International standard published by the International Organization for Standardization (ISO)
- Initially published in 1987
- First revision in 1994, 2nd version in 2000
- ISO 9001:2008 is the latest version released in november 2008
- Most famous standard issued in over 150 countries
- Requirements for a corporate Quality Management System
- Strong emphasis on Customer Satisfaction and Continual Improvement

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GENERIC STANDARD

ISO 9001:2008 is a generic standard

The standard can be applied:

- To any organization, large or small, whatever its product or service
- In any sector of activity, and
- Whether it is a business enterprise, a public administration, or a government department

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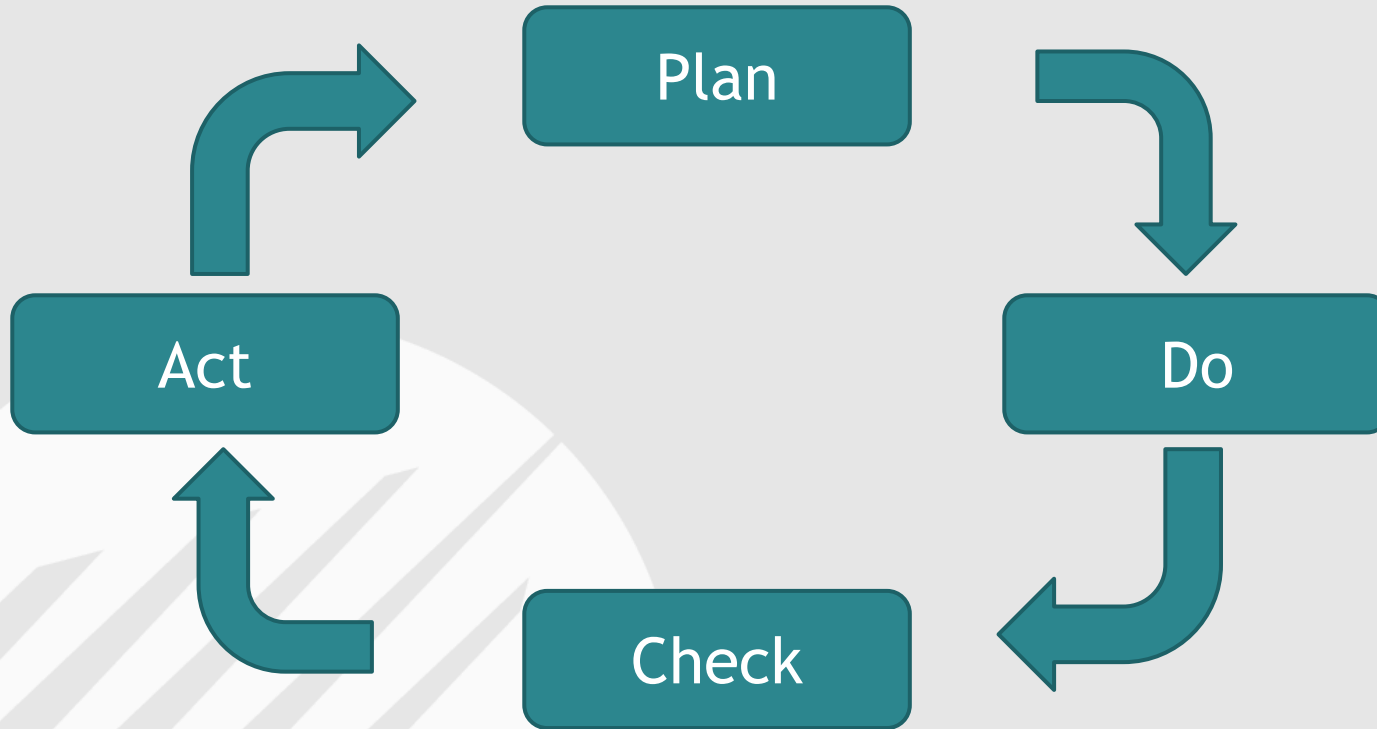
QUALITY MANAGEMENT

- ISO 9001 addresses “quality management”
- This means what the company does to fulfill:
 - Their customers’ quality requirements, plus
 - Any applicable regulatory requirements, while aiming to
 - Enhance customer satisfaction, and
 - Achieve continual improvement of its performance



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PDCA APPROACH



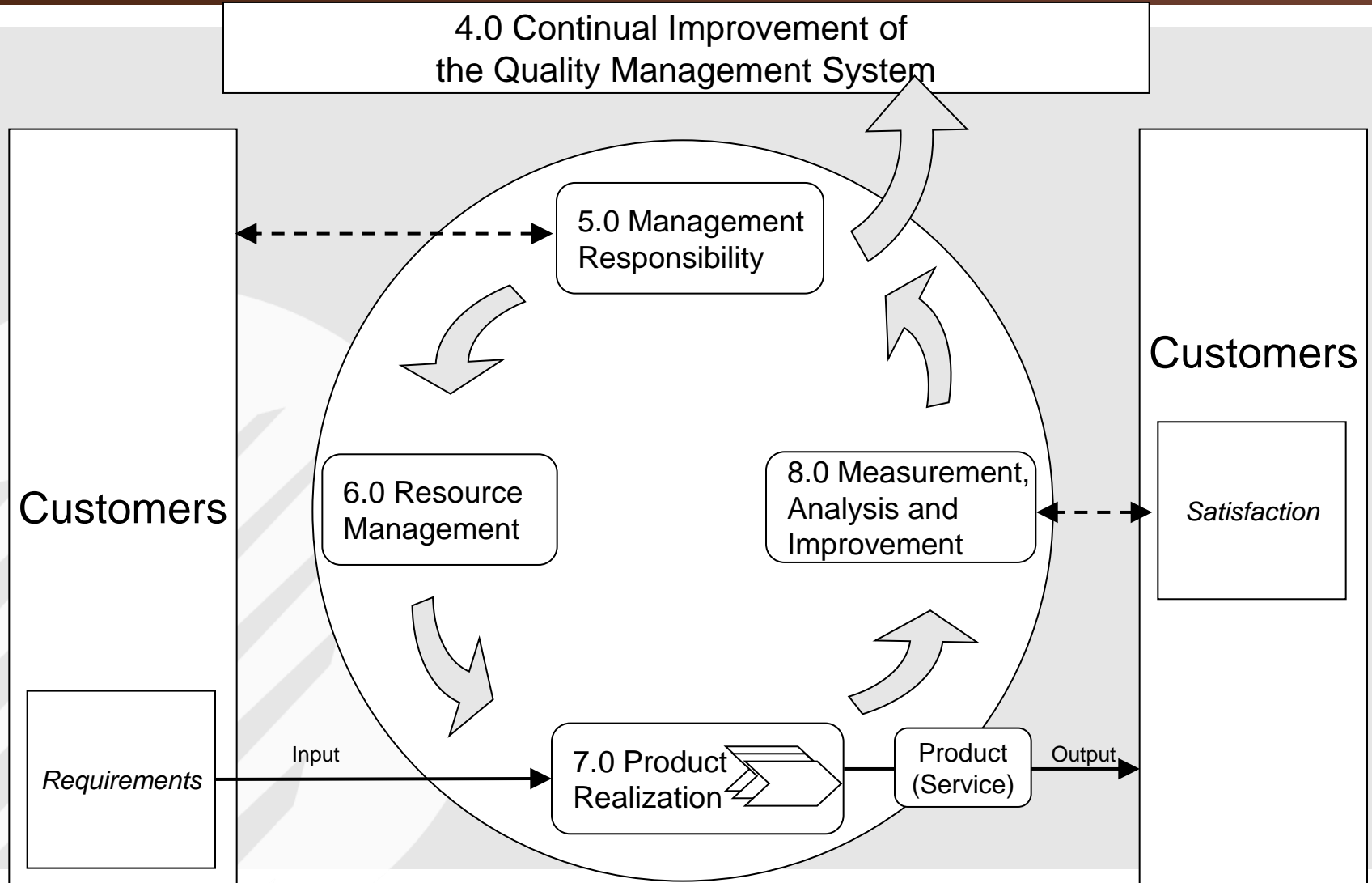
- Understanding and meeting requirements
- The need to consider process in terms of added value
- Obtaining results of process performance and effectiveness
- Continual improvement of processes based on objective measurements

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HOW ISO 9001 WORKS

MAIN CLAUSES



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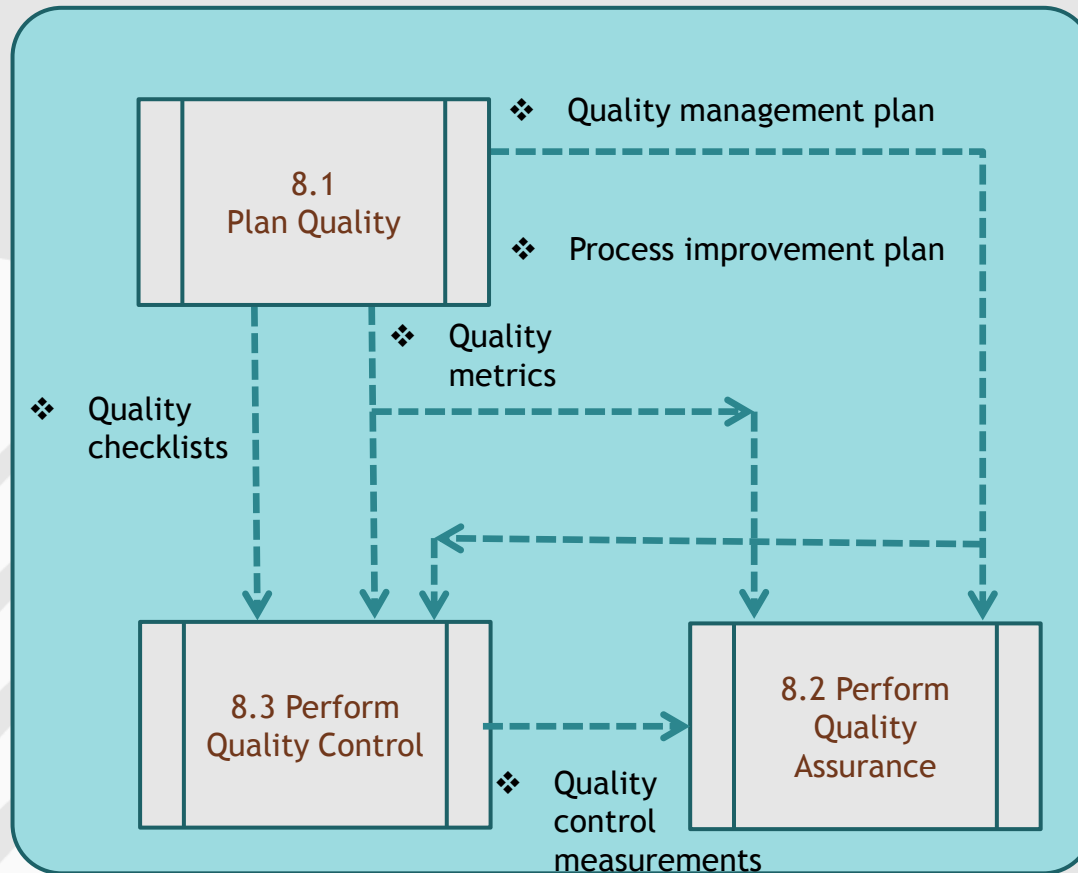
PROJECT MANAGEMENT & ISO

- Both recognize the importance of:
 - Customer Satisfaction
 - Prevention over inspection
 - Continuous improvement
 - Management Responsibility

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PROJECT QUALITY MANAGEMENT



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PLAN QUALITY

- Process of identifying quality requirements and/or standards and document how project will demonstrate compliance
- Outputs
 - Quality management plan
 - Quality metrics
 - Quality checklists
 - Process improvement plan
 - Project document updates



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PLAN QUALITY AND ISO

■ Related ISO Sections

- Section 5.3 Quality Policy
- Section 5.4 Quality Planning
 - Quality Objectives
 - Quality Management System Planning
- 7.1 Planning of product realization
- 7.2 Customer-related processes
 - Requirements, Review or requirements & Customer communication
- 7.3 Design & Development
 - Planning, Review, Verification, Validation & Control of changes
- 8.3 Control of non-conforming product and/or service
- 8.4 Analysis of data
- 8.5 Improvement
 - Continual Improvement, Corrective & Preventive Actions

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PERFORM QUALITY ASSURANCE

- The process of auditing the quality requirements and the results from quality control measurements to ensure appropriate quality standards and operational definitions are used.
- Outputs
 - Organizational Process Assets Updates
 - Change Requests
 - Project Management Plan Updates
 - Project Document Updates

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PERFORM QUALITY ASSURANCE AND ISO

■ Related ISO Sections

- Section 8.2 Monitoring & Measurement
 - 8.2.2 Internal Audits
- 8.4 Analysis of data
- 8.5 Improvement
 - 8.5.1 Continual Improvement
 - 8.5.2 Corrective action
 - 8.5.3 Preventive action

■ Change Requests & Updates

- ISO - Audit Report and Non-Conformance Reports or Corrective Actions
- ISO
 - Observations
 - Suggestions for Improvements



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PERFORM QUALITY CONTROL

- The process of monitoring and recording results of executing the quality activities to assess performance and recommend necessary changes.
- Outputs
 - Quality control measurements
 - Validated changes
 - Validated deliverables
 - Organizational Process Assets Updates
 - Change Requests
 - Project Management Plan Updates
 - Project Document Updates



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PERFORM QUALITY CONTROL AND ISO

■ Related ISO Sections

- 7.4.3 Verification of purchased product/service
- 7.5.1 Control of production and service provision
- 7.6 Control of monitoring and measuring equipment
- 8.2.4 Monitoring & measurement of product
- 8.3 Control of non-conforming product
 - Immediate action
 - Root cause analysis & corrective action
- 8.4 Analysis of data
- 8.5 Continual Improvement
 - Corrective action
 - Preventive action



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PROJECT QUALITY MANAGEMENT VS ISO

- 4 Quality management system
 - 4.1 General requirements
 - 4.2 Documentation requirements
 - 4.2.1 General
 - 4.2.2 Quality manual
 - 4.2.3 Control of documents
 - 4.2.4 Control of records
- 5 Management Responsibility
 - 5.1 Management commitment
 - 5.2 Customer focus
 - 5.3 Quality Policy
 - 5.4 Planning
 - 5.4.1 Quality Objectives
 - 5.4.2 Quality Management system planning
- 5.5 Responsibility and authority
 - 5.5.1 Responsibility & authority
 - 5.5.2 Management Representative
 - 5.5.3 Internal communication
- 5.6 Management Review
 - 5.6.1 General
 - 5.6.2 Review Input
 - 5.6.3 Review output

PROJECT QUALITY MANAGEMENT VS ISO

- 6 Resource Management
 - 6.2 Human resources
 - 6.2.1 General
 - 6.2.2 Competence, training, awareness
 - 6.3 Infrastructure
 - 6.4 Work environment
- 7 Product realization
 - 7.1 Planning of product realization
 - 7.2 Customer-related processes
 - 7.2.1 Determination of requirements related to the product
 - 7.2.2 Review of requirements related to the product
 - 7.2.3 Customer communication
 - 7.3 Design & Development
 - 7.3.1 - 7.3.7 Planning, Inputs, Outputs, Review, Verification, Validation, Control of d&d changes
 - 7.4 Purchasing
 - 7.4.1 Purchasing process
 - 7.4.2 Purchasing information
 - 7.4.3 Verification of purchased product
 - 7.5 Production & service provision
 - 7.5.1 Control of production & service provision
 - 7.5.2 Validation of processes for production and service provision
 - 7.5.3 Identification & traceability
 - 7.5.4 Customer property
 - 7.5.5 Preservation of product

PROJECT QUALITY MANAGEMENT VS ISO

- 7.6 Control of monitoring & measurement equipment
- 8 Measurement, Analysis & improvement
 - 8.1 General
 - 8.2 Monitoring & measurement
 - 8.2.1 Customer satisfaction
 - 8.2.2 Internal Audits
 - 8.2.3 Monitoring & measurement of processes
 - 8.2.4 Monitoring & measurement of product
- 8.3 Control of nonconforming product
- 8.4 Analysis of data
- 8.5 Improvement
 - 8.5.1 Continual improvement
 - 8.5.2 Corrective action
 - 8.5.3 Preventive action