



**ISO 9001:2000**  
**Making the Transition**

---



# **ISO 9001:2000 Making the Transition**

---

*Annette Dennis McCully*

*Debra L. Reese*

Excerpts from interviews conducted by the author with Garnett Davis and William Poliseo published with permission.

©2001 American Management Association. All rights reserved. This material may not be reproduced, stored in a retrieval system, or transmitted in whole or in part, in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without the prior written permission of the publisher.

Printed in the United States of America

## Contents

---

	About This Course .....	ix
	How to Take This Course .....	xi
	Pre-Test .....	xiii
<b>1</b>	<b>Introduction to ISO 9001:2000 .....</b>	<b>1</b>
	Structure of the New Standard	
	What Remains	
	Key Enhancements in ISO 9001:2000	
	Deming and Quality Management Systems	
	Continual Improvement's Plan-Do-Check-Act Cycle	
	World Trade Implications of ISO Certification	
	About the Registrars in This Book	
	Recap	
	Review Questions	
<b>2</b>	<b>International Organization for Standardization .....</b>	<b>13</b>
	Development of ISO Standards	
	Examples of ISO Standards	
	ISO 9000 Quality Management Standards	
	Fundamentals of Quality Management Systems	
	Quality Management Systems and Requirements for Products	
	Quality Management Systems Approach	
	The Process Approach	
	Establishing Quality Policy and Quality Objectives	
	Role of Top Management	
	Recap	
	Review Questions	

<b>3</b>	<b>The ISO 9000 Series of Standards</b> .....	<b>25</b>
	Quality Management Principles	
	Quality Management System Components	
	The Value of Documentation	
	QMS and Other Management Systems Focuses	
	Recap	
	Review Questions	
<b>4</b>	<b>4 Quality Management System</b> .....	<b>33</b>
	Requirements of the Standard	
	4.1 General Requirements	
	Supporting Information	
	4.2 Documentation Requirements	
	4.2.1 General	
	4.2.2 Quality Manual	
	4.2.3 Control of Documents	
	4.2.4 Control of Quality Records	
	Recap	
	Review Questions	
<b>5</b>	<b>5 Management Responsibility</b> .....	<b>53</b>
	Requirements of the Standard	
	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, Authority, and Communication	
	5.5.1 Responsibility and 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	
	Recap	
	Review Questions	

**6            6 Resource Management ..... 77**

    Requirements of the Standard

    6.1 Provision of Resources

        Developing a System for Provision of Resources

    6.2 Human Resources

        6.2.1 General

        6.2.2 Competence, Awareness, and Training

            Developing a System for Human Resources

    6.3 Infrastructure

        Developing a System for Facilities

    6.4 Work Environment

        Developing a System for Work Environment

    Recap

    Review Questions

  

**7            7 Product Realization ..... 93**

    Requirements of the Standard

    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 and Development

        7.3.1 Design and Development Planning

        7.3.2 Design and Development Inputs

        7.3.3 Design and Development Outputs

        7.3.4 Design and Development Review

        7.3.5 Design and Development Verification

        7.3.6 Design and Development Validation

        7.3.7 Control of Design and Development Changes

    7.4 Purchasing

        7.4.1 Purchasing Process

        7.4.2 Purchasing Information

        7.4.3 Verification of Purchased Product

    7.5 Production and Service Provision

        7.5.1 Control of Production and Service Provision

        7.5.2 Validation of Processes for Production and Service Provision

- 7.5.3 Identification and Traceability
- 7.5.4 Customer Property
- 7.5.5 Preservation of Product
- 7.6 Control of Monitoring and Measuring Devices
- Recap
- Review Questions

**8 8 Measurement, Analysis, and Improvement . . . . . 125**

- Requirements of the Standard
- 8.1 General
- 8.2 Monitoring and Measurement
  - 8.2.1 Customer Satisfaction
  - 8.2.2 Internal Audit
  - 8.2.3 Monitoring and Measurement of Processes
    - Process Performance Measurement
  - 8.2.4 Monitoring and Measurement of Products
    - Selecting a Measurement Method
- 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
    - Other Preventive Action Resources
- Recap
- Review Questions

**Appendix A  
Comparison of ISO 9001:2000 and ISO 9000:1994 . . . . . 147**

**Appendix B  
Comparison of ISO 9001:2000 and ISO 14001:1996 . . . . . 153**

**Post-Test . . . . . 159**

**Glossary . . . . . 163**

**Index . . . . . 171**