

# Table of Contents

---

**PREFACE TO THE FOURTH EDITION**

**HOW TO USE THIS HANDBOOK**

**ABOUT THE EDITOR**

**SECTION I**

**Introduction to ISO 9000**

**CHAPTER 1**

**ISO 9000 — THE SECOND DECADE OF  
MARKETPLACE DEVELOPMENT.....6**  
     ISO 9000 and the Future.....3

**CHAPTER 2**

**BACKGROUND AND DEVELOPMENT OF THE  
ISO 9000 STANDARDS.....9**  
     Introduction.....9  
     Need for Global Standards.....11  
     Background of the ISO 9000  
         Standards.....12  
     Standardization: Standards and their  
         Implementation.....13  
     The Role of Regional Blocks of  
         Countries.....14  
     The ISO 9000 Family of Standards.....21

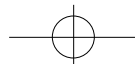
Quality Management and Quality  
 Assurance — Similarities and  
 Differences.....22  
 Roles of the ISO 9000 Standards.....24  
 The Growth of Third-Party  
 Registration.....25  
 Other ISO 9000 Implementation  
 Considerations.....27  
 Concerns About Registration.....28

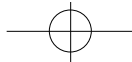
**SECTION II**

**The ISO 9000 Series Standards**

**CHAPTER 3**

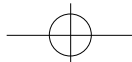
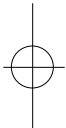
**OVERVIEW OF THE ISO 9000 SERIES  
STANDARDS.....33**  
**THE ISO 9001:2000 SERIES.....34**  
     Introduction.....34  
     Uses of the Standards.....35  
     Definitions of Terms.....35  
     Types of Standards in the ISO 9000  
         Series.....39  
     Topics Covered in ISO 9000:2000.....39  
     Other Standards in the ISO 9000  
         Family.....46

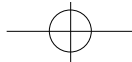




vi Table of Contents

<b>ISO 9004:2000 — QUALITY MANAGEMENT SYSTEMS — GUIDELINES FOR PERFORMANCE IMPROVEMENTS.....</b>	<b>50</b>	5.6.2 Review Input.....	<b>89</b>
Can You Compare ISO 9004:2000 with ISO 9004-1:1994?.....	50	5.6.3 Review Output.....	90
The Consistent Pair of QMS Standards.....	51	6 Resource Management.....	90
A Vehicle for Improving the Organization.....	53	6.1 Provision of Resources.....	90
Implementing the “Guidelines for Performance Improvement”.....	55	6.2 Human Resources.....	91
Key Points.....	60	6.2.1 General.....	91
<b>CHAPTER 4</b>		6.2.2 Competence, Awareness and Training.....	91
<b>THE ISO 9001:2000 STANDARD.....</b>	<b>63</b>	6.3 Infrastructure.....	97
Foreword.....	65	6.4 Work Environment.....	97
Introduction.....	65	7 Product Realization.....	98
1 Scope.....	65	7.1 Planning of Product Realization....	98
2 Normative Reference.....	65	7.2 Customer-Related Processes.....	99
3 Terms and Definitions.....	65	7.2.1 Determination of Requirements Related to the Product.....	99
4 Quality Management System.....	66	7.2.2 Review of Requirements Related to the Product.....	99
4.1 General Requirements.....	66	7.2.3 Customer Communication.....	100
4.2 Documentation Requirements.....	67	7.3 Design and Development.....	100
4.2.1 General.....	67	7.3.1 Design and Development Planning.....	104
4.2.2 Quality Manual.....	68	7.3.2 Design and Development Inputs.....	108
4.2.3 Control of Documents.....	69	7.3.3 Design and Development Output.....	108
4.2.4 Control of Quality Records.....	71	7.3.4 Design and Development Review.....	109
5 Management Responsibility.....	74	7.3.5 Design and Development Verification.....	116
5.1 Management Commitment.....	74	7.3.6 Design and Development Validation.....	120
5.2 Customer Focus.....	76	7.3.7 Control of Design and Development Changes.....	121
5.3 Quality Policy.....	77	7.4 Purchasing.....	121
5.4 Planning.....	78	7.4.1 Purchasing Process.....	121
5.4.1 Quality Objectives.....	78	7.4.2 Purchasing Information.....	129
5.4.2 Quality Management System Planning.....	78	7.4.3 Verification of Purchased Product.....	129
5.5 Responsibility, Authority and Communication.....	82	7.5 Production and Service Provision.....	129
5.5.1 Responsibility and Authority.....	82	7.5.1 Control of Production and Service Provision.....	129
5.5.2 Management Representative.....	85		
5.5.3 Internal Communication.....	89		
5.6 Management Review.....	89		
5.6.1 General.....	89		





7.5.2 Validation of Processes for  
 Production and Service Provision.. 138  
 7.5.3 Identification and Traceability.... 141  
 7.5.4 Customer Property..... 145  
 7.5.5 Preservation of Product..... 146  
 7.6 Control of Monitoring and  
 Measuring Devices..... 148  
 8 Measurement, Analysis and  
 Improvement..... 155  
 8.1 General..... 155  
 8.2 Monitoring and Measurement... 155  
 8.2.1 Customer Satisfaction..... 155  
 8.2.2 Internal Audit..... 155  
 8.2.3 Monitoring and Measurement of  
 Processes..... 164  
 8.2.4 Monitoring and Measurement of  
 Product..... 165  
 8.3 Control of Nonconforming  
 Product..... 168  
 8.4 Analysis of Data..... 170  
 8.5 Improvement..... 171  
 8.5.1 Continual Improvement..... 171  
 8.5.2 Corrective Action..... 172  
 8.5.3 Preventive Action..... 181

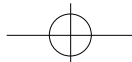
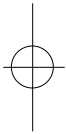
**SECTION III**  
**THE REGISTRATION AND AUDIT PROCESS**

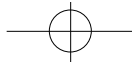
**CHAPTER 5**  
**STEPS IN THE REGISTRATION PROCESS... 185**  
 Introduction..... 185  
 Integrated Management Systems.... 185  
 ISO 9000 Registration..... 186  
 Selecting a Registrar..... 186  
 Document Review..... 187  
 Preassessment..... 188  
 Full Assessment..... 189  
 Registration..... 190  
 Approval..... 190  
 Conditional or Provisional  
 Approval..... 190

Disapproval..... 190  
 Surveillance..... 191  
 Time and Costs of Registration..... 192

**CHAPTER 6**  
**THE AUDIT PROCESS..... 195**  
**INTERNAL QUALITY AUDITS..... 196**  
 What is an Audit?..... 196  
 The Role of the Auditor..... 197  
 Phases of the Audit: PERC..... 198  
 Planning..... 198  
 Selecting the Team..... 199  
 Objective and Scope..... 199  
 Information Sources..... 200  
 Planning an Audit Program..... 200  
 Confirm the Program with the  
 Auditor..... 201  
 Develop a Checklist..... 201  
 Execution..... 201  
 The Opening Meeting..... 201  
 Collecting Information..... 202  
 Verifying Your Observation..... 203  
 Nonconformities..... 204  
 Recording Nonconformities..... 204  
 Reporting..... 205  
 The Closing Meeting..... 205  
 The Formal Audit Report..... 206  
 Corrective Action..... 207

**INTERVIEW OR INQUISITION: SUCCESSFUL**  
**COMMUNICATION TECHNIQUES..... 213**  
 Introduction..... 213  
 Putting the Auditee at Ease..... 213  
 Interview/Communication  
 Techniques..... 214  
 General Considerations..... 215  
 Dealing with Unusual Situations or  
 Conflicts..... 215  
 Ethics..... 216  
 Conclusion..... 218





viii Table of Contents

**CHAPTER 7**

**THE VALUE OF REGISTRAR**

**ACCREDITATION**.....219

Registrar Accreditation.....219

Accreditation Bodies in Europe.....220

Accreditation and Registration.....221

Accreditation in the United States.....221

Registrar Accreditation Board.....221

ANSI-RAB Accreditation Criteria.....222

ANSI-RAB Recognition.....222

NIST and the NVCASE Program.....222

Designating US Recognized Bodies..225

Independent Association of Accredited Registrars.....225

Accreditation Bodies in Canada.....226

Criteria for Registrar Accreditation..277

EN 45012 (ISO/IEC Guide 62): Criteria for Registrars.....228

The European Accreditation of Certification (EAC).....229

Definition of Certification.....299

Assessor's Technical Competence....299

Consultancy.....230

Peer Review.....230

Recognition of Registration Certificates.....231

The International Certification Network (IQNet).....231

European Committee for Quality System Assessment and Certification (EQS).....232

ISO's Committee on Conformity Assessment (CASCO).....232

International Accreditation Forum (IAF).....232

The European Organization for Conformity Assessment (EOTC)....234

EOTC Agreement Groups.....234

EOTC's Status.....234

Auditor Certification Programs.....235

The Institute for Quality Assurance..235

Registrar Accreditation Board.....237

American Society for Quality.....238

Mutual Recognition of Auditor Certification.....238

ISO 14001 for Environmental Management Systems.....240

QS-9000 Quality System Requirements.....240

ISO/TS 16949.....241

Interpretations of ISO 9000 and QS-9000.....241

ISO 9001 Interpretations.....241

QS-9000 Sanctioned Interpretations..242

Conclusion.....242

**CHAPTER 8**

**ISO 9000 REGISTRATION GROWTH AND EXPERIENCES AROUND THE WORLD**.....245

**WORLDWIDE ISO 9000:2000 TRENDS**.....246

Introduction.....246

Registration Trends Around the World.....247

Trends in North America.....251

Company Size and Registrations.....253

Registration Experiences.....253

Barriers to Registration.....253

Benefits of Registration.....254

Costs and Savings.....258

Successful Implementation Strategies.....261

1. Customizing Implementation of ISO 9000 to Specific Company Circumstances.....261

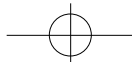
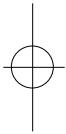
2. Routine Use of ISO 9000 Documented Practices in Business.....261

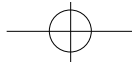
3. Learning, Meaning that ISO 9000 Practices and Findings Are Used to Make Improvements in Training...262

4. Going Beyond the Minimum Requirements for Registration.....262

Use of Outside Services.....263

Future Plans.....266





**THE IMPACT OF THE ISO 9000:2000**

**STANDARDS ON CANADA**.....269  
 Introduction.....269  
 Training.....269  
 Consulting.....270  
 Government Funding.....271  
 Registrars.....271  
 Upgrading to the New ISO 9001  
 Standard.....273  
 Conclusion.....273

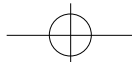
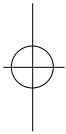
**SECTION IV  
 Implementing ISO 9000**

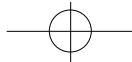
**CHAPTER 9**

**BASIC GUIDE TO IMPLEMENTING**

**ISO 9001:2000**.....277  
 What Is a Management System?.....277  
 The Principles Behind Management  
 Systems.....278  
 Step 1. Management Must Plan for  
 Quality.....280  
 Step 2. The Plan Must Be Recorded and  
 Communicated.....280  
 Step 3. The Plan Must Be  
 Implemented.....280  
 Step 4. Keep a Record of the  
 Implementation.....280  
 Step 5. Measure the results.....280  
 Step 6. Keep a Record of the  
 Results.....280  
 Step 7. Management Must Review  
 Records and Results.....280  
 Step 8. Make Decisions Based on  
 Recorded Results.....281  
 Step 9. Record the Decisions and  
 Communicate Them.....281  
 Step 10. Take Account of Customer  
 Feedback — in Steps 1, 5 and 8.....281  
 Making the Management of Quality  
 Visible.....283

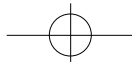
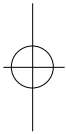
Management Responsibility and  
 Commitment.....283  
 Make the Policy Known.....283  
 Establish and Deploy Quality  
 Objectives.....283  
 Establish the Importance of Customer,  
 Statutory and Regulatory  
 Compliance.....283  
 Demonstrate Management Engagement  
 in the System.....283  
 Ensure Availability of the System.....284  
 Communicate with the  
 Organization.....285  
 Making the Management of Resources  
 Visible.....285  
 Making Customer Requirements Visible  
 and Deliverable.....286  
 Planning the Process.....286  
 Identifying Customer  
 Requirements.....287  
 Translating Requirements into  
 Deliverables — 1. Design.....288  
 Demonstrate Design Planning.....288  
 Demonstrate Control of Design  
 Input.....289  
 Demonstrate Control of Review and  
 Verification Activities.....289  
 Demonstrate Design Output and  
 Verification.....290  
 Demonstrate Control of Design  
 Change.....290  
 Translating Requirements into  
 Deliverables — 2. Realization.....292  
 Plan Product Realization.....292  
 Assure Quality of Materials.....292  
 Assure Process Controls.....294  
 Assure Reliability of Measurement...295  
 Measurement, Monitoring and  
 Analysis.....295  
 Plan the Activity.....295  
 Identify Relevant Data.....295  
 Analyze Data.....296

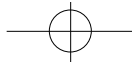




x Table of Contents

Perform System Audits.....	296	Gap Analysis.....	322
Control Nonconformity.....	297	The Executive: Quality Policy and Core Objectives.....	323
Establish Corrective and Preventive Action.....	297	The Team: Relevancy Matrix and Implementation Plan.....	323
In Summary.....	298	Executive Management Activities.....	324
Phase One. Creating Executive Management Commitment and Support and Appointing the Project Manager.....	298	Implementation Team Activities.....	327
1. Customer Pressure.....	298	Phase Four. Identifying the Need for Documentation.....	330
2. Competitive Advantage.....	299	Requirements for Documentation.....	330
3. Opportunity To Improve the Organization.....	299	Implementing the System from Customer Requirement to Fulfillment.....	333
Phase Two. Creating the Implementation Team.....	302	Deciding Who Is the Customer and Capturing the Customer Requirements.....	333
Determining System Scope.....	302	Implementing Requirements Through Design and Development.....	336
Constraints on “Permissible Exclusions”.....	303	Document the Design Plan.....	336
Examples of Legitimate Exclusions..	304	Document Design Input.....	338
Identifying Management System Scope.....	305	Design Activity.....	340
Creating the Scope Statement.....	306	When Does Design Go Under Configuration Management?.....	341
Some Examples of Current ISO 9002:1994 Scope Statements.....	307	Document Design Output.....	345
An Example of Current ISO 9003:1994 Scope Statement.....	308	Design Review, Verification and Validation.....	347
Steps in Creating the Scope Statement.....	308	Manufacturing Controls on Product Realization.....	350
A Poison Chalice?.....	310	Procurement.....	350
Critical Success Factors.....	312	Creating Competent Specifications..	352
Appoint the ISO Implementation Team.....	313	Selecting Competent Suppliers.....	353
Phase Three. The Macro Process Flowchart, Gap Analysis and the Implementation Plan.....	315	Providing Reliable Purchasing Information.....	355
Communications.....	316	Verifying Purchased Product.....	357
Implementation Action Teams.....	318	Materials Management and Handling.....	358
System Understanding.....	319	Product Identification, Status and Traceability.....	358
Functional/Unit Representatives.....	319	Handling.....	360
Statutory and Regulatory Interfaces..	320	Controlling the Processes.....	361
Existing Registration/Quality Activities.....	321	Process Requirements for Materials Management.....	361





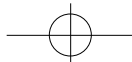
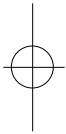
Planning of Realization Processes,  
     Operations Control and Process  
     Validation.....363  
 Planning.....363  
 Operations Control.....366  
 Process Validation (Special  
     Processes).....368  
 Delivery, Postdelivery and  
     Servicing.....369  
 Delivery.....369  
 Installation and Ongoing Servicing...370  
 Managing Installation and Servicing  
     Processes.....371  
 Warranty.....372  
 Managing Warranty Processes.....372  
 Measuring and Monitoring Processes  
     and Products.....373  
 Managing the Monitoring and  
     Measurement of Processes and  
     Products.....375  
 Managing the Control of Monitoring  
     and Measurement Devices.....380  
 Developing the System Infrastructure  
     and Key Improvement Processes...382  
 System Infrastructure.....382  
 The Quality Manual, Document  
     Control, Records and Training.....382  
 The Quality Manual.....383  
 Document Control.....384  
 Records Management.....385  
 Competence, Awareness and  
     Training.....389  
 Who Does What?.....389  
 Requirements for Training, Awareness  
     and Competency.....391  
 System Monitoring and Improvement  
     Activities.....392  
 Control of Nonconformity.....392  
 Corrective and Preventive Action  
     Programs.....395  
 Preventive Action.....400  
 Customer Satisfaction.....403

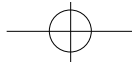
Internal Audit.....405  
 Data Analysis.....413  
 Management Review.....416  
 In Conclusion.....419

**CHAPTER 10**

**CONVERSION — MOVING FROM**

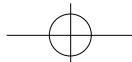
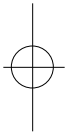
**ISO 9001:1994 TO ISO 9001:2000.....421**  
 Understand the Time Line.....421  
 The Core Changes.....422  
 Process-Based System.....422  
 Management-Driven Quality  
     Objectives.....423  
 Continual Improvement.....423  
 Customer Satisfaction.....424  
 Legal and Regulatory Issues.....424  
 Data Analysis.....425  
 In Summary.....426  
 Getting Started.....426  
 Transition 12-Step Process.....427  
 1. Have the Management  
     Representative Learn and Understand  
     the New Standard.....427  
 2. Review the Scope Statement,  
     Checking for and Documenting any  
     Exclusions Under 1.2.....428  
 3. Review and Identify the Additional  
     Changed Requirements that Impact  
     the Organization, Identifying Them  
     by Clause and Subclause.....433  
 4. Review the Quality Manual and  
     Identify the Changes Required.....434  
 5. Retrain Executive Management....435  
 6. Retrain Internal Auditors.....436  
 7. Perform a Gap Analysis on the  
     Current System Against the  
     Additional/Changed Requirements,  
     Taking Particular Note of Enhanced  
     Record-Keeping Requirements and  
     Data Analysis.....438  
 8. Develop an Overall Plan with

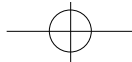




xii Table of Contents

Milestones to Enhance the Current System.....	440	5.2 Planning and Development.....	470
9. Create a Matrix of Conformity Mapping Existing System Documentation from the 1994 Standard to the New Standard.....	440	5.3 Document Format and Structure.....	471
10. Document Plans for Revising ISO 9001 References in Current Documentation as Changes/ Enhancements Occur.....	441	5.4 Identify the Need.....	473
11. Review Plans with Registrar.....	442	5.4.1 The Process Owner.....	474
12. Retrain All Staff.....	443	5.4.2 Time Line, Purpose and Scope..	474
Recertification.....	444	5.4.3 Document Development.....	476
		5.4.3.1 The Work Instruction.....	480
<b>CHAPTER 11</b>		5.5 Records.....	480
<b>DOCUMENTATION AND RECORDS MANAGEMENT.....</b>	<b>445</b>	5.6 Quality Plans.....	481
<b>DOCUMENTATION FOR ISO 9001:2000.....</b>	<b>446</b>	6 Document Administration and Control.....	482
Introduction.....	446	6.1 Documents of External Origin.....	483
Defined Requirements in ISO 9001:2000.....	447	6.2 Management System Documents.....	483
Fulfilling the Basics.....	449	6.2.1 Responsibilities.....	483
3.1 A Statement of Quality Policy.....	449	Summary.....	489
3.1.1 Control of the Policy Statement.....	451	<b>BEYOND COMPLIANCE — MANAGING RECORDS FOR INCREASED PROTECTION.....</b>	<b>490</b>
3.2 Declared Quality Objectives.....	452	ISO 9000 Records Requirements and Legal Issues.....	491
3.2.1 Control of Quality Objectives...	453	Importance of Design Process.....	492
3.3 A Quality Manual.....	453	Development of a Records Retention Schedule.....	493
3.3.1 Quality Manual Structure.....	455	Favorable Court Decisions.....	494
3.3.2 Control of the Quality Manual..	461	Records About Developing a Retention Schedule.....	494
4 Procedures and Other Documentation.....	462	Suspension of Destruction When Litigation Is Imminent.....	495
4.1 Why Document the Extra Stuff?...	464	Personal Records vs. Organization Records.....	495
4.1.1 Documentation Development....	466	Terminology.....	496
4.1.2 Functions and Areas To Be Controlled.....	467	<b>CHAPTER 12</b>	
4.1.3 Documentation Structure.....	467	<b>A QUALITY SYSTEM CHECKLIST.....</b>	<b>501</b>
4.1.4 Outside Assistance.....	468	Introduction.....	501
5 Documents — Procedures, Work Instructions and the Rest.....	469	4 Quality Management System.....	502
5.1 Advantages of Good Documentation.....	470	5 Management Responsibility.....	504
		6 Resource Management.....	506
		6.1 Provision of Resources.....	506
		6.2 Human Resources .....	507





6.3, 6.4 Infrastructure and Work Environment.....507

7 Product Realization.....508

7.1 Planning of Product Realization...508

7.2 Customer-Related Processes.....508

7.3 Design and Development.....509

7.4 Purchasing.....510

7.5 Production and Service Provision.....511

7.5.1 Control of Production and Service Provision.....511

7.5.2 Validation of Processes for Production and Service Provision...511

7.5.3 Identification and Traceability...512

7.5.4 Customer Property.....513

7.5.5 Preservation of Product.....513

7.6 Control of Monitoring and Measuring Devices.....513

8 Measurement, Analysis and Improvement.....514

8.1 General.....514

8.2 Monitoring and Measurement.....515

8.2.1 Customer Satisfaction.....515

8.2.2 Internal Audit.....515

8.2.3 Monitoring and Measurement of Processes.....516

8.2.4 Monitoring and Measurement of Product.....516

8.3 Control of Nonconforming Product.....517

8.4 Analysis of Data.....517

8.5 Improvement.....518

**SECTION V  
Industry Applications of ISO 9000**

**CHAPTER 13  
AUTOMOTIVE REQUIREMENTS.....523**

**AUTOMOTIVE QS-9000 QUALITY SYSTEM  
REQUIREMENTS.....525**

Introduction.....525

Background and Development of the Requirement.....525

The QS-9000 “7 Pack”.....527

Quality System Requirements (QS-9000 Third Edition).....527

Quality System Assessment (QSA)...528

Advanced Product Quality Planning and Control Plan (APQP).....528

Potential Failure Mode and Effects Analysis (FEMA).....529

Measurement Systems Analysis (MSA).....529

Production Part Approval Process (PPAP Third Edition).....529

Statistical Process Control (SPC).....530

The Registration Process.....530

Keys to Achieving Certification.....532

Keys to Maintaining Certification.....532

Impact of QS-9000.....533

ISO/TS 16949.....534

Future Direction of Automotive Sector ISO-Based Standards.....534

**IMPLEMENTING ISO/TS 16949.....536**

Oversight.....536

ISO/TS 16949:2002.....538

Oversight Bodies.....540

Contracts.....541

Auditor Certification and Rules.....542

Line of Sight.....542

Process Approach.....543

IATF’s Position.....544

Automotive Process Approach.....546

Customer Oriented Process.....548

Support Processes.....550

Management Process.....554

ISO/TS 16949 Requirements.....555

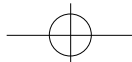
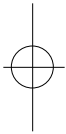
Foresight.....557

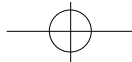
The Future.....558

Trends.....558

Conclusion.....559

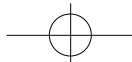
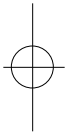
Key Terms.....559

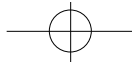




xiv Table of Contents

<b>CHAPTER 14</b>	
<b>QUALITY HEALTH CARE — A PATH</b>	
<b>FORWARD</b> .....	561
Why the Automotive Industry Cares.....	561
Isn't Health Care Accreditation Enough?.....	562
Adding ISO 9001 to the Equation.....	562
The Problem with the Existing ISO 9000 Documents.....	563
Purchased Product.....	565
An Opportunity To Harmonize.....	565
<b>CHAPTER 15</b>	
<b>AS9100 AEROSPACE QUALITY MANAGEMENT SYSTEM STANDARD</b> .....	
Origins of AS9100.....	569
AS9100:2001.....	571
Quality Management Systems — Aerospace — Requirements (Based on ISO 9001:2000).....	571
Foreword.....	571
Structure.....	571
Introduction.....	572
0.1 General.....	572
0.2 Process Approach.....	572
1 Scope.....	572
1.1 General.....	572
1.2 Application.....	573
2 Normative Reference.....	573
3 Terms and Definitions.....	573
4 Quality Management System.....	574
4.1 General Requirements.....	574
4.2 Document Requirements.....	574
4.2.1 General.....	574
4.2.2 Quality Manual.....	575
4.2.3 Control of Documents.....	575
4.2.4 Control of Records.....	576
4.3 Configuration Management.....	576
5 Management Responsibility.....	577
5.5 Responsibility, Authority and Communication.....	577
5.5.2 Management Representative.....	577
6 Resource Management.....	577
6.4 Work Environment.....	577
7 Product Realization.....	578
7.1 Planning of Product Realization.....	578
7.2 Customer-Related Processes.....	578
7.2.2 Review of Requirements Related to the Product.....	578
7.3 Design and Development.....	579
7.3.1 Design and Development Planning.....	579
7.3.3 Design and Development Outputs.....	580
7.3.4 Design and Development Review.....	581
7.3.5 Design and Development Verification.....	581
7.3.6 Design and Development Validation.....	581
7.3.6.1 Documentation of Design and/or Development Verification and Validation.....	582
7.3.6.2 Design and/or Development Verification and Validation Testing.....	582
7.3.7 Control of Design and Development Changes.....	583
7.4 Purchasing.....	583
7.4.1 Purchasing Process.....	583
7.4.2 Purchasing Information.....	585
7.4.3 Verification of Purchased Product.....	586
7.5 Production and Service Provision.....	589
7.5.1 Control of Production and Service Provision.....	589
7.5.1.1 Production Documentation.....	591
7.5.1.2 Control of Production Process Changes.....	591
7.5.1.3 Control of Production Equipment, Tools and Numerical Control (N.C.) Machine Programs.....	592





7.5.1.4 Control of Work Transferred, on a Temporary Basis, Outside the Organization's Facilities.....593

7.5.1.5 Control of Service Operations.....593

7.5.2 Validation of Processes for Production and Service Provision..594

7.5.3 Identification and Traceability....595

7.5.4 Customer Property.....596

7.5.5 Preservation of Product.....597

7.6 Control of Monitoring and Measuring Devices.....597

8 Measurement, Analysis and Improvement.....599

8.1 General.....599

8.2 Monitoring and Measurement.....599

8.2.2 Internal Audit.....599

8.2.3 Monitoring and Measurement of Processes.....600

8.2.4 Monitoring and Measurement of Product.....600

8.2.4.1 Inspection Documentation.....601

8.2.4.2 First Article Inspection.....602

8.3 Control of Nonconforming Product.....603

8.4 Analysis of Data.....605

8.5 Improvement.....605

8.5.2 Corrective Action.....605

8.5.3 Preventive Action.....606

**CHAPTER 16**

**TL 9000 QUALITY MANAGEMENT STANDARD FOR TELECOMMUNICATIONS..607**

Telecommunications Industry and TL 9000.....607

QuEST Forum.....608

QuEST Forum Goals.....609

What Is TL 9000?.....611

Requirements.....611

Shalls, Shoulds and Notes.....613

Differences with ISO 9001.....617

Measurements.....621

Common (HW, SW and/or SC).....626

Hardware (HW).....626

Software (SW).....626

Services (SC).....626

TL 9000 Measurements.....626

Eight General Product Families.....628

Business Excellence Acceleration Model (BEAM).....635

Conclusion.....637

**CHAPTER 17**

**APPLICATION OF ISO 9001:2000 TO THE CONSTRUCTION INDUSTRY.....639**

The Dorma Experience.....639

Industry Changes.....640

How the Standard Relates to Construction.....640

4 Quality Management System.....640

5 Management Responsibility.....640

5.1 Management Commitment.....640

5.2 Customer Focus.....641

5.3 Quality Policy.....641

5.4 Planning.....641

5.5 Responsibility, Authority and Communication.....641

5.6 Management Review.....641

6 Resource Management.....641

7 Product Realization.....641

7.1 Planning of Product Realization..641

7.2 Customer-Related Processes.....642

7.3 Design and Development.....642

7.4 Purchasing.....642

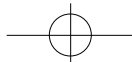
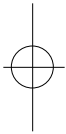
7.5 Production and Service Provision.....642

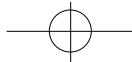
7.6 Control of Monitoring and Measuring Devices.....642

8 Measurement, Analysis and Improvement.....642

8.1 General.....642

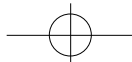
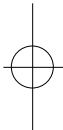
8.2 Monitoring and Measurement....643

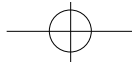




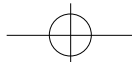
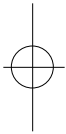
xvi Table of Contents

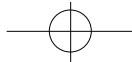
8.3 Control of Nonconforming	
Product.....	643
8.4 Analysis of Data.....	643
8.5 Improvement.....	643
<b>CHAPTER 18</b>	
<b>ISO 9000 AND QS-9000 FOR THE</b>	
<b>CHEMICAL INDUSTRY.....</b>	<b>645</b>
Introduction.....	645
ISO 9001 and the CPI.....	646
Introduction.....	646
0.2 Process Approach.....	646
1.2 Application.....	646
4 Quality Management System	
(QMS).....	648
4.1 General Requirements.....	648
4.2.1 General Documentation	
Requirements.....	648
4.2.2 Quality Manual.....	648
4.2.3 Control of Documents.....	648
4.2.4 Control of Quality Records.....	649
5 Management Responsibility.....	649
5.1 Management Commitment.....	649
5.2 Customer Focus.....	649
5.3 Quality Policy.....	649
5.4 Planning.....	650
5.4.1 Quality Objectives.....	650
5.4.2 Quality Management System	
Planning.....	650
5.5 Responsibility, Authority and	
Communication.....	650
5.5.1 Responsibility and Authority...	650
5.5.2 Management Representative...	650
5.5.3 Internal Communication.....	650
5.6 Management Review.....	651
6 Resource Management.....	651
6.1 Provision of Resources.....	651
6.2 Human Resources.....	651
6.3 Infrastructure.....	651
6.4 Work Environment.....	652
7 Product Realization.....	652
7.1 Planning of Realization	
Processes.....	652
7.2 Customer-Related Processes.....	652
7.2.3 Customer Communication.....	652
7.3 Design and/or Development.....	653
7.4 Purchasing.....	653
7.5 Production and Service	
Operations.....	653
Control of Production and Service	
Provision.....	653
7.5.2 Validation of Process.....	654
7.5.3 Identification and Traceability...	654
7.5.4 Customer Property.....	654
7.5.5 Preservation of Product.....	655
7.6 Control of Measuring and	
Monitoring Devices.....	655
8 Measurement, Analysis and	
Improvement.....	656
8.1 Planning.....	656
8.2 Measurement and Monitoring ...	656
8.2.1 Customer Satisfaction.....	656
8.2.2 Internal Audit.....	656
8.2.3 Measurement and Monitoring of	
Processes.....	657
8.2.4 Measurement and Monitoring of	
Product.....	657
8.3 Control of Nonconformity.....	657
8.4 Analysis of Data.....	658
8.5 Improvement.....	658
8.5.2 Corrective Action.....	658
8.5.3 Preventive Action.....	658
Selecting a Registrar or Certification	
Body.....	659
QS-9000, ISO/TS 16949 and ISO	
9001.....	659
A Word About ISO 14001 and the	
CPI.....	659
Conclusion.....	660





<b>CHAPTER 19</b>	
<b>THE APPLICATION OF ISO 9001:2000 TO SOFTWARE DEVELOPMENT.....</b>	<b>661</b>
Introduction.....	661
A Matter of Timing.....	661
Chapter Outline.....	662
A Brief Review: Been There, Done That.....	662
A Brief History of ISO 9000-3 and the Application of ISO 9001 to Software.....	663
Perspective 1: The ISO 9001:2000 Family of Standards.....	664
ISO 9001:2000 1.2 Permissible Exclusions.....	666
A Problem: Organization or Company?.....	666
Implications for Software.....	667
Perspective 2: The Internal Structure of ISO 9001:2000.....	667
Implications for Software.....	668
Opportunity 1: Simplification.....	668
Opportunity 2: Resolving the Definition of "Production".....	668
Get a Life...Cycle.....	669
The Application of Clause 7.5 to Software Development Processes..	670
Chapter Outline — Revisited.....	671
Perspective 3: The Requirements of ISO 9001:2000 for Software Development.....	672
Defining Quality and Quality Management System.....	672
4 Quality Management System.....	672
Too Thin. Too rich. Too Many Procedures?.....	672
Streamlining Procedures.....	673
5 Management Responsibility.....	674
5.2 Customer Focus.....	674
5.4.1 Quality Objectives.....	675
5.4.2 Quality Management Systems	
Planning.....	675
6 Resource Management.....	676
7 Product Realization.....	676
7.1 Planning of Product Realization..	677
7.2 Customer-Related Processes.....	678
7.3 Design and Development.....	679
7.5 Production and Service Provision.....	680
7.4 Purchasing.....	685
7.6 Control of Monitoring and Measuring Devices.....	687
8 Measurement, Analysis and Improvement.....	687
8.1 General.....	688
8.2 Monitoring and Measurement....	688
8.2.3 Monitoring and Measurement of Processes — Implications for Software.....	689
8.2.4 Monitoring and Measurement of Product — Implications for Software.....	689
8.3 Control of Nonconforming Product — Implications for Software.....	690
8.4 Analysis of Data.....	690
8.5.1 Continual Improvement.....	691
8.5.2 Corrective Action.....	691
8.5.3 Preventive Action.....	692
Recommendations for Implementers: Establishing ISO 9001 as a Framework.....	692
Principle 1: ISO 9001:2000 Is a Requirements Specification.....	692
About Exclusions.....	693
About Registrars and Their Auditors.....	693
Principle 2: It Is Easier To Achieve Compliance Than To Maintain Compliance.....	694
Recommendations for Maintainers in Software Organizations: Addressing the Changes.....	695
Points To Focus on for Maintainers..	695





xviii Table of Contents

Appendix 19A — Evolution of the ISO 9001 Family of Standards Between 1994 and 2000.....698

Appendix 19B — Background on Claiming Conformity.....699

Appendix 19C — Precedents for the Definition of “Production” — Lessons Learned.....701

Appendix 19D — Suggested Assignment of ISO 9001:2000 Clauses and Requirements to ISO 12207:1995 Software Life Cycle Processes.....703

Appendix 19E — Sources of Standards and Information.....706

**CHAPTER 20**  
**ISO 13485 FOR THE REGULATED MEDICAL DEVICE INDUSTRY SECTOR.....713**

General.....713

Background.....713

Purpose of This Chapter.....713

Key Organizations.....714

Work of ISO TC 210, WG 1.....714

Work of GHTF.....714

Role of TC 176.....714

The Interaction Between TC 176 and TC 210, WG 1.....715

Differences Between ISO 9001:2000 and ISO 13485:2003.....715

Divergence of Objectives.....715

Revision of ISO 9000 Series.....715

Current Dilemma.....716

Similarities.....716

Substantive Differences.....717

Continual Improvement.....717

Customer Satisfaction.....717

Level of Procedural Documentation..718

What ISO 13485:2003 Will Look Like.....718

ISO 13488 and ISO 14969.....719

What Is ISO 13488?.....719

Will ISO 13488:2003 Be Published?...719

What Will Happen to ISO 14969?.....719

Path Forward Recommendations.....719

Key Publication Milestones.....719

Determine Standards Strategy.....720

Standards Strategy.....720

Negotiations with Registrars and Notified Bodies.....720

Internalize Process Approach.....721

Perform “Gap Analysis”.....721

Conclusion.....721

Get Started Right Away.....721

**SECTION VI**  
**Conformity Assessment and Laboratory Accreditation**

**CHAPTER 21**  
**EUROPEAN UNION AND CONFORMITY ASSESSMENT REQUIREMENTS.....725**

What Is Conformity Assessment?.....725

The EU’s Single Internal Market.....726

Technical Trade Barriers.....726

Goals of the New System.....726

1. EU-wide Directives.....727

Nonregulated Products.....727

Regulated Products.....728

Old-Approach Directives and New-Approach Directives.....728

Essential Requirements.....729

Presumption of Conformity.....729

Mutual Recognition.....729

Voluntary Standards.....729

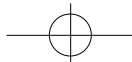
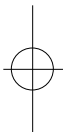
Transition Period.....730

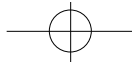
Requirements May Include Several Directives.....731

Notified Bodies.....732

The Competence of Notified Bodies.....732

Product Certification Versus ISO 9000 Registration.....732





The CE Mark.....733  
 Old-Approach Directives.....734  
 Additional Marks.....734  
 2. Harmonized Standards.....735  
 EU Standards and Regional  
 Standardization Organizations.....735  
 Committee for European  
 Standardization (CEN).....736  
 Roles in Testing and Certification.....736  
 CEN and ISO.....736  
 Types of CEN Standards.....737  
 European Committee for  
 Electrotechnical Standardization  
 (CEN-LEC).....737  
 CENELEC Priorities.....738  
 European Telecommunications  
 Standardization Institute (ETSI).....738  
 3. Consistent Conformity Assessment  
 Procedures.....738  
 The Modular Approach.....739  
 Description of Modules in Modular  
 Approach.....741  
 Internal Control of Production (A)...741  
 Type-Examination (B).....741  
 Conformity to Type (C).....743  
 Production Quality Assurance (D)...743  
 Product Quality Assurance (E).....743  
 Product Verification (F).....743  
 Unit-Verification (G).....743  
 Full Quality Assurance (H).....743  
 Degree of Complexity.....744  
 Additional Requirements.....744  
 4. Competent Certification and Testing  
 Bodies.....744  
 The European Union and Other  
 Countries.....745  
 Subcontracting.....746  
 Mutual Recognition.....746  
 EU/US Mutual Recognition  
 Agreement.....746  
 Non-EU Notified Bodies.....747

The European Union and US  
 Conformity Assessment.....748  
 The US Response to the European  
 Union.....748  
 The Critical Role of Conformity  
 Assessment.....749  
 Conclusion.....749

**CHAPTER 22**

**ISO/IEC 17025 AND LABORATORY**

**ACCREDITATION.....751**  
 Introduction.....751  
 Why Is There So Much Confusion?...751  
 The Semantics Problem.....752  
 ISO/IEC 17025-1999.....753  
 Similarities and Differences.....754  
 Fundamental Difference.....756  
 Complementary Functions.....757  
 “In-House” Laboratories.....757  
 Scope of Accreditation/  
 Certification.....757  
 The Special Role of Accredited  
 Calibration Laboratories.....758  
 European Position.....759  
 Conclusion.....759

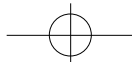
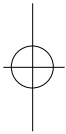
**SECTION VII**

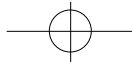
**Additional ISO 9000 Applications**

**CHAPTER 23**

**LEGAL ISSUES WITH ISO 9000 AND THE  
 FASTNER QUALITY ACT.....763**

**ISO 9000:2000 AND LEGAL LIABILITY.....764**  
 Introduction.....764  
 Areas of Liability Litigation.....765  
 Benefits of an ISO 9001 Quality  
 Management System in the Event of a  
 Lawsuit.....769  
 What About Guidance Standards?...770  
 Medical Device.....771  
 ISO 9001:2000 and ISO 9004:2000.....772





XX Table of Contents

ISO 9001:2000 Clauses That Carry Legal Implications.....772

0.1 General.....772

5.1 Management Commitment.....773

7.2.1 Determination of Requirements Related to Product.....773

7.3.2 Design and Development Inputs.....773

7.3.3 Design and Development Outputs.....773

ISO 9004:2000 Clauses That Carry Legal Implications.....773

4.2 Documentation.....773

5.2.2 Needs and Expectations.....773

5.2.3 Statutory and Regulatory Requirements.....774

5.6.2 Review Input.....774

7.1.3.3 Product and Process Validation and Changes.....774

7.3.1 General Guidance.....775

7.3.2 Design and Development Input and Output.....776

Conclusion.....776

**THE FASTENER QUALITY ACT.....778**

Introduction.....778

Background.....779

Round One: The Fastener Quality Act Becomes Law on Friday, November 16, 1990.....781

Round Two: The First FQA Amendment, Public Law 104-133 Appears in March 1996.....783

Round Three: Public Law 105-234 Creates Exemptions and Allows Further Delay.....784

Round Four: Public Law 106-34 “FQA Amendments Act of 1999” Signed June 8, 1999.....785

Conclusions.....786

**CHAPTER 24**

**ISO 9000 IN THE US PUBLIC SECTOR.....789**

Approvals and Supplier Qualification.....789

Department of Defense (DoD).....790

Department of Energy (DOE).....790

Department of Health and Human Services (HHS).....791

National Institute for Occupational Safety and Health (NIOSH).....791

Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH).....791

The Global Harmonization Task Force (GHTF).....792

National Aeronautics and Space Administration (NASA).....792

Nuclear Regulatory Commission (NRC).....792

Resources.....793

Department of Commerce.....793

National Institute of Standards and Technology (NIST).....793

Department of Agriculture (USDA).....795

US Department of Transportation.....795

Maritime Administration.....795

Department of the Treasury.....795

Internal Revenue Service.....795

Implementation.....796

Federal Agencies.....796

State and Local.....798

Education.....798

**SECTION VIII**

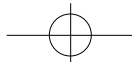
**Environmental Management**

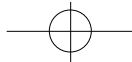
**CHAPTER 25**

**THE INTERNATIONAL ENVIRONMENTAL MANAGEMENT STANDARD.....803**

An Introduction to ISO 14000.....803

Reasons Behind Development.....804





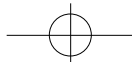
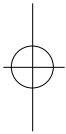
Business Management Drivers.....804  
 Marketplace Advantages.....805  
 ISO 14000, Part of an International  
     Trend.....805  
 The Development of ISO 14000  
     Standards.....806  
 The ISO 14001 Standard.....807  
 Elements of ISO 14001.....809  
 Management Commitment and  
     Environmental Policy.....809  
 Planning.....809  
 Implementation Operations.....809  
 Checking and Corrective Action.....810  
 Management Review.....810  
 ISO 9001 and ISO 14001.....811  
 Registration or Certification.....813  
 Revisions.....813  
 ISO 14001 and Regulation.....815

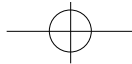
**SECTION IX  
 Opportunities and Challenges**

**CHAPTER 26**  
**COMPARING ISO 9000, MALCOLM**  
**BALDRIGE AND TQM.....819**  
 Introduction.....819  
 ISO 9000 Family and Related  
     Standards.....821  
 Overview of the Two Systems.....821  
 The ISO 9000 Series — Strengths and  
     Limitations.....821  
 ISO 9004:2000 Quality Management  
     Systems — Guidelines for  
     Performance Improvement.....823  
 The Malcolm Baldrige National Quality  
     Award.....825  
 ISO 9000 Compared to MBNQA.....831  
 Comparison of Documentation and  
     Control.....832  
 Comparison of Degree of  
     Prescriptiveness.....832

ISO 9000, MBNQA and Total Quality in  
 Summary.....834

**CHAPTER 27**  
**CHALLENGES FACING THE ISO 9000**  
**INDUSTRY.....839**  
 ISO 9000 as an Industry.....839  
 The Challenge of Credibility of  
     Registration.....840  
 Scope of Registration of an  
     Organization’s Quality System.....841  
 Which Elements of the Standards Are  
     Selected?.....841  
 Which Geographic Sites or Operating  
     Units?.....842  
 Which Products?.....842  
 Which Portions of the Supply  
     Chain?.....842  
 The Current Status.....843  
 Responsibilities of the Organizations  
     Involved.....843  
 The Challenge of Continual  
     Improvement.....844  
 The Challenge of Statistical  
     Techniques.....845  
 The Challenge of Standards  
     Interpretation.....846  
 The Challenge of Alternate Routes to  
     Registration.....847  
 The Challenge of Industry-Specific  
     Adoption and Extension of ISO 9000  
     Standards.....848  
 The Challenge of Computer  
     Software.....849  
 The Challenge of Environmental  
     Management Systems.....850  
 The Challenge of Application in  
     Nonmanufacturing  
     Organizations.....850  
 The Challenge of Linkage to Total  
     Quality Management.....851





**SECTION X  
Appendices**

**APPENDIX A**  
**AUTHOR BIOGRAPHIES.....857**

**APPENDIX B**  
**QUALITY AWARD PROGRAMS.....881**

**APPENDIX C**  
**WEBLIOGRAPHY.....893**

**APPENDIX D**  
**ACCREDITED REGISTRARS.....915**

**APPENDIX E**  
**ACRONYMS AND GLOSSARY.....963**

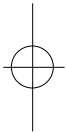
**APPENDIX F**  
**ISO 9001:2000.....981**

**INDEX.....1015**

SGS International Certification Services  
 Canada Inc.  
 ITS Intertek Services  
 National Quality Assurance Ltd.

**OTHER QSU PUBLISHING PRODUCTS**

View QSU Publishing's Electronic  
 Catalogue  
 Get the Latest Third-Party Registration  
 Counts on QSUonline  
 Contact QSU Publishing Customer  
 Service  
 Contact QSU Publishing Technical  
 Support



**THE ISO 9000 HANDBOOK  
BONUS CD-ROM**

**STANDARDS**

ISO 9000:2000  
 ISO 9001:2000  
 ISO 9004:2000

**BIG TEN TRANSITION GUIDANCE**

BSI Inc.  
 Quality Management Systems Inc.  
 Underwriters Laboratories Inc.  
 Perry Johnson Registrars Inc.  
 Bureau Veritas Quality International  
 Inc.  
 DNV Certification Inc.  
 Lloyd's Register Quality Assurance Inc.

