Contents

Preface ix

Chapter 1 Introduction to ISO 9000 Certification Process

Overview 1
The ISO 9000 Standards 2
What is a Quality System? 4
Understanding Quality Audits 6
Overview of the Certification Process 8

Chapter 2 The Twenty Sections of ISO 9001

Overview 11
4.1 Management Responsibility 13
4.2 Quality System 17
4.3 Contract Review 22
4.4 Design Control 24
4.5 Document and Data Control 28
4.6 Purchasing 31
4.7 Control of Customer-Supplied Product 34
4.8 Product Identification and Traceability 36
4.9 Process Control 38
4.10 Inspection and Testing 41
4.11 Control of Inspection, Measuring, and Test Equipment 44
4.12 Inspection and Test Status 48
4.13 Control of Nonconforming Product 50
4.14 Corrective and Preventive Action 52
4.15 Handling, Storage, Packaging, Preservation, and Delivery 55
4.16 Control of Quality Records 58
4.17 Internal Quality Audits 60
4.18 Training 62
4.19 Servicing 65
4.20 Statistical Techniques 67

Chapter 3 Strategic Planning

Overview 69
Management Responsibilities 71

Selecting a Registrar 73
Selecting a Conformance Model 75
Forming a Project Team 77
Establishing a Timeline 80
Assessing the Organization's Training Needs 82

Chapter 4 Gap Analysis and Corrective Action
Overview 83
Descriptions of Gap Analysis and Corrective Action 85
Corrective Action Teams 86
Gap Analysis and Corrective Action Process 87
Stage 1: Requirements Identification 88
Stage 2: Resolution of Requirements Differences 89
Stage 3: Existing Process Evaluation 90
Stage 4: Existing Document Compatibility 91
Stage 5: Gap Analysis 92
Stage 6: Process Corrective Action 93
Stage 7: Document Corrective Action 94
Stage 8: Training and Implementation 95
Stage 9: Change Effectiveness Verification 96

Chapter 5 Implementing a Document Structure
Overview 97
ISO Document Levels 98
Organizing your Documents 100
Creating a Functional Breakdown of your Documents 102

Chapter 6 Document Development
Overview 105
The Document Development Process 106
Stages of the Document Development Process 108
Change Notification 111

Chapter 7 Instituting Document and Quality Records Controls
Overview 113
Assigning Document Responsibilities 115
Instituting Writing Guidelines 117
Implementing Document Identification Numbers 118
Maintaining a Master List 120
Control of Quality Records Process 123
Stages of the Control of Quality Records Process 124

Chapter 8 Site Preparation
Overview 127
The Pre-Certification Audit 129
The Registrar Documentation Review 130
Preparing Management for the Certification Audit 131
Preparing your Organization for the Certification Audit 133
The Certification Audit 135

Appendix—Examples of actual Levels A through C certified documentation .. 137

Index 145