www.degrandson.co.uk

ISO GOO IMPLEMENTATION HANDBOOK

FOR CERTIFICATION TO THE QUALITY MANAGEMENT SYSTEM STANDARD



Written by

Dr. John FitzGerald, Founder
and CEO of deGRANDSON Global

Usage note

The intent of this document is to help you recognize the activities related to establishing a QMS. This document should not be considered as professional consulting for establishing or implementing a QMS.

Use of this handbook does not guarantee a successful implementation nor an implementation that is ready for certification. If you want to implement a QMS, consider hiring a professional consultant who specializes in implementing ISO 9001 compliant QMS.

Contents

USAGE NOTE	1
INTRODUCTORY NOTE	3
OVERVIEW OF A QUALITY MANAGEMENT SYSTEM	4
1 PURCHASE A COPY OF THE ISO STANDARDS	8
2 INITIATING THE QMS PROJECT	9
2.1 OBTAIN MANAGEMENT SUPPORT (#1)	9 9 11
3 THE CONTEXT OF THE ORGANISATION	14
3.1 DETERMINE THE CONTEXT OF THE ORGANIZATION (#4) 3.2 IDENTIFY THE APPLICABLE LEGAL AND REGULATORY REQUIREMENTS (#5)	15 15
4 DEFINE AND ESTABLISH A QUALITY MANAGEMENT SYSTEM	17
4.1 DEFINE THE SYSTEM'S PROCESSES AND THEIR INTER-RELATIONSHIPS (#7) 4.2 DEFINE THE SCOPE OF THE QMS (#8)	20 21 21
5 THE PLANNING	25
5.1 DETERMINE ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES (#11) Risk-based thinking, PDCA, and the process approach 5.2 ESTABLISH QMS OBJECTIVES AND PLAN TO ACHIEVE THEM (#12)	27
6 ESTABLISH DESIGN & DEVELOPMENT PROCESSES (#13)	31
7 OPERATIONAL PLANNING AND CONTROLS	35
7.1 DETERMINE THE OPERATIONAL PLANNING AND CONTROL NEEDS (#14)	36
8 DEVELOP THE DOCUMENTATION REQUIRED	
8.1 ESTABLISH CUSTOMER SATISFACTION METHODS (#17)	38 40

9	DETERMINE AND SECURE THE REQUIRED RESOURCES (#20)	44
	9.1 Determining the Resources Required	44
	9.2 IDENTIFY AND SECURE THE HUMAN RESOURCES	
	9.3 IDENTIFY AND SECURE THE INFRASTRUCTURE (HARDWARE, SOFTWARE, SUPPORT SERVICES & UTILITIES)	
	9.4 ESTABLISH SUITABLE WORKING ENVIRONMENTS	····· 45
10	ESTABLISH PROCUREMENT PROVISION (#21)	46
	10.1 ESTABLISH PROCUREMENT POLICY AND CRITERIA	46
	10.2 Supplier Evaluation	46
	10.3 PRODUCT AND SERVICE SPECIFICATION, SOURCING AND VERIFICATION	46
	10.4 ESTABLISH PROCESS FOR THE CONTROL OF OUT-SOURCED PRODUCTS AND SERVICES	47
11	PRE-LAUNCH ACTIVITIES	48
	11.1. ESTABLISH INTERNAL AND EXTERNAL COMMUNICATIONS (#22)	48
	11.2 Deliver Employee Awareness Training (#23)	48
	11.3 FINALISE & ISSUE QMS DOCUMENTATION (#24)	50
	11.4 COMPLETE JOB-SPECIFIC TRAINING (#25)	
	Example of Employee Training Record incl. competency check:	
12	GO LIVE! IMPLEMENT POLICIES, PROCEDURES AND QUALITY OBJECTIVES PLAN (#26)	
	12.1 DEPLOY POLICIES	
	12.2 IMPLEMENT PROCEDURES	
	12.3 CONTROL OF NONCONFORMING OUTPUTS	
13	ESTABLISH CUSTOMER-RELATED REQUIREMENTS (#27)	
	13.1 ESTABLISH CUSTOMER COMMUNICATION	-
	13.2 DETERMINE CUSTOMER REQUIREMENTS	_
	13.2 REVIEW CUSTOMER REQUIREMENTS, INCLUDING CHANGES	
14	ESTABLISH PRODUCTION AND SERVICE PROVISION PROCESSES (#28)	
	14.1 ESTABLISH CONTROL OF PRODUCTION & SERVICE PROVISION	-
	14.2 ESTABLISH IDENTIFICATION, TRACEABILITY AND QUALITY STATUS REQUIREMENTS	58
	14.3 ESTABLISH CONTROL OF CUSTOMER PROPERTY, PRESERVATION, POST-DELIVERY ACTIVITIES & CONTROL OF CHANGES TO PRODUCTION AND SERVICE PROVISION	58
	RELEASE OF PRODUCTS AND SERVICES (#29)	-
16	. MONITOR THE EFFECTIVENESS OF THE QMS IMPLEMENTATION	
	16.1 CONDUCT PERIODIC INTERNAL AUDITS (#30)	
	16.2 CONDUCT PERIODIC MANAGEMENT REVIEWS (#32)	-
	5 00.200. 2.1102.0 111.11.12.11.2.11.11.0 (1.02)	
17	IMPLEMENT CONTINUAL IMPROVEMENT (#33)	
	Example: of a QMS Improvement Plan outline	66
18	PREPARE FOR A CERTIFICATION AUDIT	67
19	ASK FOR HELP	68
	PPENDICES	
	APPENDIX A: THE PATH TO ISO 9001:2015 CERTIFICATION – THE 33 STEPS.	-
	APPENDIX B: THE QUESTION OF RETAINED DOCUMENTATION IN ISO 9001:2015	-
	APPENDIX C: TYPICAL QMS DOCUMENTATION	74
	Policies & Procedures	
	Records	
	APPENDIX D: SAMPLE PROCEDURES	
	QMSP-001: Customer Contract Processing	
	QMSP-002: Purchasing QMSP-003: Control of Maintained Documentation	
	QMSP-003: Control of Maintained Documentation	
	gmor out. Control of Neturied Documentation	/0

ISO 9001:2015 Quality Management System Handbook

QMSP-005: QMS Internal Audits	.76
QMSP-006: QMS Management Reviews	
QMSP-007: Control of Monitoring and Measuring Devices	76
QMSP-008: Design and Development of Products & Services	
QMSP-009: Non-conformance and Corrective Action	76
Appendix E: Example of Management Review Record	104
Appendix F: Seventeen ISO Guidance Documents for ISO 9001:2015	80
APPENDIX G: ISO 9001:2015 VS. ISO 9001:2008 - A SIDE BY SIDE COMPARISON	109

Introductory Note

We suggest that you study this Guide after you have completed Module 2 of your Course; better still, after you have completed the entire Course. This is because...

- 1. The detailed content of the Course is not needlessly repeated here.
- 2. The purpose behind many of the recommendation in this Guide will be clearer to you after you have studied the Standard itself in detail.
- 3. You will be better able to judge what is required of, and to recommend to, your organization in securing Certification to ISO 9001:2015 with a knowledge of both the Standard and the Guide.