

Table of Contents

0	Introduction.....	4
0.1	What is this ISO 9000 Quality plus Procedures Manual?	4
0.2	Customization Instructions.....	4
1	Approval and Revision.....	11
1.1	Approval	11
1.2	Revision History	11
2	Our Company.....	12
2.1	Our Vision	12
2.2	Our Mission	12
2.3	Our Company Processes.....	12
3	Scope and Exclusions.....	13
3.1	Scope	13
3.2	Exclusions	13
3.3	References and Inclusions	13
4	Quality Management System	15
4.1	General Requirements.....	15
4.2	Documentation Requirements	15
4.2.1	General	15
4.2.2	Quality Manual	16
4.2.3	Control of Documents	17
4.2.4	Control of Records.....	19
5	Management Responsibility.....	21
5.1	Management Commitment.....	21
5.2	Customer Focus	21
5.3	Quality Policy.....	21
5.4	Planning	22
5.4.1	Quality Objectives.....	22
5.4.2	Quality Management System Planning	22
5.5	Responsibility, Authority and Communication.....	22
5.5.1	Responsibility and Authority	22
5.5.2	Management Representative.....	22
5.5.3	Internal Communication.....	23
5.6	Management Review.....	23
5.6.1	General	23
5.6.2	Review Input.....	23
5.6.3	Review Output.....	24
6	Resource Management	25
6.1	Provision of Resources	25
6.2	Human Resources.....	25
6.2.1	General	25
6.2.2	Competence, Awareness and Training.....	Error! Bookmark not defined.
6.3	Infrastructure.....	25
6.4	Work Environment	26

7	Product Realization.....	27
7.1	Planning of Product Realization	27
7.2	Customer Related Processes	27
7.2.1	Determination of Requirements Related to the Product.....	27
7.2.2	Review of Requirements Related to the Product.....	28
7.2.3	Customer Communication.....	28
7.3	Design and Development	29
7.3.1	Design and Development Planning	29
7.3.2	Design and Development Inputs	29
7.3.3	Design and Development Outputs	29
7.3.4	Design and Development Review.....	30
7.3.5	Design and Development Verification.....	30
7.3.6	Design and Development Validation.....	30
7.3.7	Control of Design and Development Changes.....	31
7.4	Purchasing	31
7.4.1	Purchasing Process	31
7.4.2	Purchasing Information	31
7.4.3	Verification of Purchased Product.....	32
7.5	Production and Service Provision.....	32
7.5.1	Control of Production and Service Provision.....	32
7.5.2	Validation of Process for Production and Service Provision	32
7.5.3	Identification and Traceability.....	33
7.5.4	Customer Property	33
7.5.5	Preservation of Product.....	33
7.6	Control of Monitoring and Measuring Devices	33
8	Measurement, Analysis and Improvement	35
8.1	General	35
8.2	Monitoring and Measurement	35
8.2.1	Customer Satisfaction.....	35
8.2.2	Internal Audit.....	36
8.2.3	Monitoring and Measurement of Processes	38
8.2.4	Monitoring and Measurement of Product	38
8.3	Control of Nonconforming Product.....	39
8.3.1	General	39
8.3.2	Purpose.....	39
8.3.3	Scope	39
8.3.4	Responsibility.....	39
8.3.5	Procedure	39
8.4	Analysis of Data	41
8.5	Improvement.....	41
8.5.1	Continual Improvement	41
8.5.2	Corrective Action	42
8.5.3	Preventive Action	45