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# QUALITY MANAGEMENT SYSTEM POLICIES AND PROCEDURES

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Abstract:

This handbook documents (your Company's) quality management system policies and procedures.

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Rev: Orig

#### **REVISION LOG**

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NOTE: Company policies herein are expressed from the perspective of "As-a-Matter-of-Fact". To apply this perspective, mentally add the phrase to the beginning of each paragraph herein. Delete this note prior to release of quality handbook. COPYRIGHT

### TABLE OF CONTENTS

Section	on 1:	Scope	5
Section	on 2:	Normative references	5
Section	on 3:	Terms and Definitions	5
Section	on 4:	Context of the Organization	5
4.1	Understan	ding the organization and its context	5
4.2	Understan	ding the needs and expectations of interested parties	5
4.3		ng the scope of the quality management system	5
		cable Provisions of the QMS	5
4.4		anagement system and its processes	5
Section	on 5:	Leadership	7
5.1	Landarchit	p and commitment	7
3.1	5.1.1	General	7
	5.1.2	Customer focus	7 7
5.2			7
	5.2.1	Developing the quality policy	7
	5.2.2	Communicating the quality policy	7
5.3	Organizati	ional roles, responsibilities and authorities	7
Section		Planning	7
6.1	Actions to	address risks and opportunities	7
	6.1.1	Planning for the OMS	7
	6.1.2	Planning requirements	8
6.2	Quality ob	ojectives and planning to achieve them	8
	6.2.1	Establishing quality objectives	8
	6.2.2	Achieving quality objectives	8
6.3	Planning o	of changes	8
Section		Support	8
7.1	Descurces		Q
7.1	7.1.1	General Genera	0
	7.1.2	People	8
	7.1.3	Infrastructure	9
	7.1.4	Environment for the operation of processes	9
	7.1.5	Monitoring and measuring resources	9
	7.1.5.1	General	9
	7.1.5.2	Measurement traceability	9
	7.1.6	Organizational knowledge	9
7.2	Competen	ce	9
7.3	Awareness	s	9
7.4	Communic	cation	10
7.5	Document	ed information	10
	231)	General	10
	7.5.2	Creating and updating	10
V	7.5.3	Control of documented information	10
	7.5.3.1	Documents required by QMS and International Standard	
	7.5.3.2	Activities for control of documented information	
Section	on 8:	Operation	10

CAGE: xxxxx

#### Your Company Name

#### QMS-00 Policies and Procedures

Rev: Orig

8.1	Organiz	zational planning and control		(
8.2	Require	ements for products and services	1	. 1
	8.2.1	Customer communication	1	L
	8.2.2	Determining the requirements related to products and services	. 0.	1
	8.2.3	Review of requirements related to products and services		L
	8.2.3.1	Ability to meet requirements		l:
	8.2.3.2	Retain documented information of review		l:
	8.2.4	Changes to requirements for products and services		l:
8.3	Design	and development of products and services		. 1
	8.3.1	General through 8.3.6 Design and development changes		l
8.4		l of externally provided processes, products and services		-
0	8.4.1	General		13
	8.4.2	Type and extent of control	. (1)	13
	8.4.3	Information for external providers		13
8.5		tion and service provision		-
0.0	8.5.1	tion and service provision		1
	8.5.2	Identification and traceability	. [7]	11
	8.5.3	Property belonging to Customers or external providers		Ľ
	8.5.4	Preservation		13
	8.5.5	Post-delivery activities		13
	8.5.6	Control of changes	0)	13
8.6				-
8.7		·	1	
0.7	8.7.1	Identify and control nonconforming outputs		_
	8.7.2	Retain documented information for nonconformities		11
C4:				_
Secti			I	Ī
9.1	Monito	ring, measurement, analysis and evaluation		3
	9.1.1			13
	9.1.2	Customer satisfaction		4
	9.1.3	Analysis and evaluation		14
9.2	Internal	l audit		_
	9.2.1	Conduct internal audits at planned intervals		4
	9.2.2	Audit requirements		4
9.3	Manage	ement review	1	4
	9.3.1	General		4
	9.3.2	Management review inputs		14
	9.3.3	Management review outputs		1.
Secti	on 10:	Improvement	1	5
10.1	Ger	neral	1	4
10.2		nconformity and corrective action	1	4
10.2	10.2.1	Required actions for nonconformities		
	10.2.2	Required records for nonconformities		
10.3		ntinyal improvement		
		Company Processes and Applicable ISO 9001 Clauses		
	_ \			
Appe	ndix B:	Company Processes and Applicable Documents	1	7
Appe	ndix C:	Outsourced Processes	1	8
Арре	ndix D:	Quality Objectives	1	8
		Identification of Key Realization Processes		
			1	-



QMS-00 Policies and Procedures

Rev: Orig

#### Section 1: Scope

CAGE: xxxxx

(Your Company's) quality management system (OMS) policies and procedures summarize top management's stategic view to improve the QMS, enhance Customer satisfaction and assure consistent delivery of products and services that achieve conformance with Customer and applicable statutory and regulatory requirements.

#### Normative references Section 2:

Documents that are referenced herein are indispensable and their title's are displayed in **Bold Italics**.

#### **Terms and Definitions** Section 3:

Unless otherwise noted, the Company applies the definitions of key terms according to 180 9001 and the QMS-16 Definitions and Abbreviations Procedure

#### **Context of the Organization** Section 4:

#### Understanding the organization and its context 4.1

The Company considers, monitors and reviews internal and external issues that affect its ability to achieve intended results according to the *QMS-04 Management Process Procedure*.

#### Understanding the needs and expectations of interested parties 4.2

The Company considers the needs and expectations of interested parties that affect its ability to achieve intended results according to the QMS-04 Management Process Procedure

#### 4.3 Determining the scope of the quality management system

The Company's quality management system applies to all employees within all functional areas of the business operation. The Company provides the following products and/or services:

Producer/Provider of [Your text]

NAICS code: [Your code(s)]

SIC code: [Your code(s)]

QMS policies and/or procedures outline responsibilities, methods, measurements and related performance indicators to ensure effective operation and control of the quality management system.

## Non-Applicable Provisions of the QMS

The Company cites no exclusions to the ISO 9001 standard. (list your exclusions to ISO 9001)

#### 4.4 Quality management system and its processes

The Company's quality management system is fully documented and implemented and is maintained as needed to meet the requirements of the Company's vision and governing policies.

The Company uses a process-oriented method of management, which emphasizes the importance of:



CAGE: xxxxx

Your Company Name

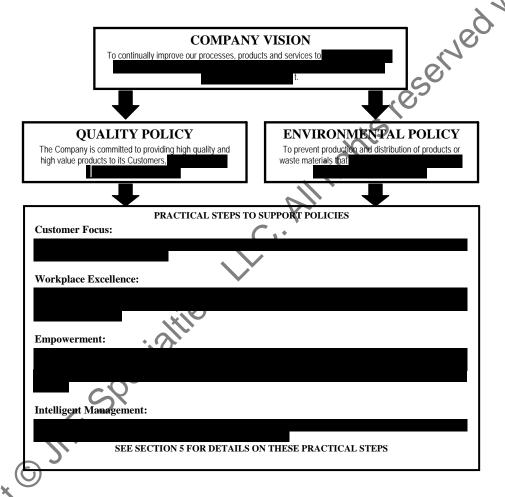
QMS-00 Policies and Procedures

Rev: Orig

During Management Review (see 9.3), process resources are discussed and allocated as applicable. Corrective action is taken to ensure processes achieve the desired results.

Every process has at least one QMS Procedure that defines it in greater detail that may include a process map. Process maps define the details of each process, which includes

The relationship between QMS procedures and their applicable *ISO 9001* clauses is shown in *Appendix A*. See *Appendix B* for applicable Company processes and documents. Outsourced processes and their controls are defined in *Appendix C*. See *Appendix E* for identification of key realization processes.



CAGE: xxxxx

Your Company Name

QMS-00 Policies and Procedures

Rev: Orig

## **Section 5:** Leadership

#### 5.1 Leadership and commitment

#### 5.1.1 General

The Company uses the quality management system to guide and validate its decisions and to

Management participation in the QMS is described in the QMS-04 Management Process

Procedure.

#### 5.1.2 Customer focus

The Company demonstrates leadership and commitment with respect to Customer focus by ensuring the maintenance and enhancement of Customer satisfaction through

#### 5.2 Policy

#### 5.2.1 Developing the quality policy

The Company's quality policy defines the purpose and context of the organization and its strategic direction, which includes a framework for

#### 5.2.2 Communicating the quality policy

The Company's quality policy is available to interested parties and is maintained as documented information that is

## 5.3 Organizational roles, responsibilities and authorities

Assignment of responsibilities and authorities for relevant roles are communicated and understood throughout the organization according to the *QMS-05 Responsibilities and Authorities Procedure* to ensure the quality management system conforms to the requirements of *ISO 9001*. Responsible authorities confirm processes are

#### **IMPORTANT:**

The quality management system is maintained at its authorized revision level until planned changes are implemented.

## Section 6 Planning

## 6.1 Actions to address risks and opportunities

#### 6.1.1 Planning for the QMS

Planning for the quality management system includes consideration of the context of the organization and the needs and expectations of interested parties. *QMS-04 Management Process Procedure* is used to address associated risks and

Your Company Name

QMS-00 Policies and Procedures

Rev: Orig

opportunities to achieve

CAGE: xxxxx

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#### 6.1.2 Planning requirements

Proportionate actions are taken to address risks and opportunities that could impact requirements that are applicable to products and services according to the QMS-13 Corrective Action Procedure. The Company integrates and implements these actions into quality management system processes (see 4.4) and evaluates their effectiveness. led m

#### 6.2 Quality objectives and planning to achieve them

#### 6.2.1 Establishing quality objectives

The Company establishes and maintains documented information for quality objectives a relevant functions, levels and processes according to the OMS-04 Management Process Procedure. Quality objectives are consistent with the quality policy and are

monitored, communicated and updated as required to enhance Customer satisfaction (see

#### 6.2.2 Achieving quality objectives

The Company determines how to achieve its quality objectives according to

#### 6.3 Planning of changes

Changes to the quality management system are performed according to the QMS-02 Configuration Management **Procedure**, which considers the purpose of changes and potential consequences and

## Support Section 7:

PROPRIETARY INFORMATION

#### 7.1 Resources

#### 7.1.1 General

The Company determines and provides the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system according to the QMS-04 Management Process Procedure, which considers

#### 7.1.2 Peop

The Company determines and provides the people necessary for the effective implementation of its quality management system and operation and control of its processes according to the OMS-04 Management Process Procedure and OMS-06 Training Procedure.



QMS-00 Policies and Procedures

Rev: Orig

#### 7.1.3 Infrastructure

CAGE: xxxxx

The Company determines, provides and maintains the infrastructure necessary for the operation of its processes to achieve according to the QMS-04 Management Process Procedure.

The Company determines, provides and maintains the environment necessary for the operation of its processes to a 7.1.5 Monitoring and measuring resources

7.1.5.1 General

The Company determines and provides resources needed to

7.1.5.2 **Measurement traceability** 

Measuring equipment is identified for traceability then calibrated and/or verified prior to use and safeguarded from according to the *QMS-15 Calibration Procedure*.

#### 7.1.6 Organizational knowledge

The Company determines, maintains, uses and internally shares knowledge that is required to operate its processes. The Company considers the need for

#### 7.2 Competence

The Company determines the necessary competence for Employees whose work affects the performance and effectiveness of the quality management system. The Company ensures Employee competence according to

the *OMS-04* 

Management Process Procedure, QMS-06 Training Procedure and QMS-01 Control of Documented Information Procedure.

#### 7.3 *Awareness*

The Company ensures Employees and Contractors are made aware of the Company's quality policy and applicable quality objectives. In addition, Employees and Contractors are made aware of their

according to the *QMS-06 Training Procedure*.



QMS-00 Policies and Procedures

Rev: Orig

#### 7.4 Communication

Internal and external communications relevant to the QMS are determined that includes

according to the

QMS-04 Management Process Procedure.

#### 7.5 Documented information

#### 7.5.1 General

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The Company's quality management system includes

#### 7.5.2 Creating and updating

During creation and update of documented information, the Company reviews and approves documents prior to release for

according to the *QMS*-

**02 Configuration Management Procedure**. In addition, the Company determines an appropriate document format, which may include

#### 7.5.3 Control of documented information

#### 7.5.3.1 Documents required by QMS and International Standard

The Company controls documented information

according to the *QMS-01 Control of* 

Documented Information Procedure.

#### 7.5.3.2 Activities for control of documented information

The Company controls the distribution, access, retrieval, use, storage, preservation, legibility, revision level, retention and disposition of documented information that is maintained as evidence of conformity to

## Section 8: Operation

## 8.1 Organizational planning and control

Processes that are used to achieve compliance with requirements for deliverable products and services are suitable for their purpose and are planned according to Section 6 herein. The Company applies *QMS-07 Proposal Development and Contract Review Procedure* to implement the processes and *QMS-02 Configuration Management Procedure* to approve processes and control changes. Consequences of unintended changes are

CAGE: xxxxx

Your Company Name

QMS-00 Policies and Procedures

Rev: Orig

#### 8.2 Requirements for products and services

#### 8.2.1 Customer communication

The Company communicates with its Customers by providing information relative to its products and services according to the *QMS-07 Proposal Development and Contract Review Procedure* and by obtaining

Additional

Customer communication channels include

according to the *QMS-10 Production Procedure*.

#### 8.2.2 Determining the requirements related to products and services

The Company ensures that it can meet the claims for products and services it offers and ensures requirements for products and services are defined, which includes

OMS-07 Proposal Development and Contract Review Procedure.

### 8.2.3 Review of requirements related to products and services

#### 8.2.3.1 Ability to meet requirements

The Company reviews Customer requirements according to the *QMS-07 Proposal Development and Contract Review Procedure* before accepting a contract, which includes

### 8.2.3.2 Retain documented information of review

The Company maintains a record for each review that includes new requirements for products and services.

## 8.2.4 Changes to requirements for products and services

When the requirements for products and services are changed, the Company

## 8.3 Design and development of products and services

## 8.3.1 General through 8.3.6 Design and development changes

The Company's design and development process ensures design activities are conducted in a controlled manner that is defined in the *QMS-17 Design and Development Procedure*, which includes policies for:

- 8.3.2 Design and development planning
- 8.3.3 Design and development inputs
- 8.3.4 Design and development controls
- 8.3.5 Design and development outputs
- 8.3.6 Design and development changes

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QMS-00 Policies and Procedures

Rev: Orig

Your Logo

CAGE: XXXXX

## 8.4 Control of externally provided processes, products and services

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8.4.1 General
The Company ensures that externally provided processes, products and services conform to requirements according to the
<b>QMS-08 Purchasing Procedure</b> and <b>QMS-09 Receiving Procedure</b> . The Company determines the controls to be applie to externally provided processes, products and services when
The Company determines and applies criteria for the evaluation, selection, monitoring of performance and re-evaluation
of external providers that is based upon according to
requirements and QMS-08 Purchasing Procedure. The Company retains documented information of these activities an
any necessary actions arising from the evaluations.
8.4.2 Type and extent of control
The Company ensures that externally provided processes, products and services do not adversely affect the Company
ability according to the QMS-08 Purchasing
Procedure and QMS-09 Receiving Procedure.
8.4.3 Information for external providers
The Company ensures that mandatory requirements are
according to the QMS-08 Purchasing Procedure.
8.5 Production and service provision
Significant and service provision
8.5.1 Control of production and service provision
The Company implements production and services under controlled conditions according to the QMS-04 Management
Process Procedure and QMS-10 Production Procedure.
8.5.2 Identification and traceability
The Company uses suitable means to identify outputs when
the <i>QMS-10 Production Procedure</i> . The Company controls the uniquidentification of outputs when
8.5.3 Property belonging to Customers or external providers
Property used by the Company or under its control that is received from outside sources is controlled according to th <i>QMS-10 Production Procedure</i> .
8.54 Preservation
The Company preserves production and service outputs to the extent necessary
according to the QMS-10 Production Procedure and QMS-11 Shipping Procedure.

Your	Logo
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Your Company Name QMS-00 Policies and Procedures

Rev: Orig

#### 8.5.5 Post-delivery activities

The Company meets requirements for post-delivery activities associated with the products and services according to the *QMS-05 Responsibilities and Authorities Procedure*.

#### 8.5.6 Control of changes

To ensure continuing conformity with requirements, the Company according to the *QMS-02 Configuration Management Procedure*, *QMS-10 Production Procedure* and *QMS-17 Design and Development Procedure*.

#### 8.6 Release of products and services

In-process inspections are conducted during production and service activities according to the *QMS-10 Production Procedure*. Products and services are released for delivery to Customers only after

## 8.7 Control of nonconforming outputs

### 8.7.1 Identify and control nonconforming outputs

The Company ensures outputs that do not conform to requirements are according to the *QMS-14 Control of Nonconformances Procedure*. The Company takes appropriate actions based on

#### 8.7.2 Retain documented information for nonconformities

Company records describe each nonconformance and include

## Section 9: Performance evaluation

#### 9.1 Monitoring, measurement, analysis and evaluation

#### 9.1.1 General

The Company's determines methods for monitoring, measurement, analysis and evaluation to

according to the *QMS*-

**04** Management Process Procedure, QMS-12 Internal Auditing Procedure and QMS-01 Control of Documented Information Procedure.

Your Company Name

QMS-00 Policies and Procedures

Rev: Orig

#### 9.1.2 Customer satisfaction

ined worldwide. To monitor and measure Customer satisfaction and fulfillment of expectations, the Company may collect information about:

The Company continuously monitors Customer satisfaction according to the *QMS-04 Management Process Procedure*.

#### 9.1.3 Analysis and evaluation

The Company evaluates Procedure.

according to the QMS-04 Management Process

#### 9.2 Internal audit

#### 9.2.1 Conduct internal audits at planned intervals

The Company conducts internal audits at planned intervals to provide information

according to the *QMS-12 Internal* 

Auditing Procedure.

## 9.2.2 Audit requirements

The Company assigns Responsible Authorities to

#### Management review 9.3

#### 9.3.1 General

Top management reviews the Company's quality management system at planned intervals to ensure

according to the QMS-04

Management Process Procedure.

## 9.3.2 Management review inputs

Management review is planned and carried out according to the QMS-04 Management Process Procedure, which takes into consideration

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QMS-00 Policies and Procedures

Rev: Orig

	9.3.3	Management	review	outputs
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Results from management reviews include

according to the QMS-04 Management Process

Procedure.

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## **Section 10: Improvement**

#### 10.1 General

The Company determines and selects

according to the QMS-04 Management Process

Procedure.

#### 10.2 Nonconformity and corrective action

#### 10.2.1 Required actions for nonconformities

When a nonconformance occurs, including

according to the QMS-13 Corrective Action

**Procedure** and **QMS-14 Nonconformance Control Procedure**. The Company evaluates the need for action to eliminate the cause of each nonconformance to prevent recurrence or occurrence somewhere else by

The Company ensures

corrective actions are appropriate to the effects of each nonconformance.

#### 10.2.2 Required records for nonconformities

The Company retains and maintains records regarding

actions according to the QMS-01 Control of Documented Information Procedure.

## 10.3 Continual improvement

The Company continually improves

according to the OMS-04 Management Process Procedure using

Rev: Orig

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## Appendix A: Company Processes and Applicable ISO 9001 Clauses

Process	Applicable ISO 9001 Clauses		
Configuration Management	See 8.3.1 for 8.3.6, 8.5.6 Design and Development Changes, Control of Changes (was		
Control of Documents	7.5.2, 7.5.3 Creating and Updating, Control of Documented Information (was		
Control of Records	7.5.2, 7.5.3 Creating and Updating, Control of Documented Information (was		
Control of Nonconformances	8.7 Control of Nonconforming Outputs (was		
Corrective Action	10.2 Nonconformity and Corrective Action (was 8.5.3		
Internal Auditing	9.2 Internal Audit (was )		
Management	4.4 Quality Management System and its Processes (was 7.5 Documented Information (was 5.1, 5.1.1 Leadership and Commitment, General (was 5.1, 2 Customer Focus (was 7.5 Documented Information (was 7.5 Documented Information (was 7.6 Documented Information (was 7.7 Documented Information (was 7.8 Documented Information (was 8.2 Documented Information (was 9.3 Organizational Roles, Responsibilities and Authorities (was 9.3 Organizational Roles, Responsibilities and Authorities (was 9.3 Management Review (was 9.3 Management Review (was 9.3 Management Review (was 9.1 Infrastructure (was 9.1.1 A Environment for the Operation of Processes (was 9.2.1 Customer Communication (was 9.3.1 for 8.3.6, 8.5.6 Design and Development Changes, Control of Changes (was 9.2.1 Customer Communication (was 9.3 In Measurement, Analysis & Improvement: General (was 9.1.1 Measurement, Analysis & Improvement: General (was 9.1.2 (was 9.1.3 Analysis and Evaluation (was 9.1.3 Continual Improvement (was 9.1.3 Analysis and Evaluation (was 9.1.4 Evaluation (was 9.1.5 Analysis and Evaluat		
Production	8.1 Operational Planning and Control (was 8.5.1, 8.5.5 Control of Production and Service Provision, Post Delivery Support (was 8.5.2 Identification & Traceability (was 8.5.3 Property Belonging to Customers or External Providers (was 7.5.4 8.5.4 Preservation (was 8.5.4 Preservation (was 8.6 Release of Products and Services (was 8.7 Control of Nonconforming Outputs (was 9.7 Control of Nonconforming Outputs (was		
Proposal Development & Contract Review	8.2.2 Determining the Requirements Related to Products and Services (was 8.2.3 Review of Requirements Related to Products and Services (was 7.2.2		
Purchasing	8.4.1, 8.4.2 General, Type and Extent of Control (was		
Receiving	8.4.3 Information for External Providers (was 8.6 Release of Products and Services (was 8.5.2 Identification & Traceability (was 8.5.3 Property Belonging to Customers or External Providers (was 8.5.4 Preservation (was 9 8.5 Release of Products and Services (was 8.7 Control of Nonconforming Outputs (was 9 8.7 Control of Nonconforming Outputs (was 9 8.7 Control of Nonconforming Outputs (was 9 8.8 Control of Nonconforming Outputs (was 9 8.9 Control of Nonconforming Outputs (was 9 8.9 Control of Nonconforming Outputs (was		
Shipping	8.2.2 Determining Requirements Related to Products and Services (was 8.5.1, 8.5.5 Control of Production and Service Provision, Post Delivery Support (was 8.5.2 Identification & Traceability (was 8.5.4 Preservation (was 8.7 Control of Nonconforming Outputs (was		

Rev: Orig

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**Appendix B: Company Processes and Applicable Documents** 

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Process	Applicable Company Procedures	Applicable Company Records
Corrective Action	QMS-13 Corrective Action	Corrective action records 10.2 (was
Design & Development	QMS-17 Design & Development	Realization processes and resulting product meet requirements 8.1 (was possible of the product meet)  Design and development planning 8.3.2 (was possible of the possible of t
Internal Auditing	QMS-12 Internal Auditing	Internal audits 9.2 (was 8.2.2)
Management	QMS-00 Quality Handbook QMS-01 Control of Documented Info QMS-02 Configuration Management QMS-04 Management Process Procedure QMS-05 Responsibilities & Authorities QMS-06 Training QMS-15 Calibration QMS-16 Definitions and Abbreviation	Management review minutes 9.3.1 (was Training records 7.2, 7.3 (was Calibration records 7.1.5
Production	QMS-10 Production QMS-14 Control of Nonconformances	Traceability records (if required) 8.5.2 (was Records of loss, damage or nonconformances 8.5.3 (was Records of release authority of inspected product 8.6 (was Records of first article inspection 8.6 (was Control of nonconformances 8.7 (was
Proposal Development &	QMS-07 Proposal Development &	Contract review records 8.2.3 (was
Contract Review	Contract Review	
Purchasing	QMS-08 Purchasing	Supplier evaluation records 8.4.1, 8.4.2 (was
Receiving	QMS-09 Receiving QMS-14 Control of Nonconformances	Records of loss, damage or nonconformances 8.5.3 (was Control of nonconformances 8.7 (was Control of n
Shipping	QMS-11 Shipping QMS-14 Control of Nonconformances	Records of loss, damage or nonconformances 8.5.3 (was Control of nonconformances 8.7 (was

Rev: Orig

## **Appendix C: Outsourced Processes**

The following processes are outsourced and controlled as indicated:



**Appendix D: Quality Objectives** 

Process	Quality Objective	Metric	
Corrective Action			
Design & Development			
Internal Auditing			
Management			
Production			
Proposal Development & Contract Review			
Purchasing			
Receiving			
Shipping			

Rev: Orig

## **Appendix E: Identification of Key Realization Processes**

