

Your Logo

REDACTED

Your Company Name

Add to Cart

SOFTWARE QUALITY HANDBOOK

Origination Date: XXXX

Document Identifier:	QMS-00 Software Quality Handbook
Date:	Latest Revision Date
Document Status:	Draft, Redline, Released, Obsolete
Document Link:	Location on Server (if used)

Abstract:

This document describes the software quality management system policies and procedures that achieve conformance with aerospace standard *ISO 9001* and *ISO 9003*.

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

REVISION LOG

Issue	Date	Comment	Author
Orig			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

Copyright © JnF Specialties, LLC. All rights reserved worldwide.

<h1>Your Logo</h1>	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

TABLE OF CONTENTS

Section 1:	Scope	5
Section 2:	Normative References	5
Section 3:	Terms and Definitions	5
Section 4:	Context of the Organization	5
4.1	Understanding the organization and its context	5
4.2	Understanding the needs and expectations of interested parties	5
4.3	Determining the scope of the quality management system	5
4.3.1	Non-Applicable provisions of the QMS	5
4.4	Quality management system and its processes	6
4.4.1	Vision and governing policies	7
4.4.2	Overview of documentation	8
4.4.3	Overall process sequence and interaction	9
Section 5:	Leadership	9
5.1	Leadership and commitment	9
5.1.1	General	9
5.1.2	Customer focus	9
5.2	Policy	10
5.2.1	Establishing the quality policy	10
5.2.2	Communicating the quality policy	10
5.3	Organizational roles, responsibilities and authorities	10
5.3.1	Organization chart	10
Section 6:	Planning	11
6.1	Actions to address risks and opportunities	11
6.1.1	Planning for the QMS	11
6.1.2	Planning requirements	11
6.2	Quality objectives and planning to achieve them	11
6.2.1	Establishing quality objectives	11
6.2.2	Achieving quality objectives	11
6.3	Planning of changes	12
Section 7:	Support	12
7.1	Resources	12
7.1.1	General	12
7.1.2	People	12
7.1.3	Infrastructure	12
7.1.4	Environment for the operation of processes	13
7.1.5	Monitoring and measuring resources	13
7.1.5.1	General	13
7.1.5.2	Measurement traceability	13
7.1.6	Organizational knowledge	13
7.2	Competence	14
7.3	Awareness	14
7.4	Communication	14
7.5	Documented information	14
7.5.1	General	14
7.5.2	Creating and updating	14
7.5.3	Control of documented information	15
7.5.3.1	Documents required by QMS and international standard	15
7.5.3.2	Activities for control of documented information	15
Section 8:	Operation	15
8.1	Organizational planning and control	15
8.1.5	Software Life Cycle	16
8.1.6	Software Quality Planning	16
8.2	Requirements for products and services	17
8.2.1	Customer communication	17
8.2.2	Determining the requirements related to products and services	18
8.2.2.1	Customer-Related Software Requirements	18
8.2.3	Review of requirements related to products and services	18
8.2.3.1	Ability to meet requirements	18

<h1>Your Logo</h1>	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

8.2.3.2	Retain documented information of review	18
8.2.3.2.1	Organization Concerns	19
8.2.3.2.2	Risks	19
8.2.3.2.3	Customer Representative	20
8.2.4	Changes to requirements for products and services	20
8.3	Design and development of products and services	20
8.3.1	General through 8.3.6 design and development changes	20
8.3.2	Design and development planning	20
8.3.3	Design and Development Inputs	21
8.3.4	Design and Development Outputs	22
8.3.5	Design and Development Review	22
8.3.6	Design and development verification	23
8.3.7	Design and development validation	23
8.3.8	Control of design and development changes	24
8.4	Control of externally provided processes, products and services	24
8.4.1	General	24
8.4.1.1	External provider abilities	24
8.4.2	Type and extent of control	25
8.4.3	Information for external providers	25
8.5	Production and service provision	26
8.5.1	Control of production and service provision	26
8.5.2	Identification and traceability	26
8.5.3	Property belonging to Customers or external providers	27
8.5.4	Preservation	28
8.5.5	Post-delivery activities	28
8.5.6	Control of changes	29
8.6	Release of products and services	29
8.7	Control of nonconforming outputs	30
8.7.1	Identify and control nonconforming outputs	30
8.7.2	Retain documented information for nonconformities	31
Section 9:	Performance Evaluation	31
9.1	Monitoring, measurement, analysis and evaluation	31
9.1.1	General	31
9.1.2	Customer satisfaction	31
9.1.3	Analysis and evaluation	32
9.2	Internal audit	32
9.2.1	Conduct internal audits at planned intervals	32
9.2.2	Audit requirements	32
9.3	Management review	32
9.3.1	General	32
9.3.2	Management review inputs	32
9.3.3	Management review outputs	33
Section 10:	Improvement	33
10.1	General	33
10.2	Nonconformity and corrective action	33
10.2.1	Required actions for nonconformities	33
10.2.2	Required records for nonconformities	33
10.3	Continual improvement	33
Appendix A:	Company Processes and Applicable <i>ISO 9001</i> Clauses	34
Appendix B:	Company Processes and Applicable Documents	35
Appendix C:	Outsourced Processes	36
Appendix D:	Quality Objectives	36
Appendix E:	Identification of Key Realization Processes	37

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

Section 1: Scope

(Your Company's) quality management system (QMS) policies and procedures summarize top management's 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.

Section 2: Normative References

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

Section 3: Terms and Definitions

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

Section 4: Context of the Organization

4.1 Understanding the organization and its context

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

4.2 Understanding the needs and expectations of interested parties

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.

4.3.1 Non-Applicable provisions of the QMS

The Company cites no exclusions to the *ISO 9001* standard or *ISO 90003*. (or list your exclusions to ISO 9001)

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

4.4 Quality management system and its processes

The Company has developed a quality system for software products and related services that includes identification of processes that make up the approach to software development, software development planning, software quality planning, software operation and software maintenance. 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:

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

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.

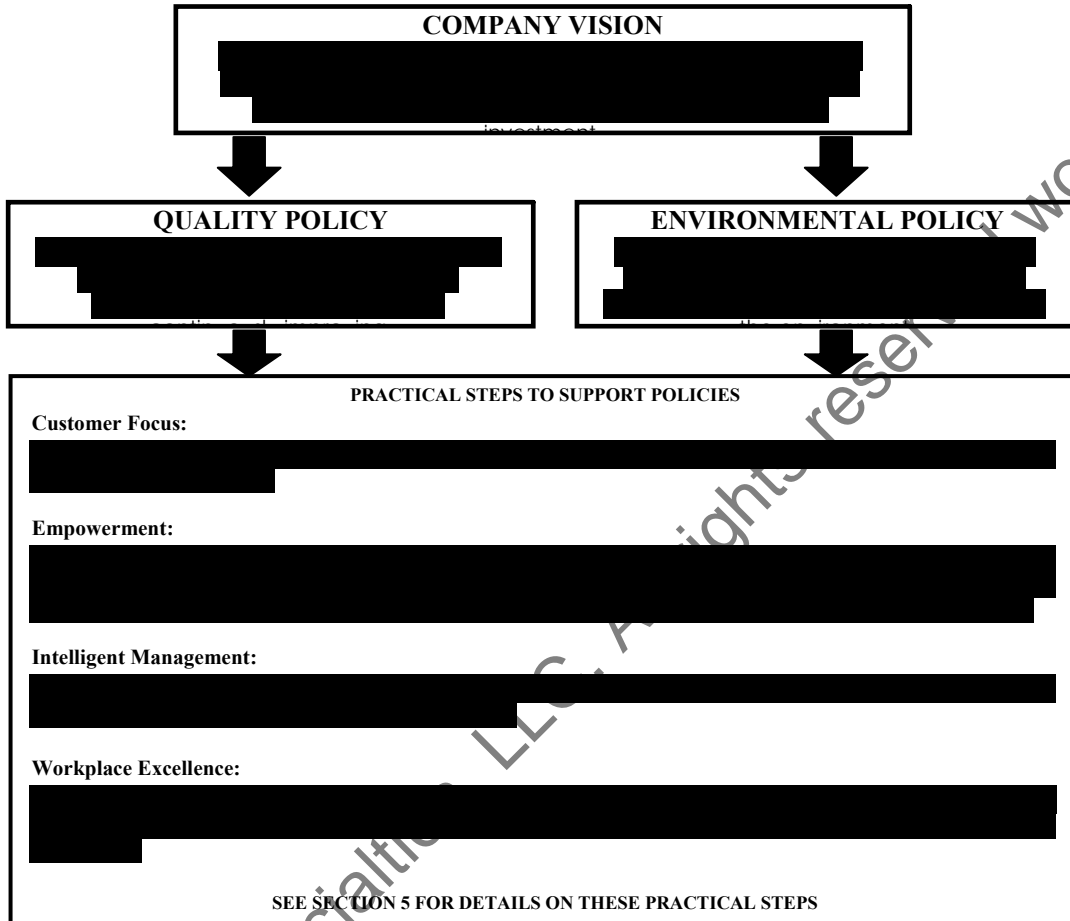
Process maps define the details of each process, which includes [REDACTED]

[REDACTED] 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.

Left blank intentionally

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

4.4.1 Vision and governing policies

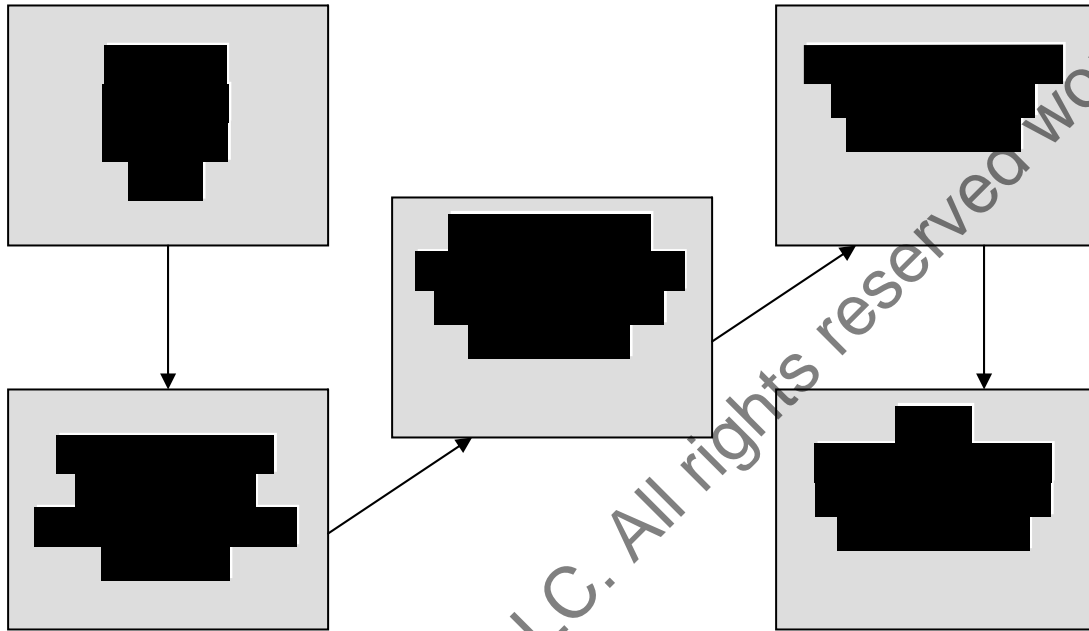


Left blank intentionally

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

4.4.2 Overview of documentation

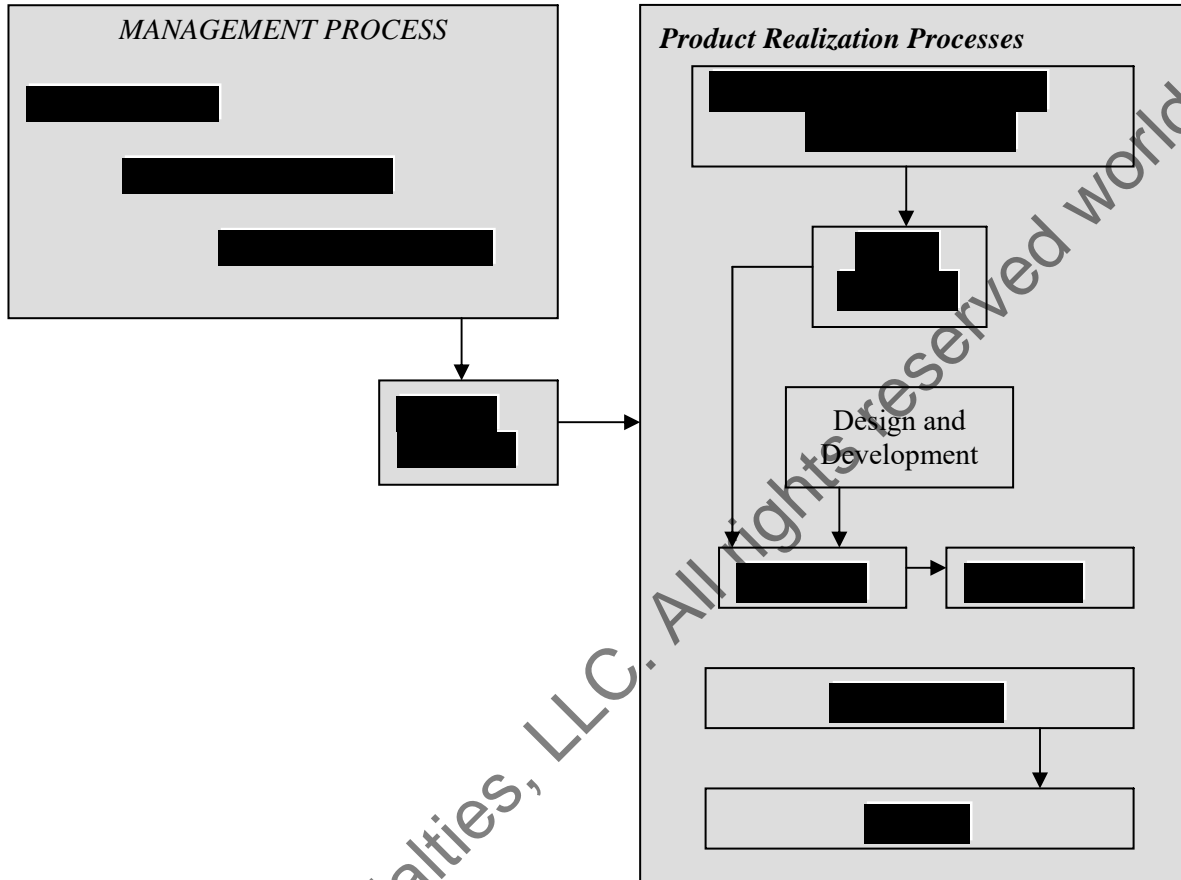
The quality system documentation is comprised of a hierarchy of documents that flow from this Quality Handbook.



Left blank intentionally

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

4.4.3 Overall process sequence and interaction



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 [REDACTED] 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 consistent determination and understanding of Customer and applicable statutory and regulatory requirements. Management pays particular attention to [REDACTED]

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

5.2 Policy

5.2.1 Establishing the quality policy

The Company's quality policy defines the purpose and context of the organization and its strategic direction, which includes [REDACTED]

5.2.2 Communicating the quality policy

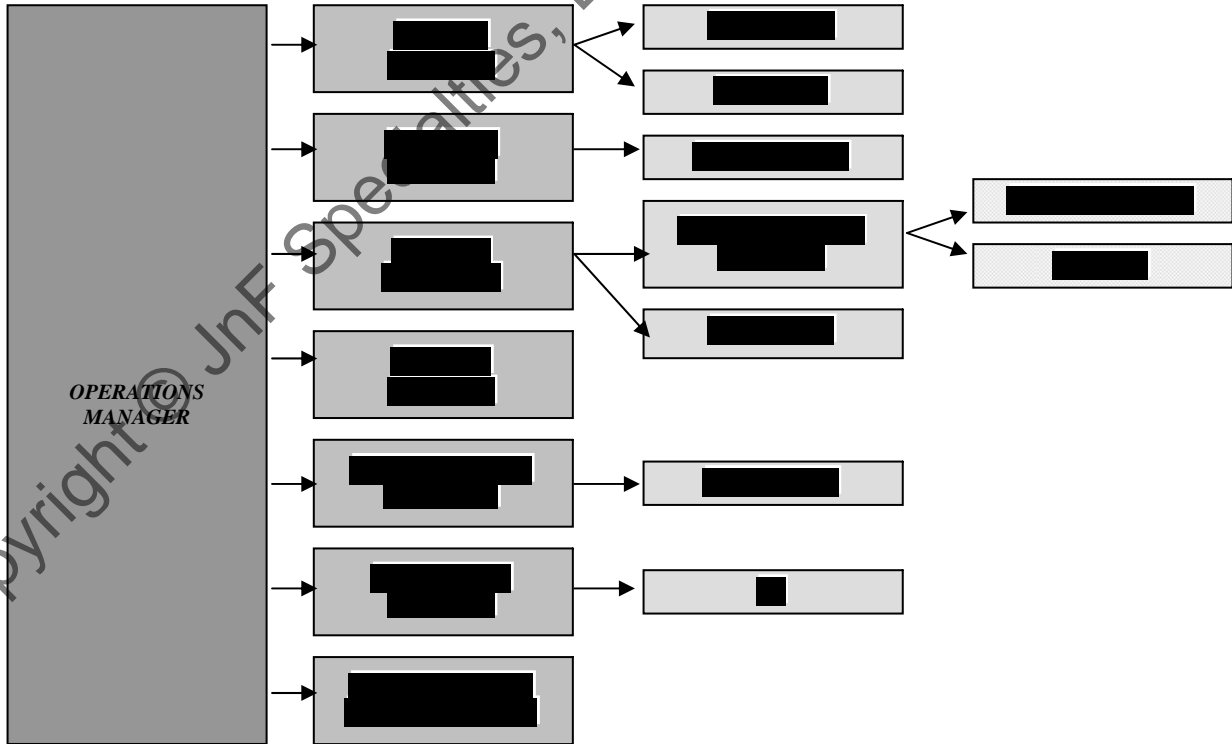
The Company's quality policy is available to interested parties and is maintained as documented information that is communicated, understood and applied throughout the organization.

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 [REDACTED]

[REDACTED] Responsible authorities confirm processes are [REDACTED]

5.3.1 Organization chart



Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

Section 6: Planning

The Company defines appropriate software life cycle models to determine the development of requirements documents, architectural design documents, detailed design documents, program code and software user documentation. In addition, the Company defines [REDACTED]

The Company defines [REDACTED]

The responsible authority for software development considers [REDACTED]

6.1 Actions to address risks and opportunities

6.1.1 Planning for the QMS

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.

6.1.2 Planning requirements

The Company determines the effectivity of actions taken to establish process controls that integrate and implement actions into the Quality Management System (see 4.4) according to [REDACTED]

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 at relevant functions, levels and processes according to the **QMS-04 Management Process Procedure**. Quality objectives are [REDACTED]

6.2.2 Achieving quality objectives

The Company determines how to achieve its quality objectives according to [REDACTED]

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

6.3 Planning of changes

Changes to the quality management system are performed according to the **QMS-02 Configuration Management Procedure**, which considers [REDACTED]

IMPORTANT:

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

Section 7: Support

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 [REDACTED]

7.1.2 People

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 **QMS-04 Management Process Procedure** and **QMS-06 Training Procedure**.

7.1.3 Infrastructure

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

Hardware, software, tools and facilities for development, operation or maintenance of software and software tools that support the design and development process include:

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

Tools and techniques that are purchased or developed internally are evaluated for fitness for their designated purpose. Prior to use, the Company [REDACTED]

7.1.4 Environment for the operation of processes

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

7.1.5 Monitoring and measuring resources

7.1.5.1 General

The Company determines and provides resources needed to ensure valid and reliable results according to the **QMS-04 Management Process Procedure**. Resources are suitable for the specific type of monitoring and measurement activities being undertaken according to the **QMS-10 Manufacturing Procedure**, and are maintained to ensure [REDACTED]

[REDACTED] Appropriate documented information is retained and maintained according to the **QMS-01 Control of Documented Information Procedure** as evidence of "fitness for purpose" for monitoring and measurement resources.

The Company considers the effect of tools, facilities and techniques on the quality of the software product when approving the conduct of any tests that verify the conformance of the software product to specified requirements; in addition, [REDACTED]

[REDACTED] The Company has developed procedures for determining how the test software is checked. Measuring and monitoring devices used in software development, testing, maintenance and operation include:

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

7.1.5.2 Measurement traceability

Measuring equipment is identified for traceability then calibrated and/or verified prior to first use, and safeguarded from adjustments, deterioration or damage 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 [REDACTED]

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

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 affirms Employee competence according to [REDACTED]

[REDACTED] The Company evaluates the effectiveness of additional training and maintains records as evidence of competence according to the **QMS-04 Management Process Procedure**, **QMS-06 Training Procedure** and **QMS-01 Control of Documented Information Procedure**.

Software training needs consider [REDACTED]

[REDACTED] Technologies employed in software development, operation and maintenance are [REDACTED]

7.3 Awareness

The Company affirms 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 contribution to the effectiveness of the quality management system (QMS) and their influence on improving QMS performance, and the consequences of noncompliance with QMS requirements according to the **QMS-06 Training Procedure**.

7.4 Communication

Internal and external communications that are relevant to the QMS are determined, which includes [REDACTED] according to the **QMS-04 Management Process Procedure**.

7.5 Documented information

7.5.1 General

The Company's quality management system includes [REDACTED]

The Company has developed documents for the effective planning, operation, and control of processes for software that describe life cycle models such as [REDACTED]

7.5.2 Creating and updating

During creation and update of documented information, the Company reviews and approves documents prior to release for [REDACTED] according to the **QMS-02 Configuration Management Procedure**. In addition, [REDACTED]

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

7.5.3 Control of documented information

7.5.3.1 Documents required by QMS and international standard

Documents are controlled so that the information on them is accessible, legible and suitably maintained. Documents are reviewed and approved prior to release and only the latest versions are available to users. Previous versions are stamped [REDACTED]. For details, see **QMS-01 Control of Documented Information Procedure** and **QMS-02 Configuration Management Procedure**.

7.5.3.2 Activities for control of documented information

The Company controls the content, change disposition, revision level, access, use, retention, distribution and retrieval, preservation of legibility and storage of documented information that is maintained as evidence of conformity to prevent unintended alterations according to the **QMS-01 Control of Documented Information Procedure**. Superseded and/or obsolete documents may be used by direction of the Responsible Authority using a **Bulletin or EO** [REDACTED] according to the **QMS-02 Configuration Management Procedure**. Management provides guidelines for managing electronic data processes according to the **QMS-04 Management Process Procedure**.

Records are controlled to provide evidence of conformity to requirements that include [REDACTED]

Records are controlled to provide evidence of the effective operation of the quality management system that include [REDACTED]

Where records are held on electronic media, consideration of the retention times and accessibility of the records takes into account [REDACTED]. Records are protected from computer viruses and unapproved or illegal access. Records include information held in email systems.

The Company assesses the method for erasure of electronic records at the end of their required retention period according to their proprietary nature.

The records subject to control are defined in the **QMS-03 Control of Documented Information Procedure**.

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.

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

The Company applies the **QMS-07 Proposal Development and Contract Review Procedure** to engage Responsible Authorities and determine requirements for products and services, required resources, and controls for critical items and key characteristics. The creation, review and approval of the **Work Order** during proposal development and contract review affirms [REDACTED]

The **QMS-02 Configuration Management Procedure** is used to approve processes and control changes. Consequences of unintended changes are [REDACTED]

Suppliers used for outsourced processes are approved according to 8.4 herein and the **QMS-08 Purchasing Procedure**.

8.1.5 Software Life Cycle

The Company plans and performs the processes, activities and tasks for software development using life cycle models that are suitable for each software project, which considers [REDACTED]

The Company determines the methods and tools that are suitable for the design and development method according to [REDACTED]

The Company determines how specific products are to be developed, assessed or maintained.

8.1.6 Software Quality Planning

Software quality planning includes:

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

The Company uses quality planning to clarify quality objectives for software being designed for a limited purpose such as [REDACTED]

The Company tests limited-purpose software to reduce the possible occurrence of unintended omissions and errors.

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 [REDACTED]

[REDACTED] according to the **QMS-04 Management Process Procedure**. Additional Customer communication channels include [REDACTED]

Customer Communication during Development

Joint reviews involving the Company and Customer are scheduled on a regular basis or at significant project events, which include as appropriate:

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

Customer Communication during Operations and Maintenance

Sources of information that involve Customer communication in operations and maintenance include the following:

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

8.2.2 Determining the requirements related to products and services

The Company determines it can meet the claims for products and services it offers and affirms operational risks and special requirements for products and services are defined, which includes [REDACTED] according to the **QMS-07 Proposal Development and Contract Review Procedure**.

8.2.2.1 Customer-Related Software Requirements

Specific actions used to determine Customer requirements include:

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

The Company expresses requirements in clear and unambiguous terms that facilitate validation throughout the development life cycle and during product acceptance.

When a system specification is applied, the Company applies methods to allocate requirements into hardware and software items with appropriate interface specifications. Configuration controls or contract amendments are used when [REDACTED]

8.2.3 Review of requirements related to products and services

8.2.3.1 Ability to meet requirements

Applicable functions within the Company review Customer requirements according to the **QMS-07 Proposal Development and Contract Review Procedure** before accepting a contract, which includes resolving requirements that differ from previous orders.

The Company pays particular attention to review of requirements that are not stated by the Customer but are necessary for performance of the product or service. The Company reviews [REDACTED]

The Company confirms mutually acceptable requirements are stated in the contract before acceptance when [REDACTED]

8.2.3.2 Retain documented information of review

The Company establishes and maintains a record for each contract review that includes [REDACTED]

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

8.2.3.2.3 Customer Representative

The Customer representative has the following authorities:

- [Redacted]
- [Redacted]

8.2.4 Changes to requirements for products and services

When the requirements for products and services are changed, the Company affirms Responsible Authorities are aware of changes and applicable configuration controlled documents are revised according to the **QMS-02 Configuration Management Procedure**.

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 is conducted in a controlled manner according to [Redacted]

8.3.2 Design and development planning

The Company performs design and development planning to prevent or minimize the occurrence of problems to reduce [Redacted]

The Company ensures that software products are [Redacted]

Design and development planning addresses the following items, as appropriate:

- [Redacted]
- [Redacted]
- identification of:
 - [Redacted]
 - [Redacted]
 - [Redacted]
 - [Redacted]
 - [Redacted]
 - [Redacted]
 - [Redacted]
 - [Redacted]
 - [Redacted]
 - [Redacted]
- [Redacted]

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

- [REDACTED]
- [REDACTED]
- requirements analysis, design and development, coding, integration, testing, installation and support for acceptance of software products, which includes the identification or reference to:
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
- schedule that identifies:
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]

For a COTS product where the Company does not have control over the design, the Company [REDACTED]

8.3.2.2 Review, Verification and Validation

Software operations and maintenance may be covered in service level agreements or maintenance procedures.

8.3.2.3 Responsibilities and Authorities

[REDACTED]

8.3.2.4 Interfaces

The boundaries of responsibility for each part of the software product and the way that technical information will be transmitted between all parties is [REDACTED]

[REDACTED]

which may include [REDACTED]

End-users and [REDACTED]

any intermediate operation function are involved to ensure [REDACTED]

8.3.3 Design and Development Inputs

The Company allocates requirements for hardware, software components and manual operations to system architectural design. Inputs to software requirements analysis are the

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

system requirements allocated to software and specifications of the interfaces between the system components. Design and development input is determined from [REDACTED]

[REDACTED] Other design and development inputs are determined from [REDACTED]

The Company reviews design and development input documents for:

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

8.3.4 Design and Development Outputs

Outputs from the design and development process are defined and documented according to [REDACTED]

[REDACTED] Design and development outputs may be expressed in textual form by diagrams or using symbolic modeling notation and may include:

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

The Company prepares design and development (output) documentation for prototyping when used. The acceptance criteria for design and development outputs are defined to [REDACTED]

[REDACTED]

8.3.5 Design and Development Review

The degree of formality and rigor of the activities associated with the review processes is appropriate for the complexity of the product, applicable quality requirements and the degree of risk associated with the specified use of the software product. The Company has established procedures for disposition of process and product deficiencies or nonconformities that are identified during design review(s).

The Company determines criteria for design and development reviews that include criteria for feasibility, security, safety, programming rules and testability. Review of design and development is performed according to planned arrangements. Elements of the review include:

- [REDACTED]

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

The Company determines additional design and development activities only when [Redacted]

8.3.6 Design and development verification

Software verification confirms that the output of design and development activities conforms to [Redacted]

[Redacted] Verification is also conducted on the output from other activities, e.g. [Redacted] The verification results and any subsequent actions are recorded and checked upon completion of the actions. Specific assurance methods are used for [Redacted]

8.3.7 Design and development validation

8.3.7.1 Validation

Prior to final acceptance, the Company validates the operation of software according to [Redacted]

Configuration audits or evaluations are performed to confirm that software complies with its contractual or specified requirements, which may require [Redacted]

8.3.7.2 Testing

Test planning addresses [Redacted] Test planning defines [Redacted] Specific testing for software includes [Redacted] implementing plans for the following:

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

Regression testing is performed to verify or validate that the capabilities of the software have not been compromised by a change. Acceptance tests are performed for the Customer's benefit with the aim of [REDACTED]

Testing procedures provide recording and analysis of results as well as [REDACTED]

8.3.8 Control of design and development changes

Changes to a software specification or component considers [REDACTED]

8.4 Control of externally provided processes, products and services

8.4.1 General

The Company affirms externally provided processes, products and services conform to requirements according to the **QMS-08 Purchasing Procedure** and **QMS-09 Receiving Procedure**. The Company determines the controls to be applied to externally provided processes, products and services when [REDACTED]

[REDACTED] external providers are intended for incorporation into the Company's own products and services.

8.4.1.1 External provider abilities

The Company determines and applies criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers that is based upon [REDACTED]

8.4.1.2 Purchased Products

Free software is considered purchased product, e.g., open source development tools.

In developing, supplying, installing and maintaining software products, types of purchased products may include:

- [REDACTED]
- [REDACTED]

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

The Company manages the risks associated with [Redacted]

8.4.1.3 Purchased Product Control

Purchased software used in deliverable products is configuration controlled throughout design and development. Care is taken to ensure [Redacted]

[Redacted]

Suppliers are selected based upon [Redacted]

8.4.2 Type and extent of control

The Company affirms externally provided processes, products and services do not adversely affect the Company's ability to consistently deliver conforming products and services to its Customers according to the **QMS-08 Purchasing Procedure** and **QMS-09 Receiving Procedure**.

8.4.3 Information for external providers

The Company affirms mandatory requirements are adequately documented prior to communicating with Suppliers according to the **QMS-08 Purchasing Procedure**.

8.4.3.1 Purchasing Information

Purchasing information for software may include, where applicable:

- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

- [Redacted]

8.5 Production 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 Manufacturing Procedure**.

The Company considers processes that may be used to compensate for the inability to fully validate a software product, which include:

- [Redacted]
- [Redacted]

Methods are commensurate with the risks and consequences of design and development failures.

8.5.1.1 Control of production equipment, tools and software programs

Software replication activities include:

- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

8.5.1.2 Validation and Control of Special Processes

See **QMS-04 Management Process Procedure** and **QMS-10 Manufacturing Procedure**.

8.5.1.3 Production and service provisions for software products include:

- [Redacted]
- [Redacted]
- [Redacted]

8.5.2 Identification and traceability

The Company uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services, and identifies the status of outputs with respect to

[Redacted]

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

8.5.2.1 Overview

For software, identification and traceability is implemented through configuration management, which includes [REDACTED]

8.5.2.2 Configuration management process

The scope of configuration management includes:

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

8.5.2.3 Traceability

The Company maintains a process to trace the components of the software item or product throughout the life cycle.

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 the **QMS-10 Production Procedure**.

Customer property may include:

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

The Company prepares maintenance agreements that address required licensing and support including [REDACTED]

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

[REDACTED] Customer-supplied products are treated as purchased products, which includes [REDACTED]

8.5.4 Preservation

The Company preserves production and service outputs to ensure conformity to requirements according to the **QMS-10 Manufacturing Procedure** and **QMS-11 Shipping Procedure**.

The Company ensures that its products are not altered from the point of production, through replication, handling and storage, to the point of delivery. The Company takes appropriate precautions to store software information on media that does not degrade. Delivery provides for [REDACTED]

[REDACTED] The Company considers the following actions when handling, packaging, storing or delivering software:

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

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**.

8.5.5.1 Control of Service Operations and Software Installation

The Company services supplies returned to it for warranty work or repair - field servicing is (is not) performed. For such product work, all normal processes and procedures apply as if the supply were a new manufacture.

The following considerations are made when the Company is responsible for installation of software:

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

8.5.5.2 Operations

The Company plans and controls operations that include [Redacted]

8.5.5.3 Maintenance

The Company has established a process for performing maintenance and verification activities. Maintenance activities include the development environment, tools and documentation. The Company stipulates requirements in the contract for maintenance of software products for a specific period of time after initial delivery and installation. Maintenance activities may include:

- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

Records of the maintenance activities are utilized for evaluation and enhancement of the software product and for improvement of the quality management system. When resolving problems, temporary fixes may [Redacted]

8.5.6 Control of changes

To ensure continuing conformity with requirements, the Company reviews and controls changes to its production and service activities according to the **QMS-02 Configuration Management Procedure**, **QMS-10 Manufacturing 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 to ensure ongoing quality of work according to the **QMS-10 Manufacturing Procedure**. Products and services are

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

released for delivery to Customers only after [REDACTED]
[REDACTED] The Company retains and maintains records for the release of products and services that includes [REDACTED]
[REDACTED]

8.6.1 Verification of Purchased Product

The Company determines the methods of verification, validation and acceptance of subcontracted work when software development is subcontracted or when purchasing associated hardware and software. The Company conducts acceptance testing and ensures the availability of adequate support when [REDACTED]
[REDACTED]

The product is also validated against the needs of the final product it is required to satisfy. Appropriate measures are in place to segregate purchased product until its integrity can be determined (e.g. virus infections).

8.7 Control of nonconforming outputs

8.7.1 Identify and control nonconforming outputs

The Company affirms outputs that do not conform to requirements are identified and controlled to prevent their unintended use or delivery according to the **QMS-14 Control of Nonconformities Procedure**. The Company takes appropriate actions based on [REDACTED]
[REDACTED]

Nonconformances are corrected then reverified to confirm outputs are in compliance with requirements. When appropriate, the Company [REDACTED]
[REDACTED]

The Company segregates nonconforming items by transferring them out of a production or testing environment into a separate environment or [REDACTED]
[REDACTED]

The Company identifies the investigation and resolution of defects and the control and recording of nonconforming product when a software item [REDACTED]
[REDACTED]

The Company considers the following during disposition of nonconformities:

- [REDACTED]
- [REDACTED]

The Company updates the software version when repair or rework is used to achieve fulfillment of specified requirements. Disposition of nonconforming software product may include:

- acceptance with or without repair by concession,

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

- [REDACTED]
- [REDACTED]
- [REDACTED]

8.7.2 Retain documented information for nonconformities

Records used to disposition nonconformities clearly describe each nonconformance and includes actions taken, identification of Responsible Authorities, and Customer approval when applicable according to the **QMS-14 Control of Nonconformities Procedure**. The Company retains and maintains records according to the **QMS-01 Control of Documented Information Procedure**.

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 ensure [REDACTED]

In addition, the Company evaluates the performance and effectiveness of the quality management system and retains appropriate records according to the **QMS-04 Management Process Procedure**, **QMS-12 Internal Auditing Procedure** and **QMS-01 Control of Documented Information Procedure**.

The software measurement process is used to collect, analyze and report data relating to the products developed and processes implemented to support [REDACTED]

Software measurements include:

- [REDACTED]
- [REDACTED]
- [REDACTED]

9.1.2 Customer satisfaction

To monitor and measure Customer satisfaction and fulfillment of expectations, the Company collects information about: [REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

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

The Company's process for requesting, measuring and monitoring feedback of Customer satisfaction includes:

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

9.1.3 Analysis and evaluation

The Company evaluates metrics, goals and performance measurements according to the **QMS-04 Management Process Procedure**.

Analysis of data for software includes [REDACTED]

9.2 Internal audit

Audit planning assesses both the compliance of project quality planning to the Company's quality management system and the compliance of the project to project quality planning to ensure [REDACTED]

9.2.1 Conduct internal audits at planned intervals

The Company conducts internal audits at planned intervals to provide information on whether the quality management system conforms to requirements and is effectively implemented and maintained according to the **QMS-12 Internal Auditing Procedure** and **QMS-04 Management Process Procedure**.

9.2.2 Audit requirements

The Company assigns Responsible Authorities to perform internal audits and report audit results to management according to the **QMS-12 Internal Auditing Procedure**.

9.3 Management review

9.3.1 General

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

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 [REDACTED]

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

9.3.3 Management review outputs

Results from management reviews include [REDACTED]

Section 10: Improvement

10.1 General

The Company determines and selects opportunities for improvement according to the **QMS-04 Management Process Procedure**.

10.2 Nonconformity and corrective action

10.2.1 Required actions for nonconformities

When nonconformity occurs in products and processes, including complaints, the Company

[REDACTED]

The Company:

- [REDACTED]
- [REDACTED]
- [REDACTED]

The Company may use configuration management to control corrective actions that directly affect software products. Management reviews corrective actions that involve [REDACTED]

10.2.2 Required records for nonconformities

The Company retains and maintains records regarding the nature of nonconformances, subsequent actions and results of corrective actions according to the **QMS-14 Control of Nonconformities Procedure** and **QMS-01 Control of Documented Information Procedure**.

10.3 Continual improvement

The Company continually improves [REDACTED]

Process improvements for software may be applied to [REDACTED]

Left blank intentionally

<h1>Your Logo</h1>	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

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 7.3.7 Control of changes)
Control of Documented Information	7.5.2, 7.5.3 Creating and Updating, Control of Documented Information (was 4.2.3 Control of documents and 4.2.4 Control of records)
Control of Nonconformances	8.7 Control of Nonconforming Outputs (was 8.3 Control of nonconformances)
Corrective Action	10.2 Nonconformity and Corrective Action (was 8.5.3 Preventive action)
Internal Auditing	9.2 Internal Audit (was 8.2.2)
Management	4.4 Quality Management System and its Processes (was 4.1 QMS general requirements) 7.5 Documented Information (was 4.2 Documentation requirements) 5.1, 5.1.1 Leadership and Commitment, General (was 5.1 Management commitment) 5.1.2 Customer Focus (was 5.2) 5.2, 5.2.1, 5.2.2 Policy, Establishing the Quality Policy, Communicating the Quality Policy (was 5.3 Quality policy) 6.0 Planning (was 5.4) 5.3 Organizational Roles, Responsibilities and Authorities (was 5.5.1 Responsibility and authority) 5.3 Organizational Roles, Responsibilities and Authorities (was 5.5.2 Management representative) 7.4 Communication (was 5.5.3 Internal communication) 9.3 Management Review (was 5.6) 7.1.1, 7.1.2 General, People (was 6.1 Provision of resources) 7.2 Competence (was 6.2 Human resources) 7.1.3 Infrastructure (was 6.3) 7.1.4 Environment for the Operation of Processes (was 6.4 Work environment) See 8.3.1 for 8.3.6, 8.5.6 Design and Development Changes, Control of Changes (was 7.3.7 Control of changes) 8.2.1 Customer Communication (was 7.2.3) 8.5.1, 8.5.5 Control of Production & Service Provision, Post Delivery Support (was 7.5.1) 7.1.5 Monitoring and Measuring Resources (was 7.6 Control of monitoring & measurement equipment) 9.1.1 Measurement, Analysis & Improvement: General (was 8.1) 9.1.2 (was 8.2.1) Customer Satisfaction 9.1.1 General (was 8.2.3 Monitoring & measurement of processes) 9.1.3 Analysis and Evaluation (was 8.4 Analysis of data) 10.1 General, Confidential Improvement (was 8.5.1)
Production	8.1 Operational Planning and Control (was 7.1 Planning of product realization) 8.5.1, 8.5.5 Control of Production and Service Provision, Post Delivery Support (was 7.5.1) 8.5.2 Identification & Traceability (was 7.5.3) 8.5.3 Property Belonging to Customers or External Providers (was 7.5.4 Customer property) 8.5.4 Preservation (was 7.5.5) 8.6 Release of Products and Services (was 8.2.4 Monitoring and measurement of product) 8.7 Control of Nonconforming Outputs (was 8.3 Control of nonconformances)
Proposal Development & Contract Review	8.2.2 Determining the Requirements Related to Products and Services (was 7.2.1 Determination of requirements) 8.2.3 Review of Requirements Related to Products and Services (was 7.2.2 Review of requirements)
Purchasing	8.4.1, 8.4.2 General, Type and Extent of Control (was 7.4.1 Purchasing process) 8.4.3 Information for External Providers (was 7.4.2 Purchasing information)
Receiving	8.6 Release of Products and Services (was 7.4.3 Verification of purchased product) 8.5.2 Identification & Traceability (was 7.5.3) 8.5.3 Property Belonging to Customers or External Providers (was 7.5.4 Customer property) 8.5.4 Preservation (was 7.5.5) 8.6 Release of Products and Services (was 8.2.4 Monitoring & measurement) 8.7 Control of Nonconforming Outputs (was 8.3 Control of nonconformances)
Shipping	8.2.2 Determining Requirements Related to Products and Services (was 7.2.1 Determination of requirements) 8.5.1, 8.5.5 Control of Production and Service Provision, Post Delivery Support (was 7.5.1) 8.5.2 Identification & Traceability (was 7.5.3) 8.5.4 Preservation (was 7.5.5) 8.7 Control of Nonconforming Outputs (was 8.3 Control of nonconformances)

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

Appendix B: Company Processes and Applicable Documents

Process	Applicable Company Procedures	Applicable Company Records
Corrective Action	QMS-13 Corrective Action	Corrective action records 10.2 (was 8.5.3.d)
Design & Development	QMS-17 Design & Development	Realization processes and resulting product meet requirements 8.1 (was 7.1.d) Design and development planning 8.3.2 (was 7.3.1) Design inputs records 8.3.3 (was 7.3.2) Design review records 8.3.4 (was 7.3.4) Design verification records 8.3.4 (was 7.3.5) Design validation records 8.3.4 (was 7.3.6) Design and development outputs 8.3.5 (was 7.3.3) Design change records see 8.3.1 for 8.3.6 (was 7.3.7)
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 5.6.1) Training records 7.2, 7.3 (was 6.2.2) Calibration records 7.1.5 (was 7.6)
Production	QMS-10 Production QMS-14 Control of Nonconformances	Traceability records (if required) 8.5.2 (was 7.5.3) Records of loss, damage or nonconformances 8.5.3 (was 7.5.4) Records of release authority of inspected product 8.6 (was 8.2.4) Records of first article inspection 8.6 (was 8.2.4.2) Control of nonconformances 8.7 (was 8.3)
Proposal Development & Contract Review	QMS-07 Proposal Development & Contract Review	Contract review records 8.2.3 (was 7.2.2)
Purchasing	QMS-08 Purchasing	Supplier evaluation records 8.4.1, 8.4.2 (was 7.4.1)
Receiving	QMS-09 Receiving QMS-14 Control of Nonconformances	Records of loss, damage or nonconformances 8.5.3 (was 7.5.4) Control of nonconformances 8.7 (was 8.3)
Shipping	QMS-11 Shipping QMS-14 Control of Nonconformances	Records of loss, damage or nonconformances 8.5.3 (was 7.5.4) Control of nonconformances 8.7 (was 8.3)

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

Appendix C: Outsourced Processes

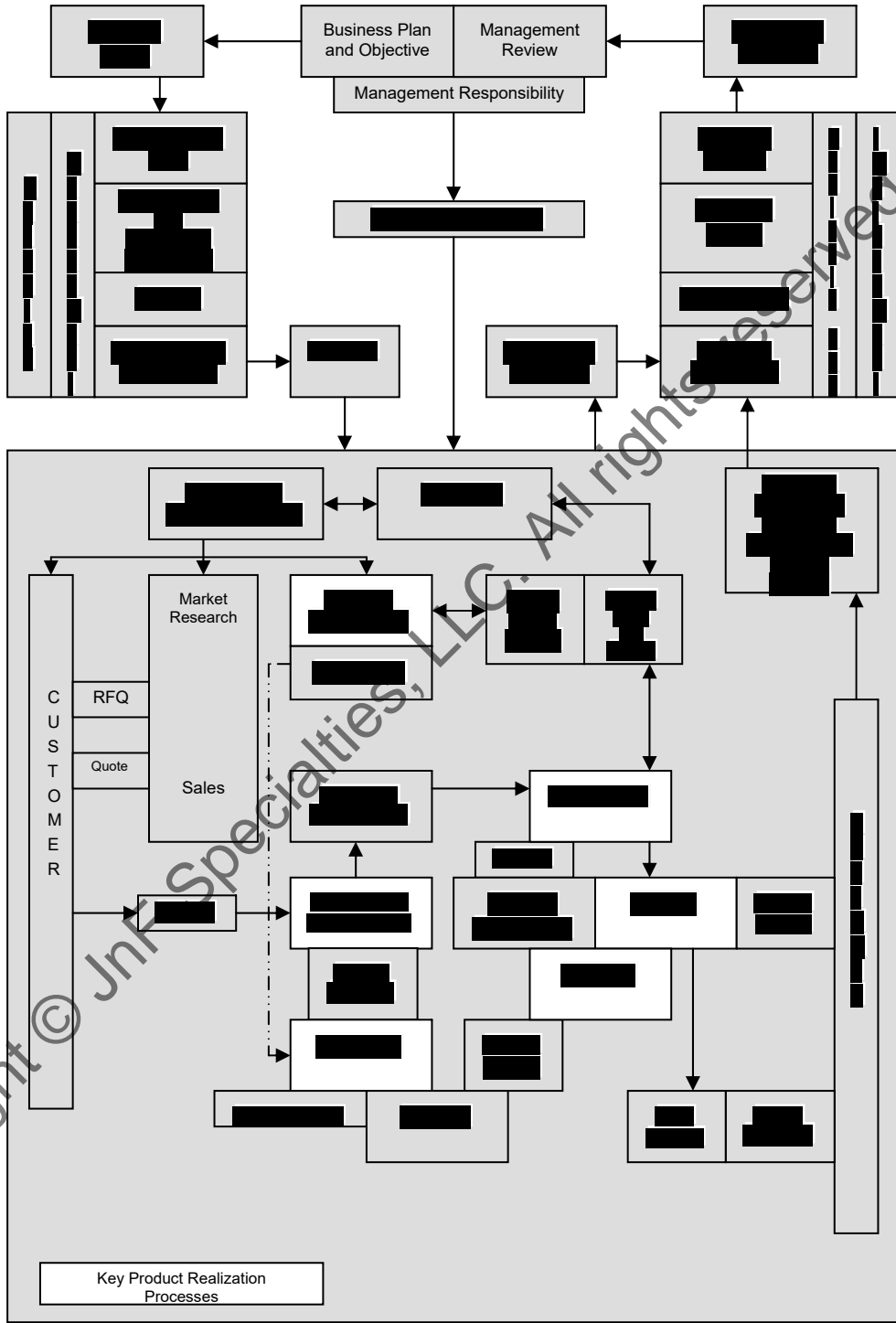
The following processes are outsourced and controlled as indicated:

- **Acceptance Testing:** [Redacted]
- **Calibration:** [Redacted]
- **Internal Auditing:** [Redacted]

Appendix D: Quality Objectives

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

Appendix E: Identification of Key Realization Processes



Copyright © Jnk Specialties, LLC. All rights reserved worldwide.

Your Logo	Your Company Name	QMS-00 Quality Handbook
CAGE: xxxxx		Rev: Orig

Delete this page prior to release of quality handbook.



Add to Cart

Copyright © JnF Specialties, LLC. All rights reserved worldwide.