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Your Company Name

QUALITY HANDBOOK

Origination Date: XXXX

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Document Link:	Location on Server (if used)

Abstract:
This document describes the quality management system policies and procedures that achieve conformance with aerospace standard SAE AS9100D.

REVISION LOG

Issue	Date	Comment	Author
Orig			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

Section 1: Scope

(Your Company's) quality management system (QMS) policies and procedures summarize top management's strategic 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 ***AS9100D*** and the ***QMS-16 Definitions and Abbreviations Procedure***.

Section 4: Context of the Organization

4.1 Understanding the organization and its context

The Company [redacted] according to the ***QMS-04 Management Process Procedure***.

4.2 Understanding the needs and expectations of interested parties

The Company considers [redacted] 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 [redacted]

The primary purpose of the Quality Handbook and QMS Procedures is to [redacted]

Copies of the handbook are controlled by [redacted]

This Quality Handbook has been developed by top management to [redacted]

Additional procedures and work instructions have been developed to [redacted] Where subordinate documents are referenced, they are shown in ***bold italics***.

4.3.1 Non-Applicable provisions of the QMS

The Company cites [redacted]

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 [redacted] which emphasizes the importance of:

- [redacted]

During Management Review (see 9.3), process resources are [redacted]

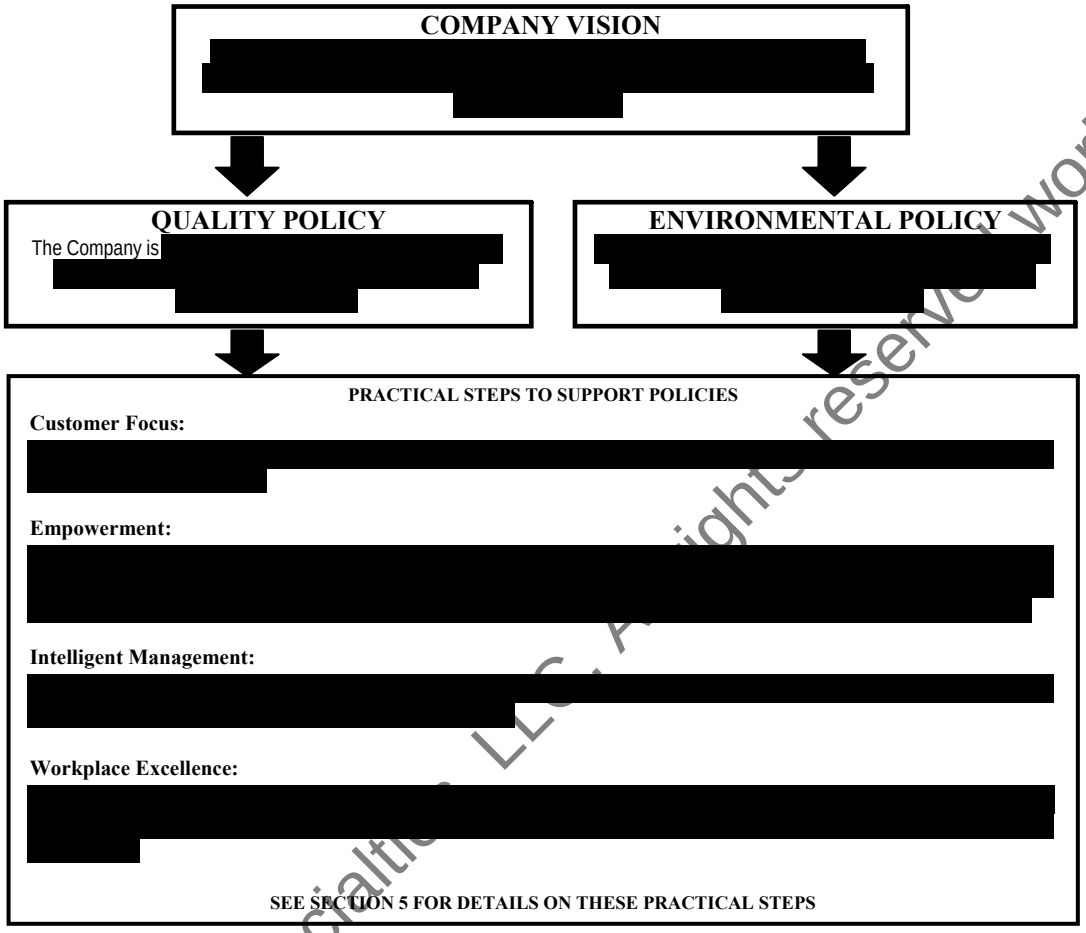
Every process has at least one QMS Procedure that defines it in greater detail that may [redacted]

For each process identified in use by the Company, the sequence and interaction of processes has been determined (see ***Process Orientation Checklist***) and the process controlled by [redacted]

Process maps define the details of each process, which includes [redacted] The relationship between QMS procedures and their applicable ***AS9100D*** 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.

The Company maintains all required documentation to [redacted]

4.4.1 Vision and governing policies



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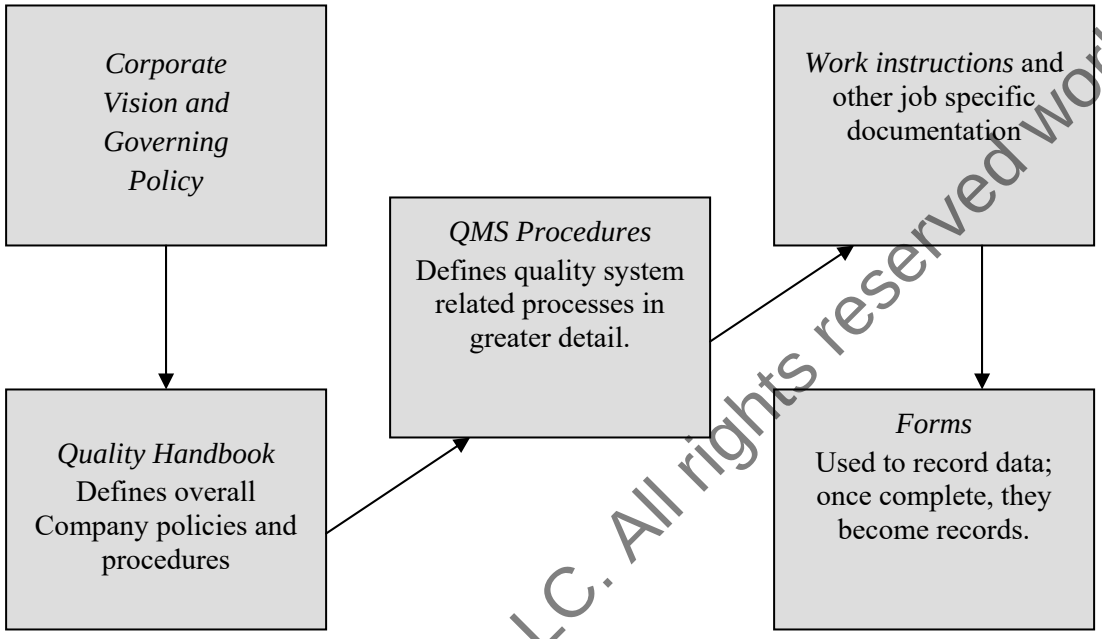
4.4.2 Overview of documentation

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



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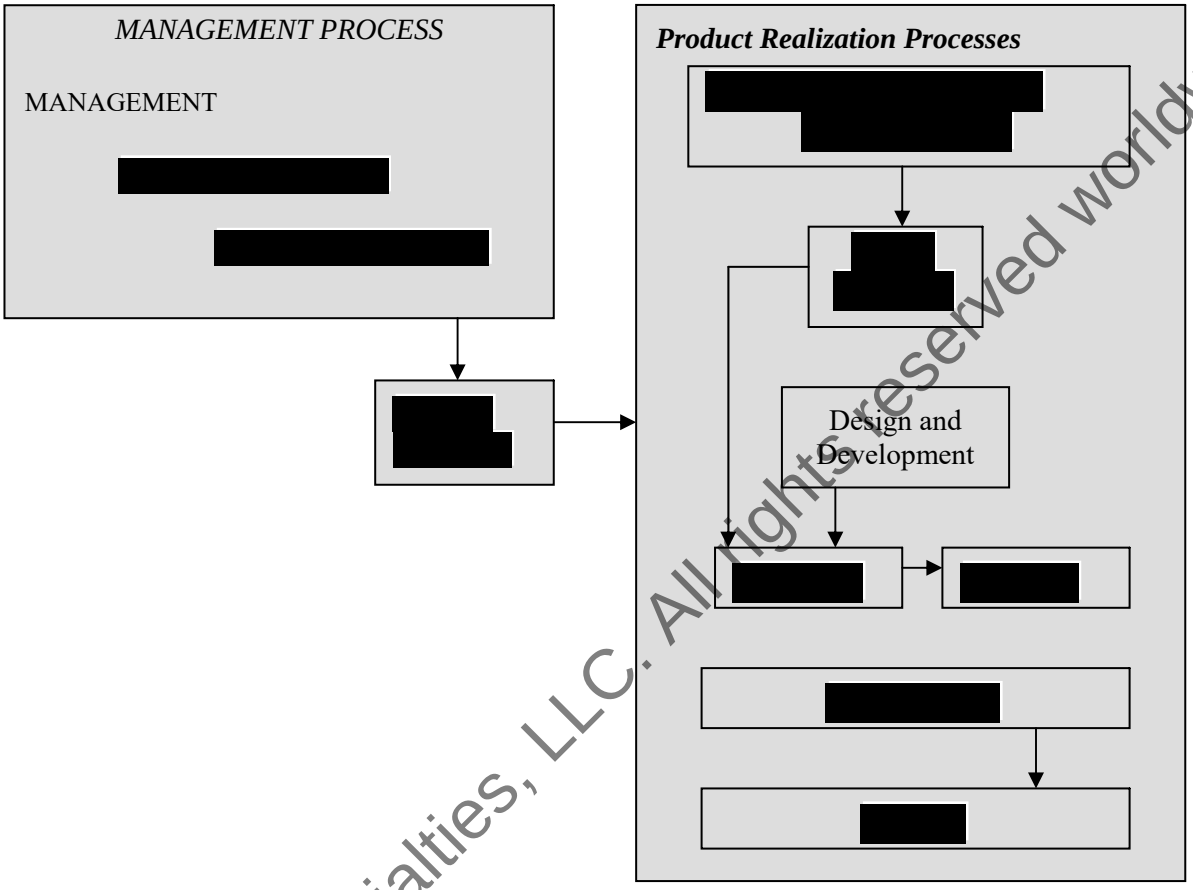
4.4.3 Overall process sequence and interaction



Section 5: Leadership

5.1 Leadership and commitment

The Company's Management is [redacted]

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 [redacted]

[redacted] according to the ***QMS-04 Management Process Procedure***.

5.2 Policy

5.2.1 Establishing the quality policy

The Company's quality policy defines [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 [redacted]

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]

The organization chart below describes the basic management structure of the Company. In all cases, the appropriate person has [redacted], which is further defined in the ***QMS-05 Responsibilities and Authorities Procedure***.

All employees are empowered to [redacted]

The Quality Manager has been assigned the role of Responsible Quality Authority (RQA). As RQA, the Quality Manager is responsible for:

- [redacted]

The Quality Manager has the responsibility and authority to [redacted]

5.3.1 Organization chart

Section 6: Planning

This quality system was planned in advance and its documented policies and procedures were reviewed prior to implementation. Management affirms the QMS is [redacted]

The QMS documentation acts as the overall quality plan for the Company. As required, specific quality processes [redacted]

Quality system planning and control is treated as a process (called the Management Process) and is defined in the ***QMS-04 Management Process Procedure***.

6.1 Actions to address risks and opportunities

6.1.1 Planning for the QMS

Planning for the quality management system includes [redacted]

6.1.2 Planning requirements

The Company determines the effectivity of actions taken to establish process controls that [redacted] according to the ***QMS-04 Management Process Procedure***.

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]

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 [redacted]

7.1.2 People

The Company determines and provides the people necessary for [redacted]

7.1.3 Infrastructure

The Company determines, provides and maintains the infrastructure necessary for [redacted]

The Company has determined and provides [redacted] and include a review of:

- [redacted]
- [redacted]
- [redacted]
- [redacted]

The Company utilizes maintenance practices and skilled maintenance personnel to [redacted]

The Company utilizes corrective maintenance and skilled maintenance personnel to [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. The work environment is [redacted]

7.1.5 Monitoring and measuring resources

7.1.5.1 General

When monitoring or measuring is used to verify the conformity of products and services, the Company determines [redacted]

7.1.5.2 Measurement traceability

All measuring and test equipment instruments and devices used to determine an item's conformance to specified requirements are [redacted] according to the ***QMS-15 Calibration Procedure***.

Measuring equipment is [redacted] according to the ***QMS-15 Calibration Procedure***.

7.1.6 Organizational knowledge

The Company determines [redacted] The Company considers [redacted] according to the ***QMS-07 Proposal Development and Contract Review Procedure***.

7.2 Competence

The Company determines and periodically reviews the necessary competence for Employees whose work affects the performance and effectiveness of the quality management system. The Company affirms [redacted]

All Company personnel are [redacted]

The Company has implemented a training program that:

- [redacted]

Management conducts [redacted]

7.3 Awareness

The Company affirms [redacted]

7.4 Communication

Internal and external communications that are relevant to the QMS are [redacted] according to the ***QMS-04 Management Process Procedure***.

To ensure proper communication [redacted] which is documented in the ***QMS-04 Management Process Procedure***.

Management periodically [redacted]

Employees are encouraged to use the ***Request for Support (RFS)*** to submit suggestions for improvements. This system requires management to take action on quality related issues within the Company.

7.5 Documented information

7.5.1 General

The Company's quality management system includes documented information required by ***AS9100D*** and records necessary for the effectiveness of the quality management system.

The Company maintains all required documentation to [redacted]

All Managers are responsible for [redacted]

The quality system documentation is comprised of a hierarchy of documents that flow from this Quality Handbook (see 4.4.2).

All documents must [redacted]

The order of precedence of order-specific documentation is as follows unless otherwise directed by Customer requirements:

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

7.5.2 Creating and updating

During creation and update of documented information, the Company reviews and approves documents [redacted] according to the ***QMS-01 Control of Documented Information Procedure***.

The Company has developed a secure web-based document portal that enables [redacted] according to the ***QMS-02 Configuration Management Procedure***.

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 [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 [redacted] according to the ***QMS-01 Control of Documented Information Procedure***. Superseded and/or obsolete documents may [redacted] according to the ***QMS-02 Configuration Management Procedure***. Management provides guidelines for managing [redacted] according to the ***QMS-04 Management Process 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 [redacted]

The Company applies the ***QMS-07 Proposal Development and Contract Review Procedure*** to engage Responsible Authorities and [redacted]

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

Inspection, testing and "on-time delivery" requirements are [redacted]

Project management is used to [redacted]

Key product realization processes include the following procedures:

- [redacted]

Quality objectives have been established for each key process. At times, additional quality objectives and measurements may [redacted]

Suppliers used for outsourced processes are approved according to 8.4 herein and the ***QMS-08 Purchasing Procedure***. When the Company provides supplies for outside processing, such as acceptance testing, the work is performed under the following conditions:

- [redacted]

8.1.1 Operational risk management

Risk management for operational processes is conducted according to ***QMS-18 Risk Mitigation and Planning Procedure.*** Proportionate actions are [redacted]

8.1.2 Configuration management

The configuration of products and services is controlled [redacted] according to the ***QMS-02 Configuration Management Procedure***.

8.1.3 Product safety

The Company plans, implements and controls the processes [redacted] according to the ***QMS-10 Manufacturing Procedure***.

8.1.4 Prevention of counterfeit parts

The Company [redacted] according to the ***QMS-03 Counterfeit Parts Prevention Procedure and QMS-04 Management Process Procedure***.

8.2 Requirements for products and services

8.2.1 Customer communication

The Company communicates with its Customers by [redacted]

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 [redacted] according to the ***QMS-07 Proposal Development and Contract Review Procedure***.

The Company captures all contractual and special requirements of the Customer as well as [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*** [redacted]

The Company pays particular attention to [redacted]

8.2.3.2 Retain documented information of review

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

8.2.4 Changes to requirements for products and services

When the requirements for products and services are changed, the Company affirms [redacted]

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] which are defined in the ***QMS-17 Design and Development Procedure*** that includes policies for:

- 8.3.2 Design and development planning
- 8.3.3 Design and development inputs
- 8.3.4 Design and development controls
- 8.3.4.1 Validation and verification tests
- 8.3.5 Design and development outputs
- 8.3.6 Design and development changes

8.4 Control of externally provided processes, products and services

The Company [redacted] does not [redacted]

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]

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]

processes or products and services according to requirements and ***QMS-08 Purchasing*** [redacted]

8.4.2 Type and extent of control

The Company affirms externally provided processes, products and services [redacted]

8.4.3 Information for external providers

The Company affirms mandatory requirements are [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***, which includes provisions for:

- 8.5.1.1 Control of Equipment, Tools and Software Programs
- 8.5.1.2 Validation and Control of Special Processes
- 8.5.1.3 Production Process Verification

The Company plans and carries out processes for product realization. In general, this includes assurances that:

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

- [redacted]

In-process inspection is conducted according to [redacted] the ***QMS-10 Manufacturing Procedure*** and ***QMS-02 Configuration Management Procedure***.

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]

QC stamps or registered names and initials of inspectors may [redacted]

8.5.3 Property belonging to Customers or external providers

When outside sources provide property for processing or use, it is suitably identified as such to [redacted]

Property is controlled according to the ***QMS-10 Manufacturing Procedure***, [redacted]

8.5.4 Preservation

According to contractual directives, instructions are detailed in the applicable job documentation [redacted] according to the ***QMS-10 Manufacturing Procedure*** and ***QMS-11 Shipping Procedure***.

8.5.5 Post-delivery activities

The Company meets requirements for post-delivery activities associated with the products and services according to [redacted]

The Company provides as applicable:

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

8.5.6 Control of changes

To ensure continuing conformity with requirements, the Company reviews and controls [redacted]

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 released for delivery to Customers only [redacted]

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 [redacted] Nonconforming outputs may be identified by [redacted] The Company takes appropriate actions based on [redacted] Nonconformances are corrected then reverified to confirm outputs are in compliance with requirements. When appropriate, the Company [redacted]

8.7.2 Retain documented information for nonconformities

Records used to disposition nonconformities clearly describe each nonconformance and includes [redacted]

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 valid results by [redacted]

Documented information that is used for determining the acceptability of this quality management system may include, but are not limited to:

- [redacted]

- [redacted]

9.1.2 Customer satisfaction

To monitor and measure Customer satisfaction and [redacted] the Company collects information about: (adjust "your list" as required - retain mandatory items - delete this note prior to release of quality handbook)

- [redacted]

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

9.1.3 Analysis and evaluation

The Company evaluates [redacted] according to the ***QMS-04 Management Process Procedure***.

9.2 Internal audit

9.2.1 Conduct internal audits at planned intervals

The Company conducts internal audits at planned intervals to provide [redacted]

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 [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]

9.3.3 Management review outputs

Results from management reviews include [redacted]

Section 10: Improvement

It is the goal of all employees to [redacted]

10.1 General

[redacted]

10.2 Nonconformity and corrective action

10.2.1 Required actions for nonconformities

When nonconformity occurs in products and processes, including [redacted], the Company takes action and [redacted]

The Company affirms corrective actions are appropriate to the effects of nonconformities, and:

- [redacted]

- [redacted]

10.2.2 Required records for nonconformities

The Company retains and maintains records regarding the nature of nonconformances, subsequent actions and [redacted]

10.3 Continual improvement

The Company continually improves [redacted]

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Appendix A: Company Processes and Applicable *AS9100D* Clauses

Process	Applicable ***AS9100D*** Clauses
Configuration Management	8.5.6 Control of Changes (was [redacted])
Control of Documented Information	7.5.2 Creating and Updating (was [redacted]) 7.5.3 Control of Documented Information (was [redacted])
Control of Nonconformities	8.7 Control of Nonconforming Outputs (was 8.3 [redacted])
Corrective Action	10.2 Nonconformity and Corrective Action (was [redacted])
Design & Development	8.3 Design and Development of Products and Services (was [redacted]) 8.5.1 Control of Production and Service Provision (was [redacted])
Internal Auditing	9.2 Internal Audit (was [redacted])
Management	4.1 Understanding the organization and its context (was [redacted]) 4.2 Understanding the needs and expectations of interested parties (was [redacted]) 4.3 Determining the scope of the quality management system (was [redacted]) 4.4 Quality Management System and its Processes (was [redacted]) 5.1.1 Leadership and commitment: General (was 5.1 [redacted]) 5.2.1 Establishing the Quality Policy (was [redacted]) 5.3 Organizational Roles, Responsibilities and Authorities (was [redacted]) 6.1.1 Determine risks and opportunities when planning for the QMS (new), 6.1.2 Planning actions (new) 6.2.1 Establishing quality objectives (was [redacted] (new) 6.3 Planning of changes (was [redacted]) 7.1.1 Support: Resources: General (was [redacted]), 7.1.2 People (was [redacted]), 7.1.3 Infrastructure (was [redacted]), 7.1.4 Environment for the Operation of Processes (was [redacted], 7.1.5.1 Monitoring and measuring resources: General (was [redacted]) 7.1.6 Organizational knowledge (new) 7.2 Competence (was [redacted]) 7.3 Awareness (was [redacted]) 7.4 Communication (was [redacted]) 7.5.1 Documented Information: General (was [redacted]), 7.5.2 Creating and updating (was [redacted]) 7.5.3.1 Control of documented information required by International Standard (new) 8.1 Operational planning and control (was [redacted]), 8.1.1 Operational risk management (new), 8.1.2 Configuration management (was [redacted]), 8.1.3 Product safety (new), 8.1.4 Prevention of counterfeit parts (new) 8.2.1 Customer Communication (was [redacted]) 8.5.6 Control of changes (was 7.3.7 [redacted]) 9.1.1 Monitoring, measurement, analysis and evaluation: General (was [redacted]), 9.1.2 Customer Satisfaction (was [redacted]), 9.1.3 Analysis and evaluation (was [redacted]) 9.2 Internal audit (was [redacted]) 9.3.1 Management Review: General (was [redacted]), 9.3.2 Management review inputs (was [redacted]), 9.3.3 Management review outputs (was [redacted]) 10.1 Improvement: General (was [redacted]) 10.2.1.e,h Required actions for nonconformities (was [redacted])

Process	Applicable ***AS9100D*** Clauses
	10.3 Continual Improvement (was [redacted])
Manufacturing	8.1 Operational Planning and Control (was [redacted]) 8.5.1.3 Production Process Verification (was [redacted] 8.1 Operational Planning and Control (was [redacted] 8.5.1.1 Control of Production Equipment, Tools and Software Programs (was [redacted]) 8.5.5 Post-Delivery Activities (was [redacted]) 8.5.2 Identification and Traceability (was [redacted]) 8.5.3 Property Belonging to Customers or External Providers (was [redacted]) 8.5.4 Preservation (was [redacted]) 8.6 Release of Products and Services (was [redacted]) 8.7 Control of Nonconforming Outputs (was [redacted])
Proposal Development & Contract Review	8.2.2 Requirements Related to Products and Services (was [redacted]) 8.2.3 Review of Requirements Related to Products and Services (was [redacted] 8.2.4 Changes to Requirements for Products and Services (was [redacted]
Purchasing	8.4.1 Control of Externally Provided Processes, Products and Services: General (was [redacted]) 8.4.3 Information for External Providers (was [redacted])
Receiving	8.4.3 Information for External Providers (was [redacted]) 8.5.2 Identification and Traceability (was [redacted]) 8.5.3 Property Belonging to Customers or External Providers (was [redacted]) 8.5.4 Preservation (was [redacted]) 8.6 Release of Products and Services (was [redacted] 8.7 Control of Nonconforming Outputs (was 8.3 [redacted])
Shipping	8.2.2 Determining Requirements Related to Products and Services (was [redacted]), 8.5.1, 8.5.5 Control of Production & Service Provision, Post Delivery Support (was [redacted]), 8.5.2 Identification and Traceability (was [redacted]) 8.5.4 Preservation (was [redacted]) 8.7 Control of Nonconforming Outputs (was [redacted])

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Appendix B: Company Processes and Applicable Documents

Process	Applicable Company Procedures	Applicable Company Records
Corrective Action	QMS-13 Corrective Action	Nonconformity and Corrective Action 10.2 (was [redacted])
Design & Development	QMS-17 Design & Development	Operational Planning and Control 8.1.e.1 (was [redacted]) Design and Development Inputs 8.3.3 (was [redacted]) Design and Development Controls 8.3.4 (was [redacted]) Design and Development Changes 8.3.6 (was [redacted])
Internal Auditing	QMS-12 Internal Auditing	Internal audit 9.2 (was [redacted])
Management	QMS-00 Quality Handbook QMS-01 Control of Documented Information QMS-02 Configuration Management QMS-04 Management Process QMS-05 Responsibilities & Authorities QMS-06 Training QMS-15 Calibration QMS-16 Definitions and Abbreviation	Management Review: General 9.3.1 (was [redacted]) Competence 7.2 (was [redacted]) Awareness 7.3 (was [redacted]) Monitoring and Measuring Resources 7.1.5, 7.1.5.1, 7.1.5.2 (was [redacted])
Manufacturing	QMS-10 Manufacturing QMS-14 Control of Nonconformities Procedure	Identification and Traceability (if required) 8.5.2 (was [redacted]) Property Belonging to Customers or External Providers 8.5.3 (was [redacted]) Release of Products and Services 8.6 (was [redacted]) Control of Nonconforming Outputs 8.7 (was [redacted])
Proposal Development & Contract Review	QMS-07 Proposal Development & Contract Review	Review of Requirements Related to Products and Services 8.2.3 (was [redacted])
Purchasing	QMS-08 Purchasing	Control of Externally Provided Processes, Products and Services: General 8.4.1 (was [redacted])
Receiving	QMS-09 Receiving QMS-14 Control of Nonconformities Procedure	Property Belonging to Customers or External Providers 8.5.3 (was [redacted]) Control of nonconforming product 8.7 (was [redacted])
Shipping	QMS-11 Shipping QMS-14 Control of Nonconformities Procedure	Property Belonging to Customers or External Providers 8.5.3 (was [redacted]) 8.5.4 Preservation (was [redacted]) Control of Nonconforming Outputs 8.7 (was [redacted])

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Appendix C: Outsourced Processes

The following processes are outsourced and controlled as indicated:

- [redacted]
- [redacted]
- [redacted]

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Appendix D: Quality Objectives

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

COMMENT:

The quantity of quality objectives listed above should be evaluated and adjusted to meet actual value-added goals of the Company, and match the list of procedures displayed in paragraph 8.1 and highlighted in Appendix E. The objectives that are listed above are [redacted]

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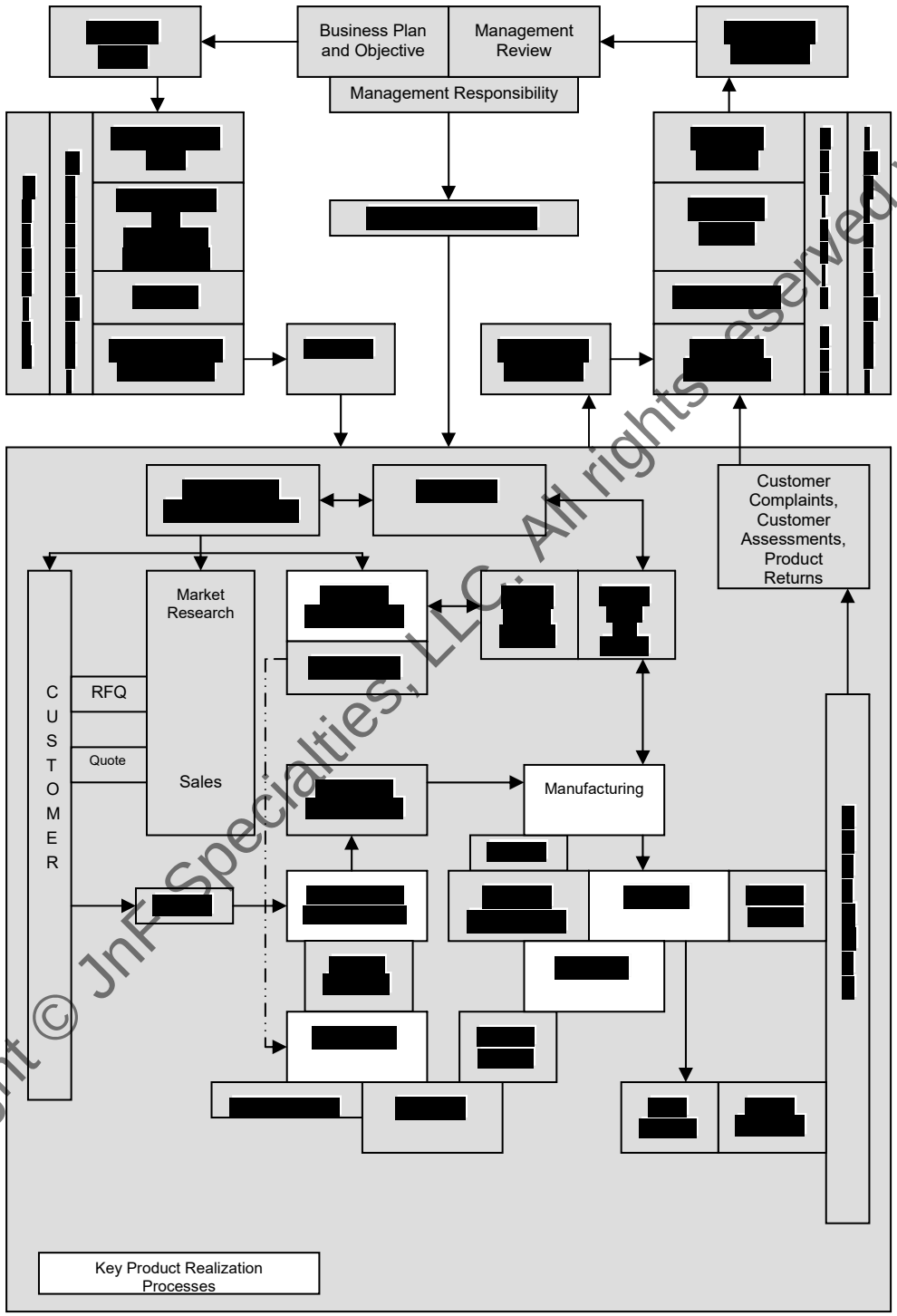
Appendix E: Identification of Key Product Realization Processes



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(paragraph numbers in parentheses are from the AS9100D standard)

Mandatory Procedures:

- [redacted]

Recommended Procedures:

- [redacted]

Applicable Records:

- [redacted]

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(paragraph numbers in parentheses are from the AS9100D standard)

Applicable Records continued…

- [redacted]

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[redacted]

CONTROL OF DOCUMENTED INFORMATION PROCEDURE

Origination Date: XXXX

Document Identifier:	QMS-01 Control of Documented Information Procedure
Date:	Latest Revision Date
Project:	Customer, Unique ID, Part Number
Document Status:	Draft, Redline, Released, Obsolete
Document Link:	Location on Server (if used)

Abstract:
This document describes procedures for controlling documents.

REVISION LOG

Issue	Date	Comment	Author
Orig			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

1.0 PURPOSE

This procedure defines the requirements for the control of documents within the quality management system (QMS). The scope of this procedure is to control documents specifically defined in section 3.0.

The following documents are not subject to this procedure:

- [redacted]
-
-
-
-
-

2.0 THEORY

Documents must be controlled so that only reviewed and approved information is released and used by employees. This ensures [redacted]

3.0 DOCUMENT TYPES

The Document Control Center maintains documented information to ensure [redacted]

3.1. Quality Handbook: [redacted]

3.2. QMS Procedures: [redacted]

3.3. General Work Instructions: [redacted]

3.4. Inspection Instructions: [redacted]

3.5. Forms: [redacted]

Any department manager or area supervisor [redacted]

3.6. Records that are created for temporary retention of miscellaneous information are [redacted]

4.0 QUALITY HANDBOOK

4.1. Creating the Quality Handbook

The Quality Handbook has been established by top management of the Company, which includes [redacted]

4.2. Review and Approval

The Quality Handbook is reviewed and approved by top management before release. Approval is indicated by [redacted]

4.3. Distribution

The Quality Handbook is distributed electronically through the Company's internet server.
The Document Control Center may [redacted]
In some cases, a hardcopy of the Quality Handbook may [redacted]
Each employee must [redacted]

4.4. Change Control

Any employee may request a change to the Quality Handbook. Requests for changes may be made by [redacted]

5.0 QUALITY MANAGEMENT SYSTEM PROCEDURES

5.1. Creating New QMS Procedures

QMS procedures should be created as soft files (MS Word, etc.). It is recommended that files [redacted]

5.2. Review and Approval

QMS Procedures are reviewed and approved by top management. [redacted]
Approval is indicated by [redacted]

5.3. Distribution

QMS procedures are distributed electronically through the Company's internet server and/or via the intranet.
The Document Control Center may [redacted]

In some cases, a hardcopy of the procedure may [redacted] Each employee must [redacted].

5.4. Change Control

Changes to QMS procedures are performed in the same manner as the Quality Handbook.

6.0 GENERAL WORK INSTRUCTIONS

6.1. Creating New Work Instructions

Where necessary, work affecting quality is [redacted]

NOTE REGARDING JOB SPECIFIC WORK INSTRUCTIONS:

Engineering may develop work instructions that are specific to a given job, which [redacted]

6.2. Review and Approval

Work instructions must be reviewed and approved by [redacted]

6.3. Distribution

General work instructions are distributed electronically through the Company's internet server and/or via the intranet. The Document Control Center may retain [redacted]

In some cases, a hardcopy of the work instruction may [redacted] Each employee must [redacted]

6.4. Change Control

Changes to general work instructions are performed in the same manner as the Quality Handbook. When general work instructions are changed, [redacted]

7.0 INSPECTION INSTRUCTIONS

7.1. Creating New Inspection Instructions

New inspection instructions are developed by or under the supervision of the Responsible Authority using [redacted]

NOTE REGARDING JOB SPECIFIC INSPECTION INSTRUCTIONS:
Engineering may develop inspection instructions that are specific to a given job, which [redacted]

7.2. Review and Approval
Approval is indicated by [redacted]

7.3. Distribution
Inspection instructions are distributed electronically through the Company's internet server and/or intranet. The Document Control Center may [redacted]
In some cases, a hardcopy of the inspection instruction may [redacted] Each employee must [redacted]

7.4. Change Control
Any employee may request a change to inspection instructions by [redacted]

8.0 FORMS

8.1. Creating New Forms
Forms undergo a streamlined creation and control process. Any department manager or area supervisor may [redacted]

8.2. Review and Approval
Forms may be reviewed and approved by [redacted]

8.3. Distribution

Forms are made available through the Company's internet server, intranet or Document Control Center. These may [redacted]

8.4. Change Control

Any employee may submit a ***Request for Change*** to the appropriate area manager responsible for the form and [redacted]

9.0 EXTERNAL DOCUMENTS

9.1. Some external (third party) standards or specifications may [redacted]

9.2. Third party specifications and engineering drawings, including those of the Customer, are controlled according to the ***QMS-02 Configuration Management Procedure***. Where control of an external document is [redacted]

10.0 PERIODIC RE-EVALUATION OF DOCUMENTS

The entire set of quality documentation is subject to continuous improvement. Change control documents are filed as needed to request changes or updates.

11.0 CONTROL OF RECORDS

11.1 The controls for each type of record are defined in **Appendix A** of this procedure.

11.2 The listed "controller" must [redacted]

11.3 Records for active contracts are [redacted]

11.4 The Document Control Center [redacted]

11.5 Records that are discarded after retention shall [redacted]

11.6 Hardcopy records are [redacted]

11.7 Records are available for review by the Customer and copies [redacted]

11.8 Records are [redacted]

11.9 The Company does not require vendors to maintain records for the Company; instead, [redacted]

11.10 Electronic records are [redacted]

11.11 Local computer data that is stored on company computers must [redacted]

11.12 When making corrections to written record entries, the error is [redacted]

11.13 Correction fluid or correction tape is not to be used on any quality records.

Left blank intentionally

APPENDIX A: RECORD RETENTION MATRIX

Required Record or Document Type	Company Record	Controller	Type	Location	Minimum Retention
Calibration records	Calibration		Form		[redacted]
Contract review records	Contract review		Form		[redacted]
Control of nonconformities	RFS		Form		[redacted]
Corrective actions	RFS		Form		[redacted]
Design change records	Engineering order		Form		[redacted]
Design input records	Engineering order		Form		[redacted]
Design review records	Engineering order		Form		[redacted]
Design validation records	Production inspection		Form		[redacted]
Design verification records	Production inspection		Form		[redacted]
First Article Inspection	First article		Form		[redacted]
Internal audit records	Internal audit		Form		[redacted]
Lost, damaged or unsuitable Customer property	Customer property		Form		[redacted]
Management review meeting reports	Management review report		Form		[redacted]
Record of realization process	Engineering order		Form		[redacted]
Record of release of product	Production inspection		Form		[redacted]
Supplier evaluation	Supplier evaluation		Form		[redacted]
Traceability records	Production inspection		Form		[redacted]
Training records	Training record		Form		[redacted]

Your Logo

[redacted]

CONFIGURATION MANAGEMENT PROCEDURE

Origination Date: XXXX

Document Identifier:	QMS-02 Configuration Management Procedure
Date:	Latest Revision Date
Project:	Customer, Unique ID, Part Number
Document Status:	Draft, Redline, Released, Obsolete
Document Link:	Location on Server (if used)

Abstract:
This document describes configuration management procedures.

REVISION LOG

Issue	Date	Comment	Author
Orig			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

1.0 PURPOSE

This procedure defines the requirements for the management of the configuration of products produced by the Company's configuration management activities include the following:

- [redacted]
- [redacted]
- [redacted]
- The following are not governed by this control procedure:
- [redacted]
- [redacted]

2.0 THEORY

Part configuration includes a variety of aspects of a given part, including [redacted]

This procedure has been developed based on practices defined in [redacted]

3.0 CONFIGURATION DOCUMENTATION

3.1. The current configuration of a given part is identified through applicable technical documents. These may include, but are not limited to:

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

3.2. All such technical documents are developed and approved by the Responsible Authority, which are then controlled according to this procedure. (See section 4.0)

3.3. Configuration documents and Customer intellectual property received by is the Company are [redacted]

4.0 CONFIGURATION CONTROL BOARD (CCB)

4.1. Responsible Authorities (RA) serve as the Configuration Control Board, which has full authority and responsibility for [redacted]

4.2. CCB responsibilities include:

- [redacted]

5.0 CONFIGURATION CHANGE CONTROL

5.1. Evaluation of a change in configuration for a deliverable item takes into consideration [redacted]

5.2. All associated changes and affected hardware items or computer programs are [redacted]

5.3. Types of Configuration Change

Changes to the configuration are implemented after approval of engineering changes, deviations or waivers. The definition for each is as follows:

5.3.1. Engineering Change: [redacted]

5.3.2. Deviation: [redacted]

5.3.3. Waiver: [redacted]

5.4. Change Classification

Changes in configuration are classified by the CCB as either Class I or Class II. The change classification assigned by the CCB is entered on the Engineering Order, which serves as the document to describe the proposed change and to record CCB decisions relating to the change. Proposed Class I engineering changes are [redacted]

5.4.1. Class I Changes

The engineering change is classified as Class I when it affects one or more of the following:

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- Non-technical contractual provisions are affected, such as, but not limited to:
  - [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
  - [redacted]

5.4.2. Class II Changes

Any change that does not fall within the Class I definition is a Class II change. Class II changes are [redacted]

5.5. Change Implementation

5.5.1. The Responsible Authority verifies that changes have been incorporated into affected units and [redacted]

5.5.2. Superseded revision levels of electronic documents are [redacted]

5.5.3. Proposed Class I engineering changes are approved by the CCB and are submitted to the Customer in the form of an Engineering Order (EO) or as required by contract. A Class I Engineering Change is not [redacted]

5.6. Document approval is indicated by any of the following methods:

- [redacted]
- [redacted]

6.0 SUBCONTRACTOR AND VENDOR CHANGES

6.1. Supplier and vendor requests for change are controlled according to the ***QMS-08 Purchasing Procedure***.

7.0 PRODUCT AND TEST SOFTWARE CONTROL

Revision control is [redacted]

Your Logo

Your Company Name

COUNTERFEIT PARTS PREVENTION PROCEDURE

Origination Date: (your date)

Document Identifier:	QMS-03 Counterfeit Parts Prevention Procedure
Date:	Latest Revision Date
Project:	Customer, Unique ID, Part Number
Document Status:	Draft, Redline, Released, Obsolete

Abstract:
This document describes the procedure applied for prevention of counterfeit parts and materials.

REVISION LOG

Issue	Date	Comment	Author
Orig			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

1.0 Purpose

The purpose of this document is to describe the process and due diligence performed to prevent the purchase and/or use of counterfeit parts. The Company pays particular attention to:

- [redacted]

2.0 Scope

This document applies to the procurement activities at the Company to the extent specified herein.

3.0 Applicable Documents

The following publications are applicable to the extent specified herein, or as defined on the contract or purchase order. The latest revision publication shall be applied. Compliance with any other issues of these publications requires prior written approval from the Company. Insofar as any of the publications referred to herein conflict with the requirements of the specification, this specification shall govern.

- [redacted]
- ***AS9100, Quality Management System***
- ***QMS-14 Control of Nonconformities Procedure***
- [redacted]

4.0 Definitions

Aftermarket Manufacturer - A manufacturer meeting one or more of these criteria:

[redacted]

Note: The Aftermarket Manufacturer must [redacted]

Approved Supplier - [redacted]

Authorized Supplier - [redacted]

Broker - [redacted]

Certificate of Conformance (C of C) - [redacted]

Certificate of Conformance and Traceability (C of CT) - [redacted]

Counterfeit Part - [redacted]

ERAI - Privately held global trade associates that monitors, investigates, reports and mediates issues affecting the global supply chain of electronics including the supply of counterfeit and substandard parts.

Franchised Distributor - [redacted]

[redacted]

Independent Distributors - [redacted]

Packaging - [redacted]

Refinishing - [redacted]

Refurbished - [redacted]

Suspect Part - [redacted]

Upscreened - [redacted]

Used - [redacted]

Note: Other definitions are available for review in [redacted]

5.0 Responsibility

Personnel training and orientation regarding prevention of counterfeit parts is based upon [redacted]

Responsible Authorities from Purchasing and Engineering are [redacted]

5.1 Purchasing is responsible for [redacted]

5.2 Engineering is responsible for [redacted]

5.3 Receiving Inspection and other appropriate Responsible Authorities are responsible for [redacted]

6.0 Procedure

6.1 The Company maximizes the availability of authentic, originally designed and/or qualified parts throughout the product's life cycle, including management of [redacted]

6.2 Purchasing must [redacted]

6.3 Purchasing must [redacted]

6.4 Purchasing should [redacted]

6.5 [redacted]

Note: Purchasing may [redacted]

In general, product with electronic components destined for Government or military use requires [redacted]

The electronic component requirements for the product may be identified from a review of [redacted]

6.6. Purchasing must specify the flowdown requirements from this Counterfeit Parts Prevention Procedure applicable to the Supplier or Subcontractor. Purchasing must [redacted]

6.7 The purchase document must [redacted]

To minimize the risk of procuring counterfeit parts, the purchasing document should [redacted]

6.8 Responsible Authorities that receive, inspect or process parts shall [redacted]

6.9. All occurrences of counterfeit parts shall be reported, as appropriate, to [redacted]

7.0 Verifications

The Company considers due diligence has been applied when [redacted]

When a part is suspected of being counterfeit, the Company [redacted]

All inspection and testing shall be performed according to [redacted] The following inspection operations should be performed in sequence.

A: [redacted]

Each lot to be delivered shall be subjected to [redacted] but is not limited to:

- [redacted]

B: [redacted]
Each lot to be delivered shall be subjected to a sample inspection at an AQL of 1.0 or tighter. Testing shall include [redacted]

C: [redacted]
Each lot to be delivered shall be subjected to [redacted]

D: [redacted]
[redacted] shall be sampled at an AQL of 1.0 or tighter. [redacted]

E: [redacted]
Each lot to be delivered shall be subjected to [redacted]

F: [redacted]
Each lot shall be verified for [redacted]

See Table 1.

Left blank intentionally.

Table 1: Testing/Analysis Requirements by Component Type

Component Type	[redacted] (A)	[redacted] (B)	[redacted] (C)	[redacted] (D)	[redacted] (E) (DPA)	[redacted] (F)
[redacted]	[redacted]			[redacted]		[redacted]
[redacted]	[redacted]	[redacted]				[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]			[redacted]		[redacted]
[redacted]	[redacted]			[redacted]		[redacted]
[redacted]	[redacted]	[redacted]				
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]		[redacted]		[redacted]
[redacted]	[redacted]			[redacted]		[redacted]
[redacted]	[redacted]	[redacted]				
[redacted]	[redacted]			[redacted]		[redacted]
[redacted]	[redacted]	[redacted]		[redacted]		[redacted]
[redacted]	[redacted]			[redacted]		[redacted]
[redacted]	[redacted]			[redacted]		
[redacted]	[redacted]	[redacted]				
[redacted]	[redacted]	[redacted]		[redacted]		[redacted]
[redacted]	[redacted]			[redacted]		[redacted]

Your Logo

Your Company Name

MANAGEMENT PROCESS PROCEDURE

Origination Date: XXXX

Document Identifier:	QMS-04 Management Process Procedure
Date:	Latest Revision Date
Project:	Customer, Unique ID, Part Number
Document Status:	Draft, Redline, Released, Obsolete

Abstract:
This document describes the management review process.

REVISION LOG

Issue	Date	Comment	Author
Orig			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

1.0 PURPOSE

This document defines the Management process, including or making reference to procedures for the various activities within the Management process.

2.0 THEORY

The Company believes in “intelligent management,” which enables the Company to make decisions based on facts, data and verifiable evidence. Intelligent management reduces the need to make decisions based on personal opinion, whims or mood and ensures results of decisions are measurable.

3.0 MANAGING AS A PROCESS

The Company recognizes that it has to manage processes identified in the quality handbook; however, management itself is also treated as a process. This means [redacted]

The process map in the Appendix identifies how Management is treated as a process and provides an overview of how management is performed.

Management is responsible for implementation and application of the following QMS requirements:

- [redacted]

- [redacted]

4.0 PROCEDURE: MANAGEMENT REVIEW

4.1 The management of the Company performs formal review of the Quality Management System a minimum of [redacted]

Minimum attendance for Management Review: [redacted]

4.2 This review includes [redacted]

The Company pays particular attention to [redacted]

4.3 Minutes of the meetings are taken and maintained, which includes [redacted]

4.4 The Management Review meeting should include analysis of the following inputs:

- [redacted]
  - o
  - o
  - o
- [redacted]

- [redacted]

4.5 Management uses action items or the corrective action system to take recorded actions as a result of [redacted]

4.6 Management determines internal issues that affect its ability to achieve intended results, which may include, but are not limited to:

- [redacted]

- [redacted]

4.7 Management determines external issues[36] that affect its ability to achieve intended results, which may include, but are not limited to:

- [redacted]

5.0 PROCEDURE: MEASURING AND MONITORING PROCESS OBJECTIVES

5.1 Each process identified in the Quality Management System has at least one objective. The objective is [redacted]

5.2 Each process objective is [redacted]

5.3 Top management [redacted]

5.4 Throughout the year, assigned managers and staff [redacted]

5.5 During Management Review, [redacted]

5.6 When a process [redacted]

5.7 The current metrics, [redacted]

5.8 Over time, management [redacted]

6.0 PROCEDURE: INTERNAL and EXTERNAL COMMUNICATION

[redacted]

The following methods are used for internal communications:

- [redacted]
- [redacted]
- [redacted]
- [redacted]

6.2 External communications that are relevant to the quality management system are [redacted]

6.2.1 Confidential Company Information

Company Employees do not reveal Confidential Company Information to External Parties except [redacted]

[redacted]

6.2.1.1 Basic Company Information

Company Employees do not communicate Basic Company Information to External Parties except [redacted]

Only Authorized Responsible Authorities may communicate about the Company or its business, or communicate as a representative of the Company, with any of the following External Parties:

- [redacted]

Only Authorized Responsible Authorities may communicate about the Company or its business or communicate as a representative of the Company [redacted]

6.2.1.2 Written Company Information

All Written Company Information conforms to [redacted]

All Written Company Information is approved by [redacted]

With respect to any Written Company Information regarding [redacted]

Written Company Information regarding [redacted]

7.0 PROCEDURE: RESOURCE MANAGEMENT

7.1 The management of resources is a critical component to the management activities of the Company.

Resources requiring such management includes:

- [redacted]

7.2 Like other management activities, resource management is [redacted]

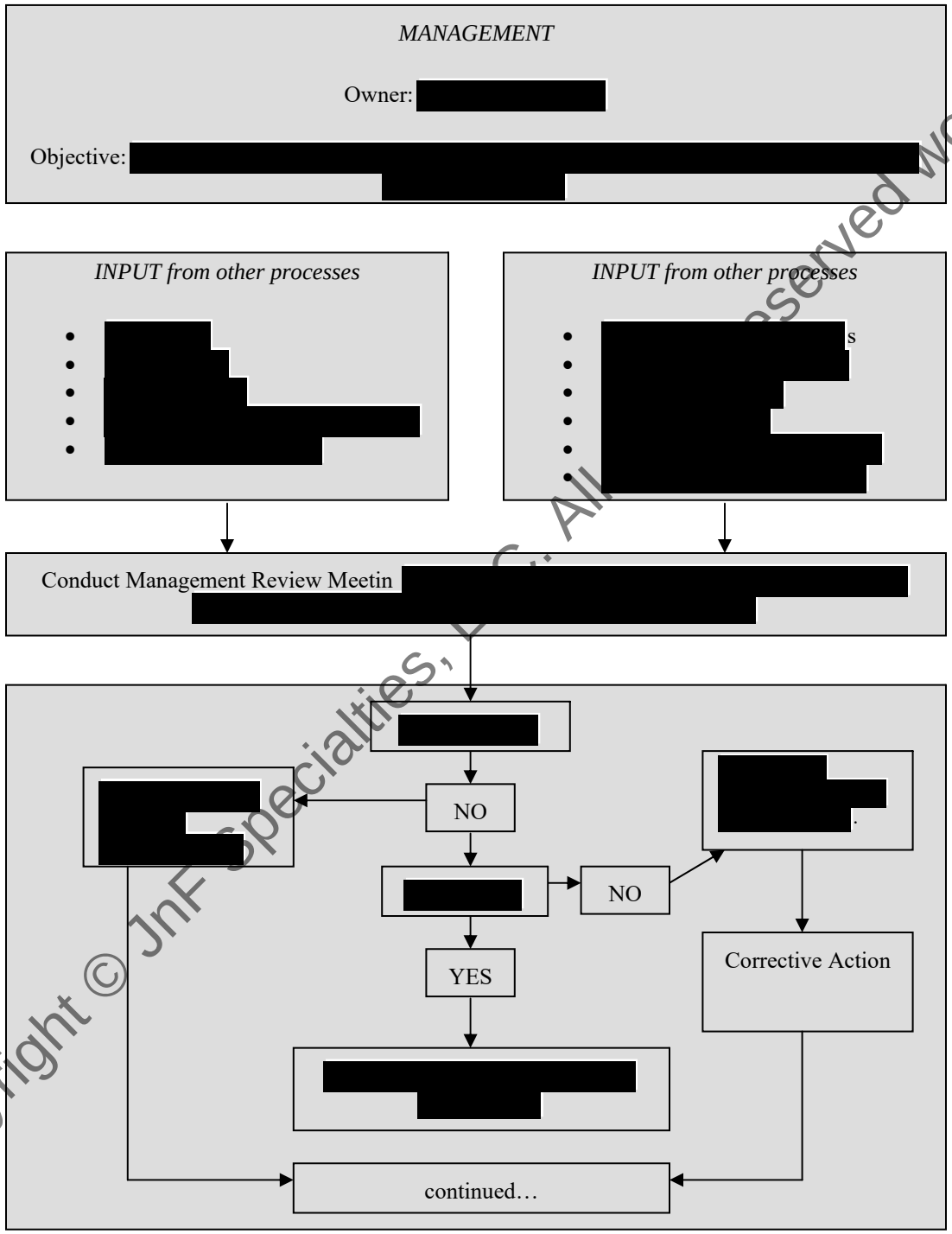
7.3 To manage resources, top management [redacted]

7.4 During Management Review, managers [redacted]

7.5 [redacted]

Left blank intentionally

Appendix A: Process Map



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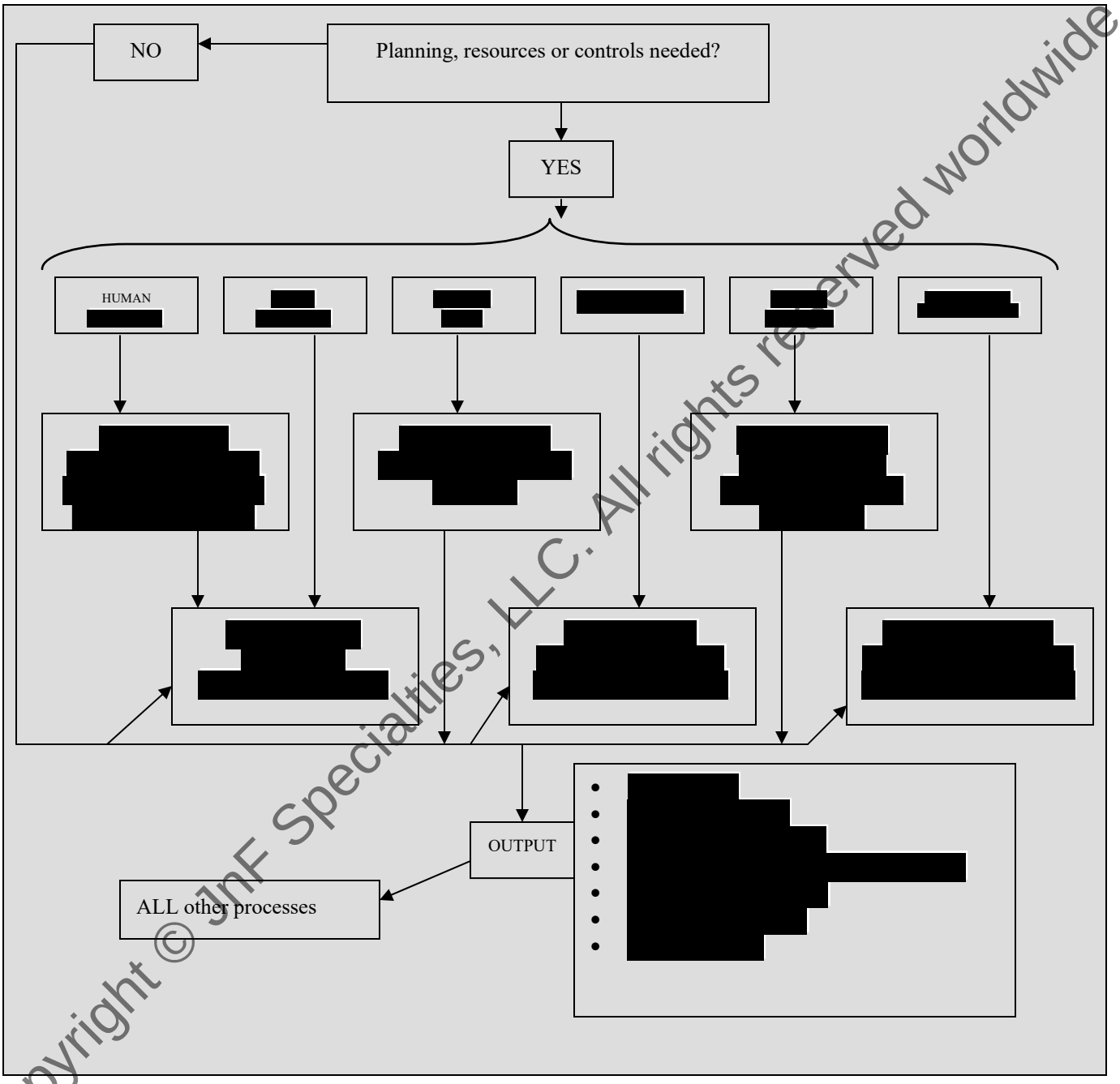


Your Logo

Your Company Name

RESPONSIBILITIES AND AUTHORITIES PROCEDURE

Origination Date: XXXX

Document Identifier:	QMS-05 Responsibilities and Authorities Procedure
Date:	Latest Revision Date
Project:	Customer, Unique ID, Part Number
Document Status:	Draft, Redline, Released, Obsolete
Document Link:	Location on Server (if used)

Abstract:
This document describes responsibilities and authorities of Company personnel.

REVISION LOG

Issue	Date	Comment	Author
Orig			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

1.0 PURPOSE

This document provides an overview of the responsibilities and authorities for key positions within the Company.

2.0 THEORY

It is important to define the responsibilities and authorities of key positions so that employees understand their work and the relationships they have with other positions within the Company.

3.0 RESPONSIBILITIES & AUTHORITIES

3.1 Operations Manager

The Operations Manager is responsible for [redacted]

3.2 Quality Manager

The Quality Manager is responsible for [redacted]

The Quality Manager:

- [redacted]

3.3 Facilities Manager

The Facilities Manager is responsible for [redacted]

3.4 Manufacturing Manager

The Manufacturing Manager is responsible for [redacted]

3.5 Business Manager

The Business Manager is responsible for [redacted]

3.6 Product Managers

The Company utilizes Product Managers for [redacted]

Product managers are responsible for:

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

3.7 Administrative Assistant

The Administrative Assistant is responsible for [redacted]

3.8 Accounting Manager

The Accounting Manager is responsible for [redacted]

3.9 Environmental Health & Safety Manager

The EHS Manager is responsible for [redacted]

3.10 Quality Group Staff & Inspectors (including Receiving)

The Quality Group includes [redacted]

3.11 Production Operators

Production operators include [redacted]

3.12 Internal Auditors

Internal Auditors are responsible for [redacted]

3.13 Shipping Personnel

Shipping personnel are responsible for [redacted]

3.14 Human Resources Staff

Human Resource staff is responsible for [redacted]

3.15 Purchasing Staff

Purchasing staff is responsible for [redacted]

Your Logo

Your Company Name

TRAINING PROCEDURE

Origination Date: XXXX

Document Identifier:	QMS-06 Training Procedure
Date:	Latest Revision Date
Project:	Customer, Unique ID, Part Number
Document Status:	Draft, Redline, Released, Obsolete
Document Link:	Location on Server (if used)

Abstract:
This document describes training program and requirements.

REVISION LOG

Issue	Date	Comment	Author
Orig			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

1.0 PURPOSE

This document provides details on the Company's training program and requirements.

2.0 THEORY

Employees can only perform their duties adequately when properly trained. The Company intends to ensure adequate employee performance through a robust training program that includes initial orientation, assessment of abilities and on-the-job training to enhance those abilities.

3.0 TRAINING PROCEDURE

3.1 Hiring

Employees are hired on their ability to [redacted]

To accomplish this, potential candidates are compared against the requirements of the ***QMS-05 Responsibilities and Authorities Procedure*** as well as [redacted]

3.2 Initial Indoctrination and Orientation

Once hired, new employees are assigned to their position and undergo initial indoctrination and orientation. This introduces the employee to [redacted]

3.3 On the Job Training

Once an employee has completed initial indoctrination, they undergo on-the-job training relative to their position, which includes [redacted]

3.4 Additional Training

At the discretion of management, additional training may be conducted at any time, which may be necessitated by [redacted]

Your Logo

Your Company Name

PROPOSAL DEVELOPMENT AND CONTRACT REVIEW PROCEDURE

Origination Date: XXXX

Document Identifier:	QMS-07 Proposal Development and Contract Review Procedure
Date:	Latest Revision Date
Project:	Customer, Unique ID, Part Number
Document Status:	Draft, Redline, Released, Obsolete
Document Link:	Location on Server (if used)

Abstract:
This document describes the procedures used to review contracts and develop proposals.

REVISION LOG

Issue	Date	Comment	Author
Orig			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

1.0 PURPOSE

This document defines the Proposal Development and Contract Review process including or making reference to procedures for the various activities within the process.

2.0 THEORY

The Company can only meet Customer requirements by ensuring that all such requirements are obtained from the Customer, then reviewed and understood. This process ensures the suitable capture of contractual and special requirements and ensures the Company's understanding of those requirements is communicated to the Customer prior to and through contract acceptance.

3.0 PROCEDURE

When addressing Customer needs and industry trends, the Company considers [redacted]

Documentation is not required for contract review and proposal development for Customers that purchase [redacted]

The Company determines its capability to meet Customer requirements by:

a) determining the requirements for products and services, which may include consideration for:

- [redacted]

- [redacted]

b) establishing the criteria for:

1) [redacted]
2) [redacted]

c) determining the organizational requirements and resources needed to [redacted]

d) implementing control of processes according to requirements;

e) determining, retaining and maintaining required records that demonstrate:

1) [redacted]
2) [redacted]

f) determining the processes and controls needed to [redacted]

g) [redacted]

h) [redacted]

i) [redacted]

j) [redacted]

k) [redacted]

The organization negotiates a mutually acceptable requirement with the Customer when it is determined that [redacted]

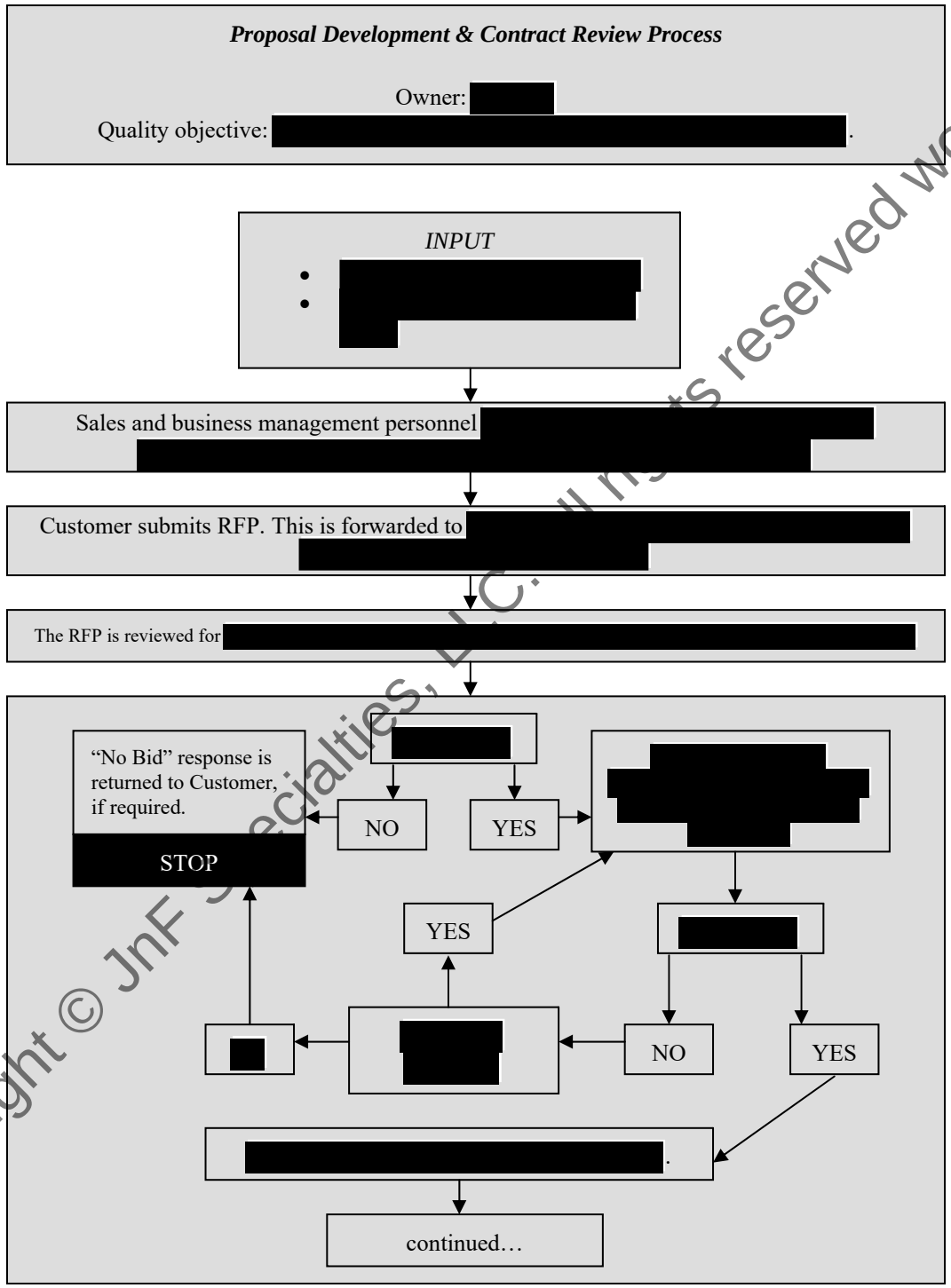
The Company plans and manages product and service provision in a planned sequence to meet requirements at acceptable risk within resource and schedule constraints using resources such as [redacted]

Risk mitigation planning for the provision of products and services is detailed in the ***QMS-18 Risk Mitigation and Planning Procedure***, with particular attention paid to:

- [redacted]

See Process Map.

4.0 PROCESS MAP



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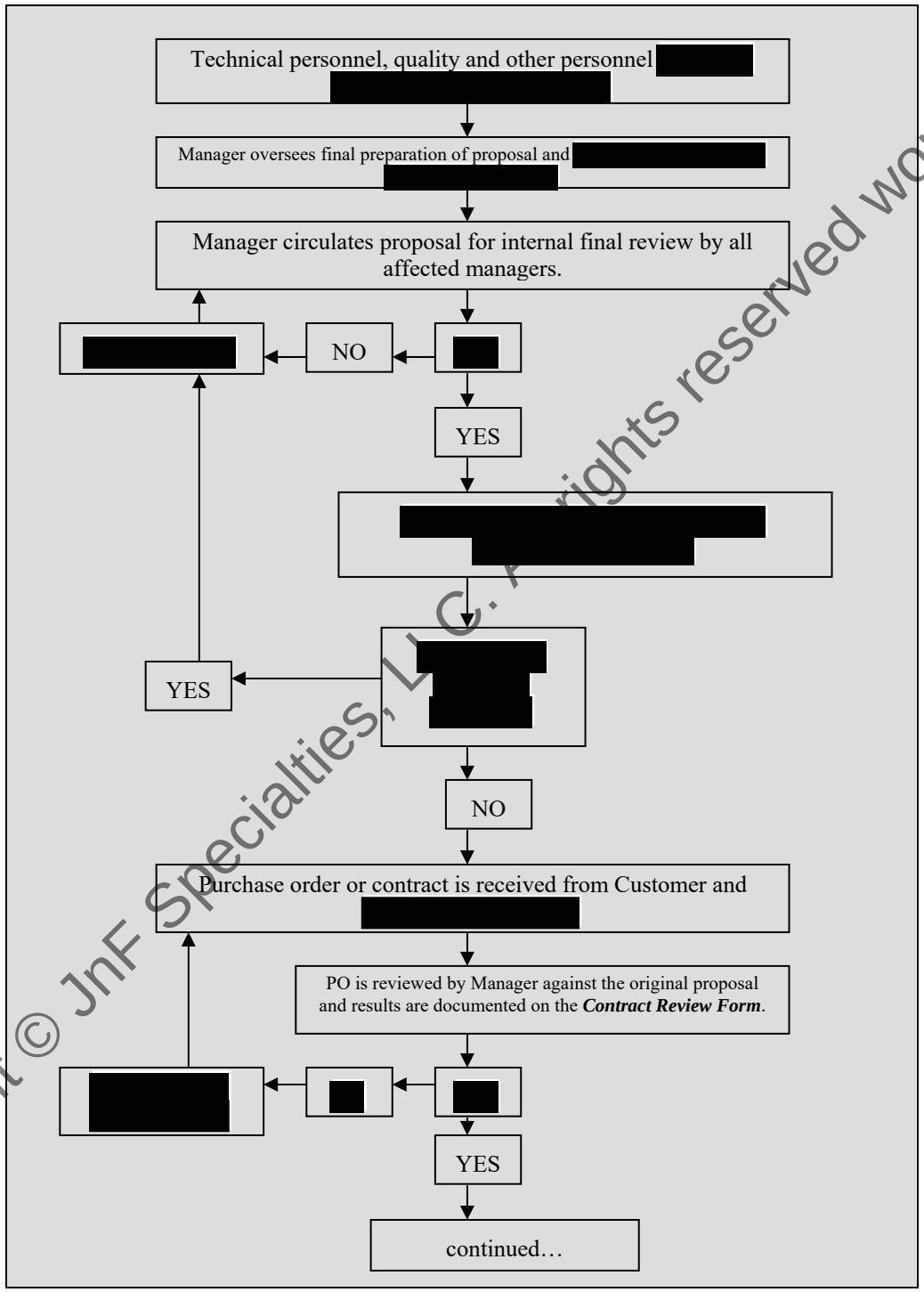

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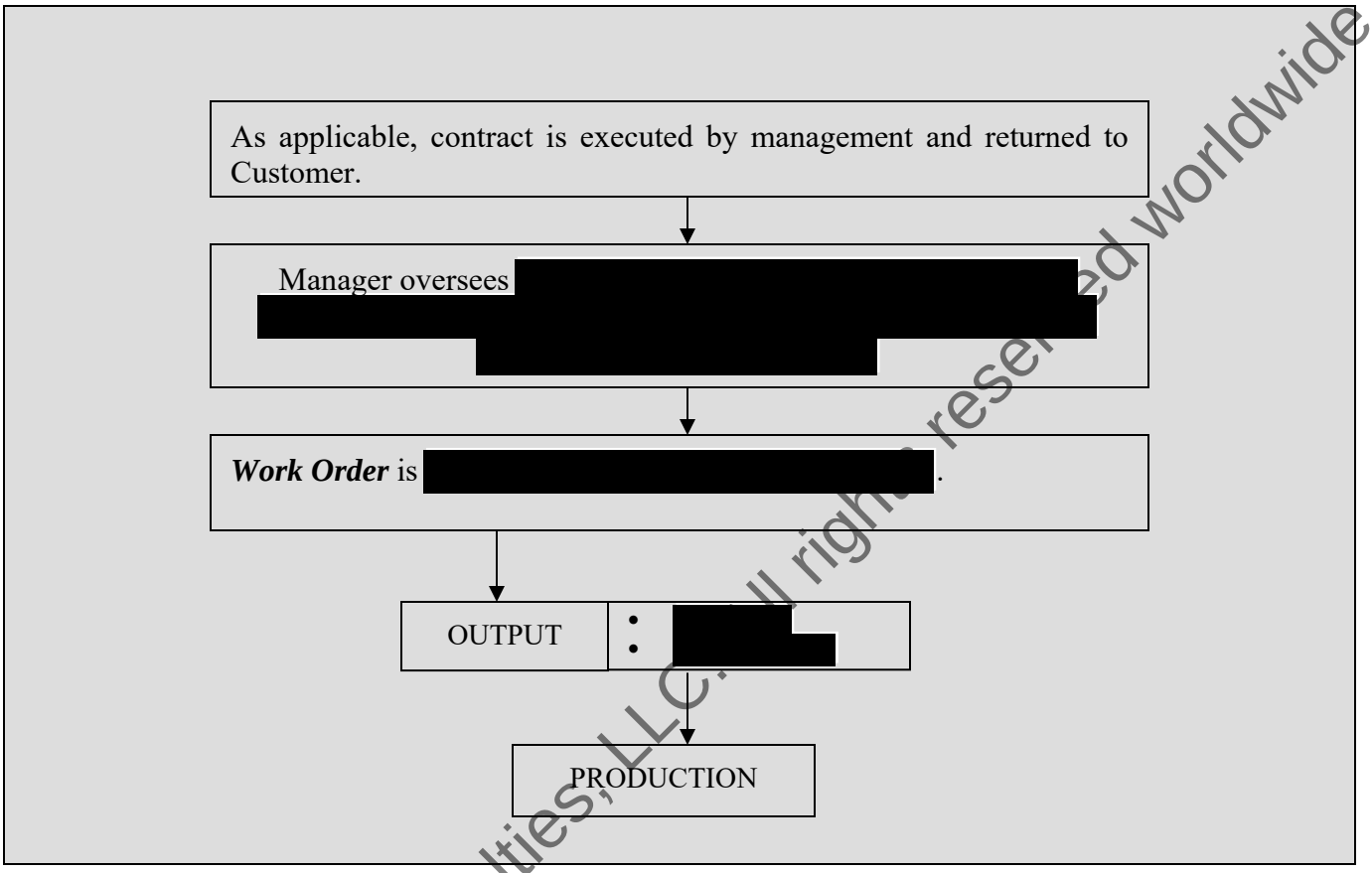


Your Logo

Your Company Name

PURCHASE ORDER REVIEW

Origination Date: XXXX

Document Identifier:	QMS-08-1 Purchase Order Review
Date:	Latest Revision Date
Project:	Customer, Unique ID, Part Number
Document Status:	Draft, Redline, Released, Obsolete
Document Link:	Location on Server (if used)

Abstract:
This document describes the work instruction for reviewing purchase order content.

REVISION LOG

Issue	Date	Comment	Author
Orig			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

1	Quality Group	-- The reviewer determines the need for, and if justified, imposes the requirements of Supplier Quality Requirements to the Requisition or P.O. -- Complete the Used-On and Contract# sections on the cover page of the PO Used-On = [redacted]; Contract# = [redacted] -- Check-off applicable requirement boxes on Requisition
2	Quality Group	-- Forward Requisition to [redacted] -- Check mark the appropriate field in the "Type of Certs" section; multiple types of Certs may be required. -- Verify Raw Material Requirements are recorded on Requisitions, *except* [redacted] -- Suppliers should be evaluated according to the Supplier Evaluation -- Determine if a Supplier has been designated by the Customer - notify Purchasing when [redacted] -- Initial and date (should be Mo/Day) the Requisition in the "Approved By" field and forward it to the Purchasing Group. -- Add known QA requirements to the requisition for entry on the PO; *such as* [redacted] -- [redacted] *may not be* -- [redacted] *may not be* [redacted]
	IF	THEN
2.1	Older Revision Supply Required	-- [redacted]
2.2	Requisition is marked "Under Revision"	-- [redacted] -- It is acceptable to [redacted]
2.3	A Raw Material Requirement **is not** Specified	-- Specify a Raw Material Requirement on the Requisition. -- A Material Note Number is not required for [redacted]
2.4	*Deviation to drawing is noted on Requisition such as "Less Note"* *Deviation to drawing is noted on Requisition such as "Less Note"*	[redacted]
2.5	*Order is for production*	[redacted]

	activity without reference to engineering drawing	*This provision is not applicable to* [redacted]
3	Quality Group	Add provisions for any one or combination of the following to the Requisition or P.O. when justified: [redacted]
4	Quality Group	Relative to the procurement of software, the reviewer determines the need for, and if justified, adds to the procurement document provisions for any one or combination of the following: [redacted]

		-- [redacted]
5	Discrepancy in Requisition or P.O.	-- Return to Purchasing Group for correction(s)
5.1	Supplier Quality Requirements applies	-- Attach prepared original to Requisition or P.O. -- Copy to R&I
5.2	P.O. requires additional conditions related to supplier	-- [redacted]
	IF	THEN
5.2.1	P.O. requires additional conditions related to in-house processing	[redacted]
5.2.2	Requisition or P.O. Ok	-- [redacted]
6	Quality Group	Forward Supplier Evaluation to the Supplier; perform required follow-up routines.

Your Logo

Your Company Name

PURCHASING PROCEDURE

Origination Date: XXXX

Document Identifier:	QMS-08 Purchasing Procedure
Date:	Latest Revision Date
Project:	Customer, Unique ID, Part Number
Document Status:	Draft, Redline, Released, Obsolete
Document Link:	Location on Server (if used)

Abstract:
This document describes the purchasing process.

REVISION LOG

Issue	Date	Comment	Author
Orig			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

1.0 PURPOSE

This document defines the Purchasing process including or making reference to procedures for the various activities within the process.

Note: this procedure applies to suppliers of products or providers of services that directly affects the quality of products and services. Suppliers that provide office and maintenance supplies, furniture, grounds keeping services, etc. are not subject to the controls of this procedure.

2.0 THEORY

The purchase of materials that go into our products or services that help us produce products affects everything we make. As a result, it is important to monitor and control the quality of both products and services that we receive as well as the suppliers of such products and services.

3.0 PROCEDURE: SUPPLIER EVALUATION AND SELECTION

3.1 All suppliers of product related materials or services are evaluated unless these Suppliers are listed on:

- [redacted]

3.2 Supplier evaluation is established according to Company requirements, [redacted], and is documented following the format on the ***Supplier Evaluation Form***.

3.3 The ***Supplier Evaluation Form*** ensures that all new suppliers are properly evaluated for criteria related to [redacted]

3.4 Once approved through the ***Supplier Evaluation Form***, the Responsible Authority will update the ***Approved Supplier List***.

3.5 The following ratings apply to suppliers:

- RESTRICTED: [redacted]
- CONDITIONAL: [redacted]
- UNRESTRICTED: [redacted]
- DOCK-TO-STOCK: [redacted]

3.6 Once entered into the ***Approved Supplier List***, suppliers are rated as [redacted]

3.7 Using incoming (receiving) inspection results for product suppliers and employee feedback on service providers, the Responsible Authority [redacted]

3.8 Using the results from combination of the following functions for product suppliers, the Responsible Authority [redacted]

3.9 For suppliers providing product, incoming inspection results are recorded on the ***Subcontractor Performance Rating Spreadsheet***, which calculates the Supplier's current quality rating based on items received and items accepted. A new Supplier that rates [redacted]

3.10 If a new Supplier rates [redacted]

3.11 If any Supplier rates less than [redacted]

3.12 If items are returned [redacted]

3.13 Any Supplier may be [redacted]

3.14 Management may override [redacted]

3.15 During management review, the entire ***Approved Supplier List*** is subject to [redacted]

3.16 The Company performs verification activities of externally provided processes, products and services when [redacted]

Customer verification activities performed at any level of the supply chain [redacted]

Verification activities may include:

- [redacted]
- [redacted]
- [redacted]

- [redacted]
- [redacted]
- [redacted]

When external provider test reports are utilized to verify externally provided products, the Company [redacted]

When the Company or Customer identifies raw material as a significant operational risk (critical item), the Company [redacted]

4.0 PROCESSING REQUISITIONS AND PURCHASE ORDERS

4.1 During review of each requisition, the Responsible Authority [redacted]

4.2 Responsible Authorities take into consideration [redacted]

4.3 Responsible Authorities ensure the adequacy of requirements prior to their communication to a Supplier, which includes:

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

4.4 When appropriate, the purchase order defines acceptance criteria for [redacted]

4.5 As applicable, purchase order information includes:

a) [redacted]

b) [redacted]

c) [redacted]

d) requirements relative to:

- [redacted]
- [redacted]
- [redacted]
- [redacted]

e) [redacted]

f) [redacted]

g) [redacted]

h) [redacted]

i) [redacted]

j) [redacted]

k) the need to:

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

l) [redacted]

m) ensuring that Responsible Authorities at the Supplier's facility are aware of:

- [redacted]
- [redacted]
- [redacted]

4.6 The requirements for delegation are defined when [redacted]

4.7 When the Company or its Customer needs to perform verification activities at a Supplier facility, the ***Purchase Order*** will define the methods for the intended verifications and method of product release.

4.8 See the process map herein.

4.9 Emergency Purchasing Authority: The Company will authorize the shift foreman and/or the maintenance foreman emergency purchase authority for [redacted]

5.0 OTHER PURCHASING RULES

5.1 In all instances, the Purchasing Department will [redacted]

5.2 Any employee of the Purchasing Department that has any financial or other interest in a supplier company, either directly or through any member of his/her immediate family, shall [redacted]

5.3 The acceptance by purchasing personnel of gifts or gratuities from suppliers is [redacted]

5.4 The acceptance of items intended for the purpose of advertisement and bearing the name of the Supplier is [redacted]

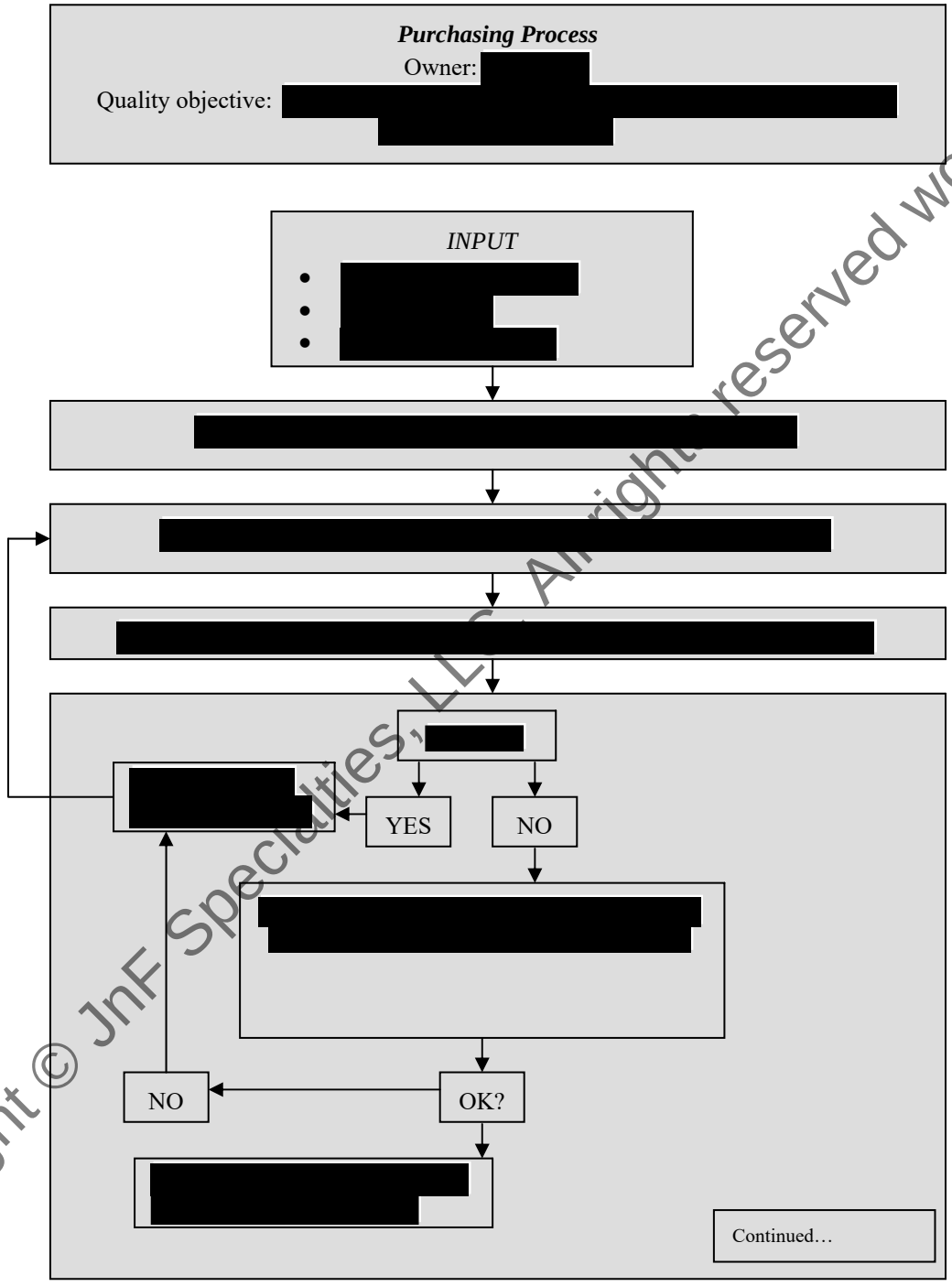
5.5 The Purchasing Department will [redacted]

5.6 The Purchasing Department will [redacted]

5.7 The Company will [redacted]

Left blank intentionally

6.0 PROCESS MAP



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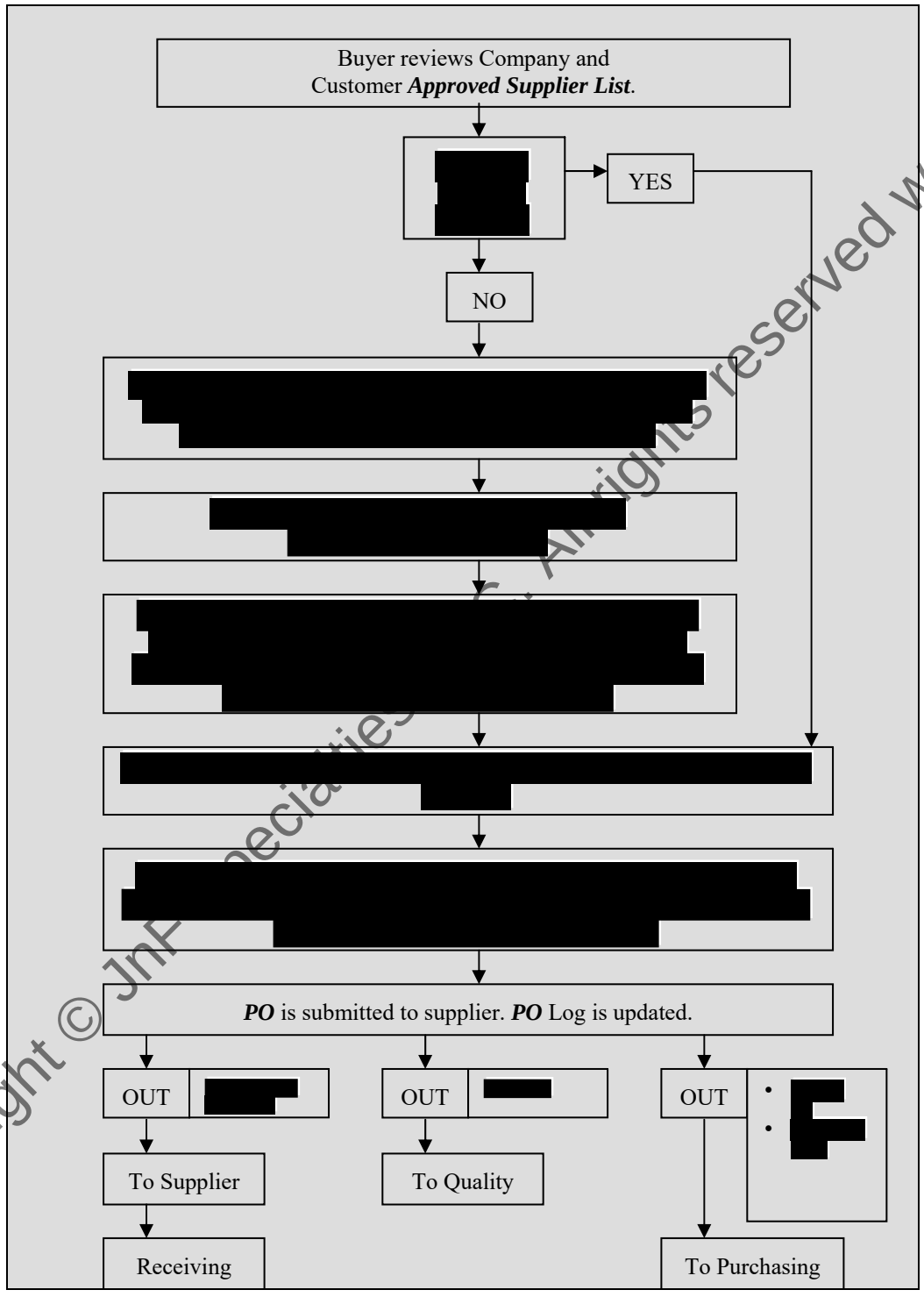


Your Logo

Your Company Name

RECEIVING PROCEDURE

Origination Date: XXXX

Document Identifier:	QMS-09 Receiving Procedure
Date:	Latest Revision Date
Project:	Customer, Unique ID, Part Number
Document Status:	Draft, Redline, Released, Obsolete
Document Link:	Location on Server (if used)

Abstract:
This document describes the receiving and inspection process.

REVISION LOG

Issue	Date	Comment	Author
Orig			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

1.0 PURPOSE

This document defines the Receiving process including receiving inspection activities and includes or makes reference to procedures for the various activities within the process.

2.0 THEORY

Receiving is the first line of defense to prevent sub-standard supplies from affecting the Company's process or product quality; however, sampling and 100% incoming inspection is only a part of the collection of applications that are necessary to assure the release of conforming supplies to stock. Receiving inspection cannot provide 100% assurance of product or process quality because the affect that the supplies have on production-level activities cannot be assessed or verified - only by 100% use of supplies will defects be detected in product or process quality.

As a result of teaming and intelligent design, the Company ensures that deliverable supplies meet Customer requirements prior to packaging and shipping.

3.0 PROCEDURE: RECEIVING

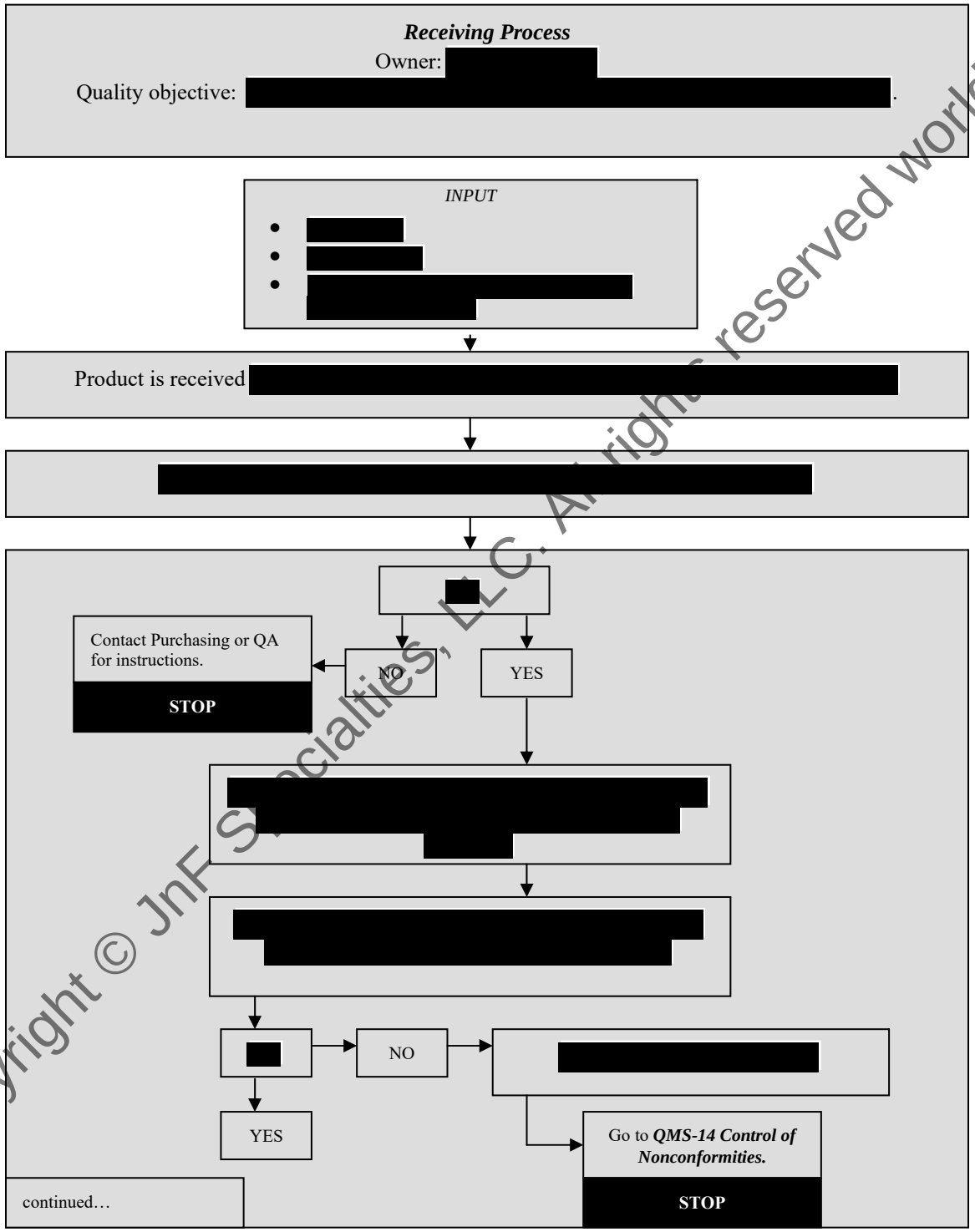
- [redacted]

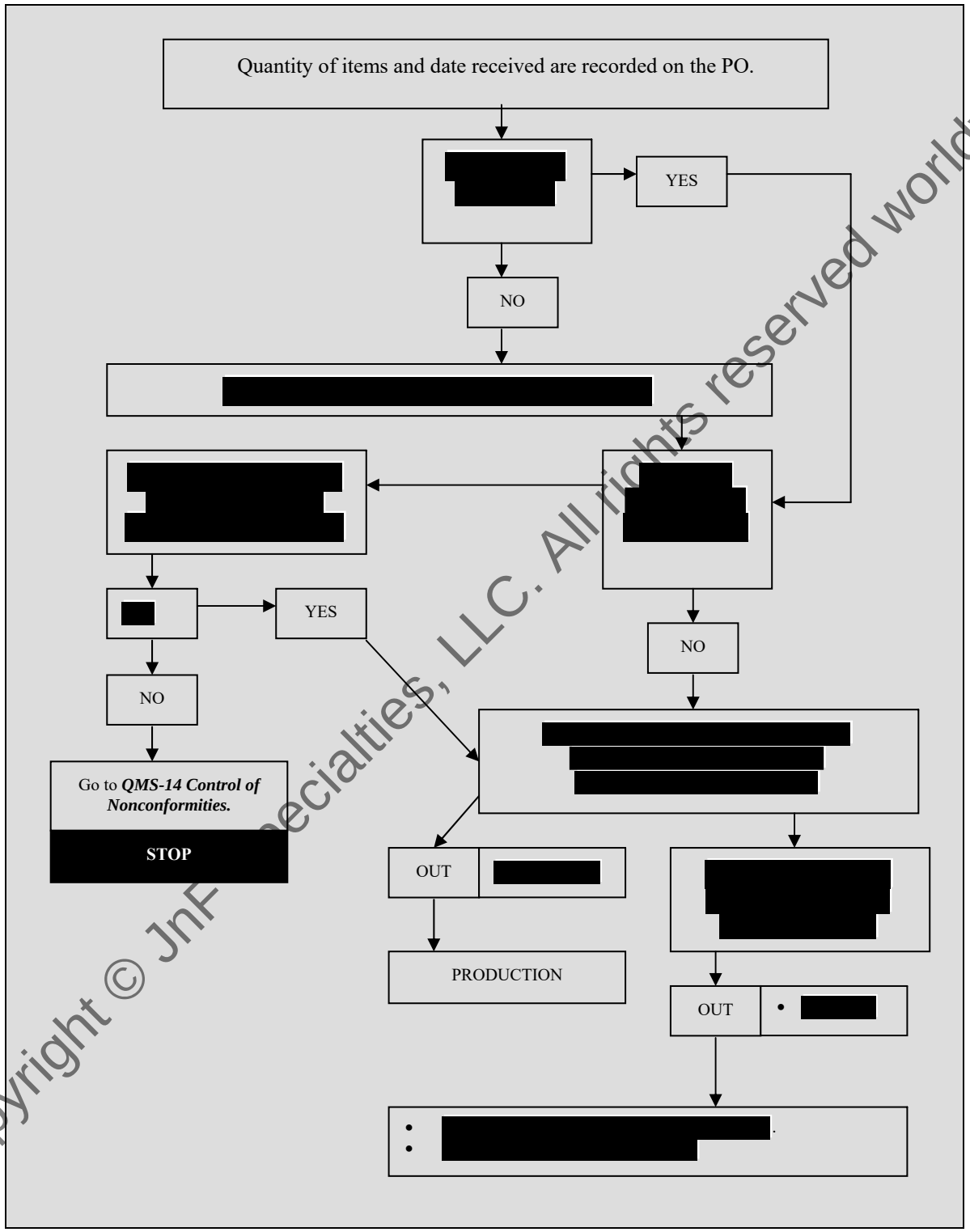
4.0 PROCEDURE: RECEIVING INSPECTION

4.1 The inspector will receive the items and original paperwork from the RA and acquire the applicable PO. (see the ***Purchasing Procedure***)

4.2 Inspections are performed according to Appendix A or as required by work instruction, Customer requirements or other documentation. The results are recorded on the applicable forms and the purchase order is processed according to Appendix B.

5.0 PROCESS MAP





APPENDIX A - RECEIVING INSPECTION WORK INSTRUCTIONS

Op 1: Acquire copy of purchase order. Perform [redacted]

Op 2: Verify supply [redacted]

Op 3: Count the quantity of items received. Items exempt from counting include [redacted]

Op 4: Verify the Supplier is approved according to the current ***Approved Supplier List*** - if Supplier is not listed then [redacted]

If Supplier provides a non-chemical item and is approved for [redacted]

If Supplier provides a chemical and is approved for [redacted]

Op 5: If the supply is a <Catalog/Commercial> item, [redacted]

Op 6: Perform First Piece Mechanical/Visual inspection [redacted]

Op 7: SAMPLING PLAN:

ANSI Z1.4 AQL=1.0 for all supplies that are [redacted] then…

Op 8: [redacted] then…

Op 9: [redacted] then…

Op 10: Verify conformance to the required chemical composition according to [redacted]

Op 11: When raw material is accepted only by review of Supplier certificate of analysis, review the current ***Approved Supplier List*** for item criticality and perform the following activities:

For critical item: [redacted]

[redacted]

For non-critical item: [redacted]

Op 12: When product is released [redacted]

Op 13: Verify lot traceability is [redacted]

Op 14: If the Supplier is a distributor [redacted]

Op 15: Affix a ***Good Material Tag*** to accepted supplies. For supplies that exhibit [redacted]

Op 17: Complete the inspection record following its format (record applicable M&TE, lot traceability, etc).

Op 18: Complete shelf life expiration log for supplies that have an expiration date.

Op 19: Record the quantity and date received on the PO then [redacted]

Op 20: If the Supplier's packaging is [redacted]

Op 21: Inspect Customer/Government furnished property upon receipt to verify condition and quantity. [redacted]

APPENDIX B - PURCHASE ORDER PROCESSING

Step	IF	THEN
1	Supply is not the Last Item on PO	[redacted]
2	Supply is the last Item on PO	[redacted] **NOTE:** Each entry into the ***Supplier Performance Report*** is [redacted]
2.1	Supply is the last Item on PO	Optional: [redacted]

Your Logo

Your Company Name

MANUFACTURING PROCEDURE

Origination Date: XXXX

Document Identifier:	QMS-10 Manufacturing Procedure
Date:	Latest Revision Date
Project:	Customer, Unique ID, Part Number
Document Status:	Draft, Redline, Released, Obsolete
Document Link:	Location on Server (if used)

Abstract:
This document describes the manufacturing process.

REVISION LOG

Issue	Date	Comment	Author
Orig			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

1.0 PURPOSE

This document defines the overall Manufacturing process and includes or makes reference to the procedures necessary for the process.

NOTE: The Manufacturing process includes all QC inspections and tests within it. Quality is not a separate process.

2.0 THEORY

Manufacturing operations or tasks must be conducted under controlled conditions to ensure product quality. By this we mean:

- [redacted]

3.0 PROBLEM RESOLUTION

All employees are instructed to immediately notify a Responsible Authority (RA) whenever a process or product related problem occurs that cannot be corrected according to established process controls and could [redacted]

It is understood that the appropriate responsible authority will [redacted]

- [redacted]

4.0 REQUIREMENTS

The Company implements production and service provision under controlled conditions, which includes:

- [redacted]

- [redacted]
- [redacted]
- [redacted]

5.0 PRODUCTION DOCUMENTATION

Documented information includes [redacted]

Documented information that defines characteristics of products and services includes [redacted]

When required to demonstrate product qualification, the Company [redacted]

The Company ensures all documented information required to accompany the products and services are present at delivery.

5.1 All revision controlled production documents are [redacted]

5.2 In addition to this process procedure, additional production documentation may be required for a given order or production operation. Where required, these are [redacted]

5.3 Such documentation includes [redacted]

5.4 Records that are created for temporary retention of miscellaneous information are not [redacted]

6.0 PRODUCT IDENTIFICATION

The Company maintains the identification of the configuration of products and services to identify [redacted]

The Company controls acceptance authority media, such as [redacted]

6.1 Product is identified in shop areas by any of the following methods:

- [redacted]
- [redacted]
- [redacted]

[redacted]

6.2 Lot traceability or individual serialization of parts is to be maintained on the paperwork (travelers, routers, etc.) as required. Supervisory staff will [redacted]
Traceability requirements include:

- [redacted]

6.3 Bad (nonconforming) product that has failed an inspection or test and cannot be reworked to comply with requirements is [redacted]
See the ***QMS-14 Control of Nonconformities Procedure***.

6.4 Any parts or product not marked with a tag are [redacted]

6.5 IDENTIFICATION OF TRANSFER CONTAINERS
6.5.1 Whenever a portion of chemical is transferred from its original container to a smaller temporary container, [redacted]
6.5.2 Whenever a portion of chemical is transferred from its original container to a smaller permanent container, [redacted]

7.0 PRODUCT HANDLING

7.1 Work instructions and/or training operations instruct Operators on the proper and safe handling of product throughout its life cycle, and includes [redacted]

7.2 In all cases, Operators are [redacted]

7.3 The Company provides suitable safety and personal protection equipment for handling hazardous or toxic materials. Operators are [redacted]

8.0 PRESERVATION

8.1 Operators will [redacted]

8.2 Operators will [redacted]

8.3 Operators will [redacted]

8.4 Operators will [redacted]

8.5 FOD: Foreign Object Damage, Prevention, Detection and Removal: Work instructions and training methods ensure that handling and preservation practices reduce the introduction of foreign objects (FOD) into products.

8.6 [redacted]

8.7 [redacted]

9.0 EXTERNAL PROVIDER PROPERTY CONTROL

The Company identifies, verifies, protects and safeguards External Provider property provided for use or incorporation into products and services. When property is lost, damaged or otherwise found to be unsuitable for use, the Company documents findings and reports to the Customer.

9.1 External Provider Property (Property) means [redacted]

Hardware property includes:

- [redacted]

9.2 All External Provider furnished hardware property shall [redacted]

9.3 Property shall be identified [redacted]

9.4 Sensitive material, as defined by the External Provider, shall [redacted]

9.5 Property shall only be used as instructed or required by External Provider contract and [redacted]

9.6 External Provider equipment shall [redacted]

9.7 The Responsible Authority investigates [redacted]

9.8 Requirements for the control of External Provider property shall [redacted]

10.0 VALIDATION OF PROCESSES

10.1 Unless otherwise specified by engineering requirements, the form named ***Validation-Verification*** is used to record results of validation and verification activities (may be referred to as "special processes").

10.2 Validation and verification activities include [redacted]

Provisions for validation and verification includes:

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

11.0 PRODUCTION PROCESS VERIFICATION

The Company implements production process verification activities to [redacted]

11.1 Control of Equipment, Tools, and Software Programs

Equipment, tools, and software programs used to automate, control, monitor or measure production processes are [redacted]

12.0 INSPECTION AND TEST OF PRODUCT OR SERVICE

The Company maintains suitable infrastructure for the provision of products and services, which includes [redacted]

12.1 Receiving inspection is performed according to the ***QMS-09 Receiving Procedure***.

12.2 First Article Inspection

The Company uses a representative item from the first production run of a new part or assembly to verify the production processes, production documentation and tooling are able to produce parts and assemblies that meet requirements. This activity is [redacted]

12.2.1 First article inspections are [redacted]

12.2.2 The Company will [redacted]

12.2.3 Where not provided, the Company will [redacted]

12.2.4 Complete the first article inspection form according to its format and submit to CCB.

12.2.5 Calibrated tools shall be used for first article inspection; however, [redacted] under the following conditions:

1) [redacted]

2) [redacted]

12.2.6 [redacted]

12.2.7 Any item failing first article inspection must be processed according to the ***QMS-14 Control of Nonconformities Procedure***.

12.3 In Process Inspections

12.3.1 In-process inspection is performed by [redacted]

12.3.2 In-process inspections are performed [redacted]

The Company ensures documented information for monitoring and measurement activity for product acceptance includes:

- [redacted]
- [redacted]
- [redacted]
- [redacted]

When sampling is used as a means of product acceptance, the sampling plan is [redacted]

12.3.3 Calibrated tools shall be used for in-process inspection; however, [redacted] under the following conditions:

1) [redacted]

2) [redacted]

12.3.4 When applicable, complete the production inspection form according to its format.

12.3.5 [redacted]

12.3.6 Any item failing in-process inspection must be processed according to the ***QMS-14 Control of Nonconformities Procedure***.

12.4 Final Inspection

12.4.1 Final inspection is performed by Responsible Authority(s) prior to release of product for packaging and shipping.

12.4.2 100% sampling is required for final inspection unless otherwise specified by Customer contract. When sampling is permitted by Customer contract, [redacted]

12.4.3 Calibrated equipment is used for final inspection and documented information provides traceability to specific monitoring and measurement equipment; however, [redacted] under the following conditions:

1) [redacted]

2) [redacted]

12.4.4 Complete the production inspection form according to its format. Prior to final acceptance, confirm [redacted]

12.4.5 Any item failing final inspection must be processed according to the ***QMS-14 Control of Nonconformities Procedure***.

12.4.6 Prior to product delivery to Customer, the Responsible Authority [redacted]

13.0 SHELF LIFE EXTENSION

[redacted]

13.1 Items that are subject to expiration may [redacted] for instance:

13.1.1 [redacted]

13.1.2 [redacted]

13.1.3 [redacted].

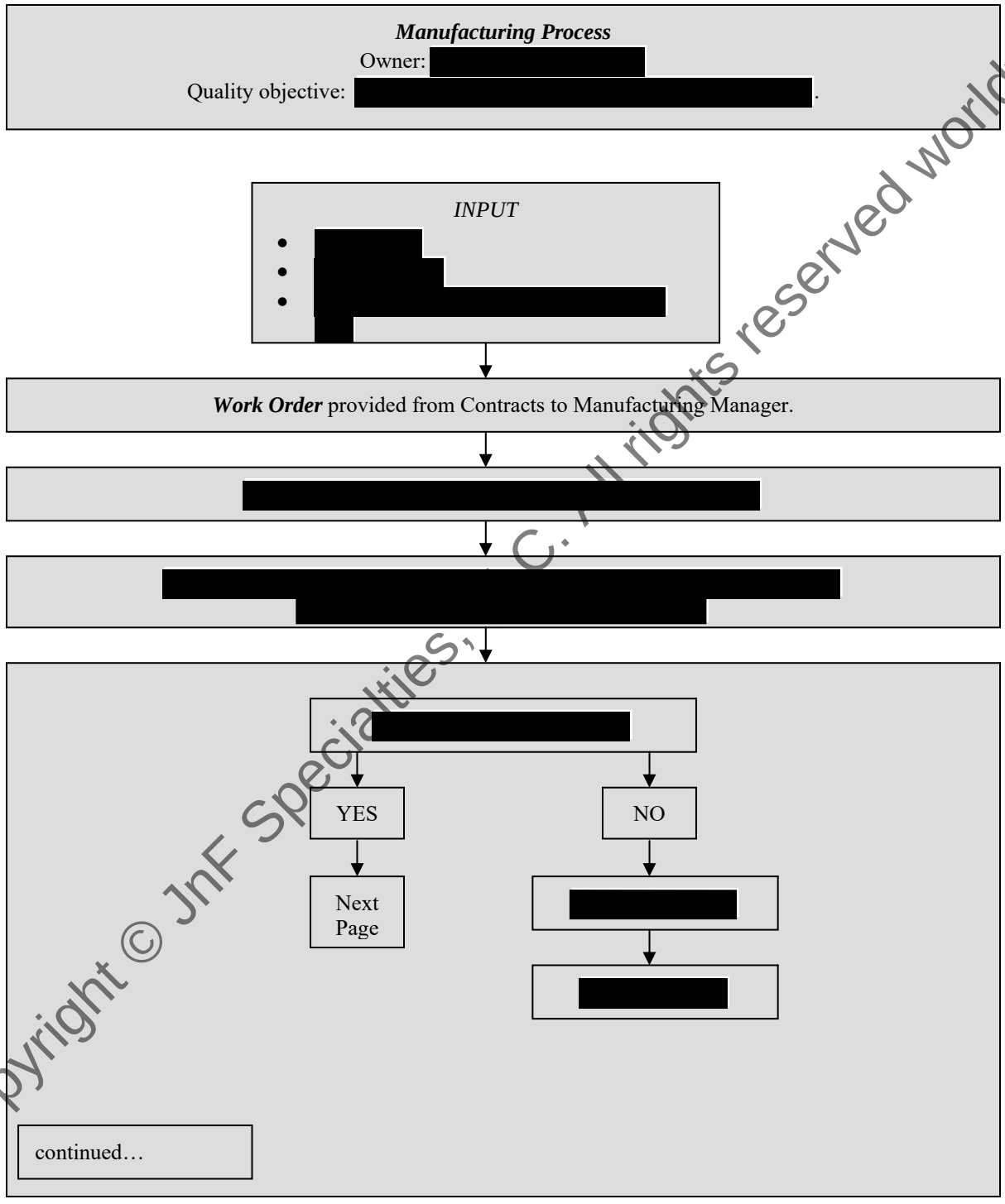
13.1.4 [redacted]

13.2 Chemicals that are purchased or prepared by the chem-lab are [redacted]

13.3 Raw material components whose shelf life has [redacted]

Left blank intentionally

14.0 PROCESS MAP



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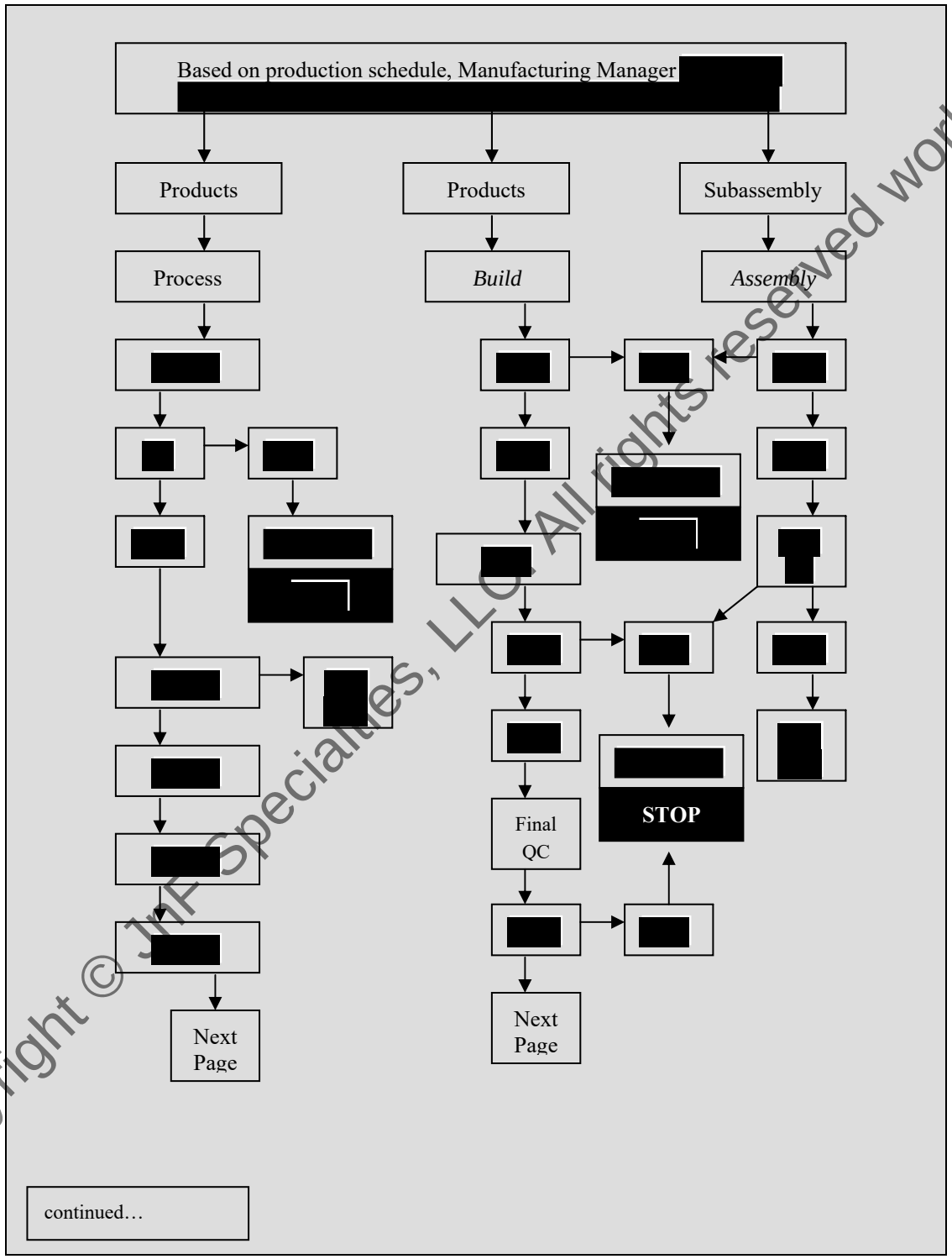

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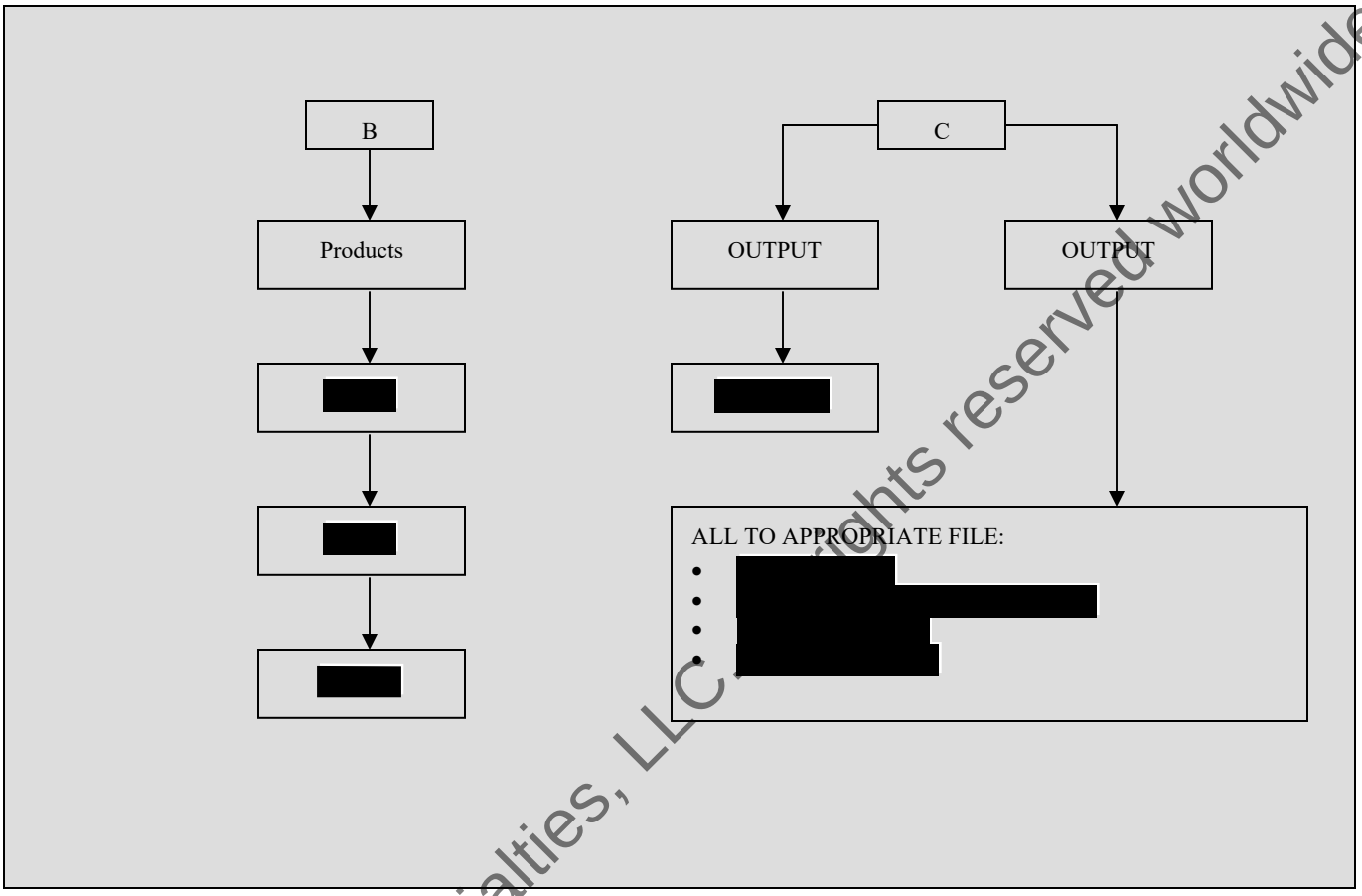


Your Logo

Your Company Name

SHIPPING PROCEDURE

Origination Date: XXXX

Document Identifier:	QMS-11 Shipping Procedure
Date:	Latest Revision Date
Project:	Customer, Unique ID, Part Number
Document Status:	Draft, Redline, Released, Obsolete
Document Link:	Location on Server (if used)

Abstract:
This document describes the shipping process.

REVISION LOG

Issue	Date	Comment	Author
Orig			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

1.0 PURPOSE

This document defines the Shipping process including product packaging activities.

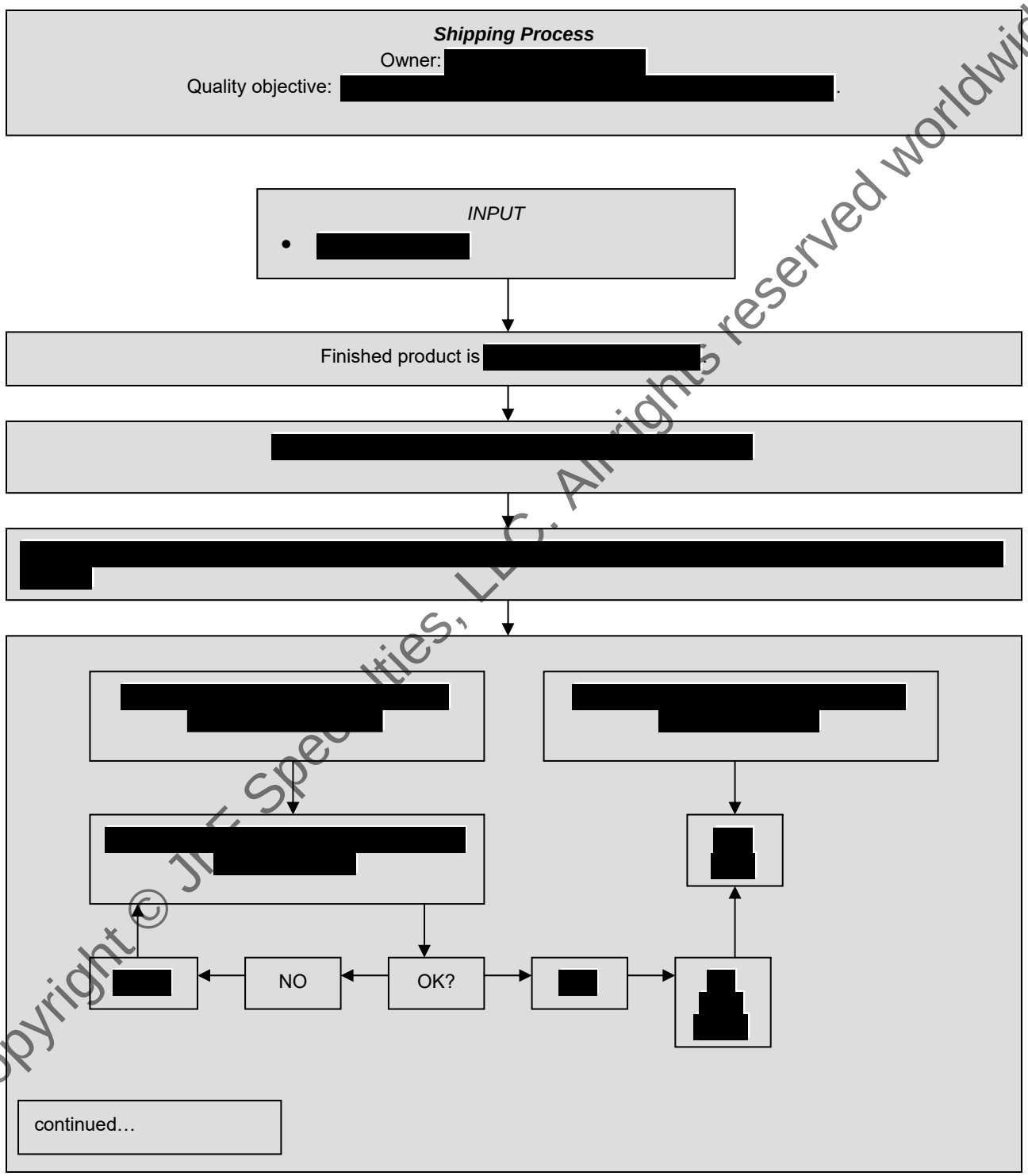
2.0 THEORY

The final packaging and arrangement of shipping is critical to the quality of product as received by the Customer; as a result, the Company [redacted]

3.0 PROCEDURE: PACKAGING AND SHIPPING

See process map.

PROCESS MAP



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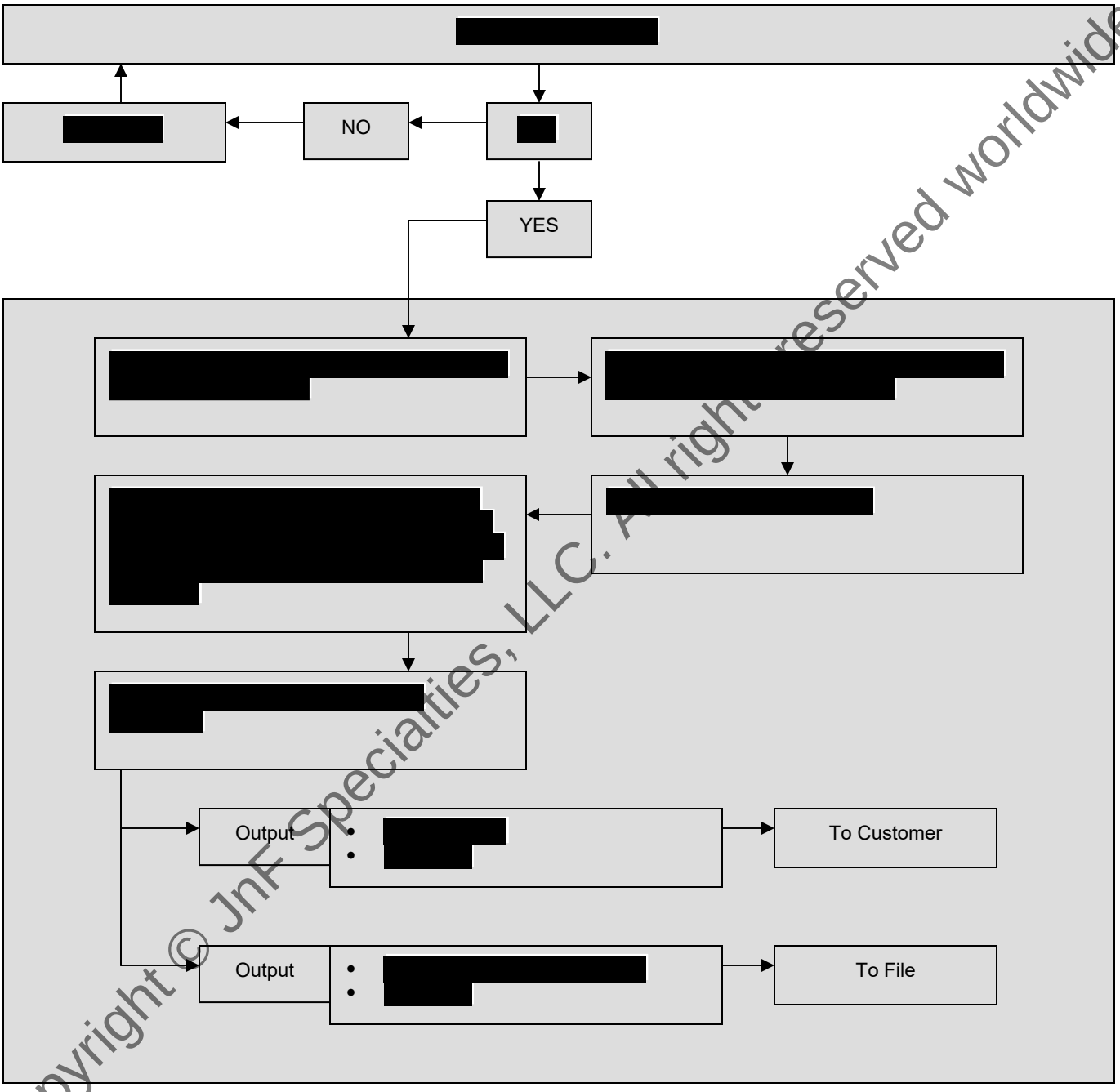


Your Logo

Your Company Name

INTERNAL AUDITING PROCEDURE

Origination Date: XXXX

Document Identifier:	QMS-12 Internal Auditing Procedure
Date:	Latest Revision Date
Project:	Customer, Unique ID, Part Number
Document Status:	Draft, Redline, Released, Obsolete
Document Link:	Location on Server (if used)

Abstract:
This document describes the procedure used to audit the quality management system.

REVISION LOG

Issue	Date	Comment	Author
Orig			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

1.0 PURPOSE

This document provides details and procedures for the internal auditing process.

NOTE: At this time, only quality system audits are conducted. When environmental system or other audits are implemented, this procedure will be amended to include rules for additional audits.

2.0 THEORY

Internal auditing of a Company's quality system is critical for maintaining good processes and documentation and for identifying areas for improvement opportunity.

3.0 INTERNAL AUDITING PROCEDURE

The Responsible Authority takes into consideration [redacted]

3.1 Internal quality audits are conducted on time according to [redacted]

3.2 Audit requirements include those of ***AS9100*** and the Company's quality system documents (policies, procedures, processes, instructions, specifications, etc.) as well as requirements of Customers and statutory/regulatory requirements (published legislation and regulations) and quality management system standards. [redacted]

3.3 Auditors may [redacted]

3.4 Minimum auditor training requirements are as follows:

- Contract (third party) auditors: [redacted]
- Internal auditors: [redacted]

3.5 The Responsible Authority assigns a Lead Auditor for each audit. The Responsible Authority applies [redacted] then considers:

- [redacted]

The Responsible Authority defines the criteria, [redacted]) and scope ([redacted]) for each identified audit.

3.6 The Responsible Authority maintains the ***Internal Audit Schedule*** that records this information.

3.7 Using the ***Internal Audit Report***, the Lead Auditor [redacted]

3.8 [redacted]

3.9 The internal audit [redacted]

3.10 [redacted]

3.11 The completed ***Internal Audit Report*** is then returned to the Responsible Authority for logging and the ***Internal Audit Schedule*** is updated.

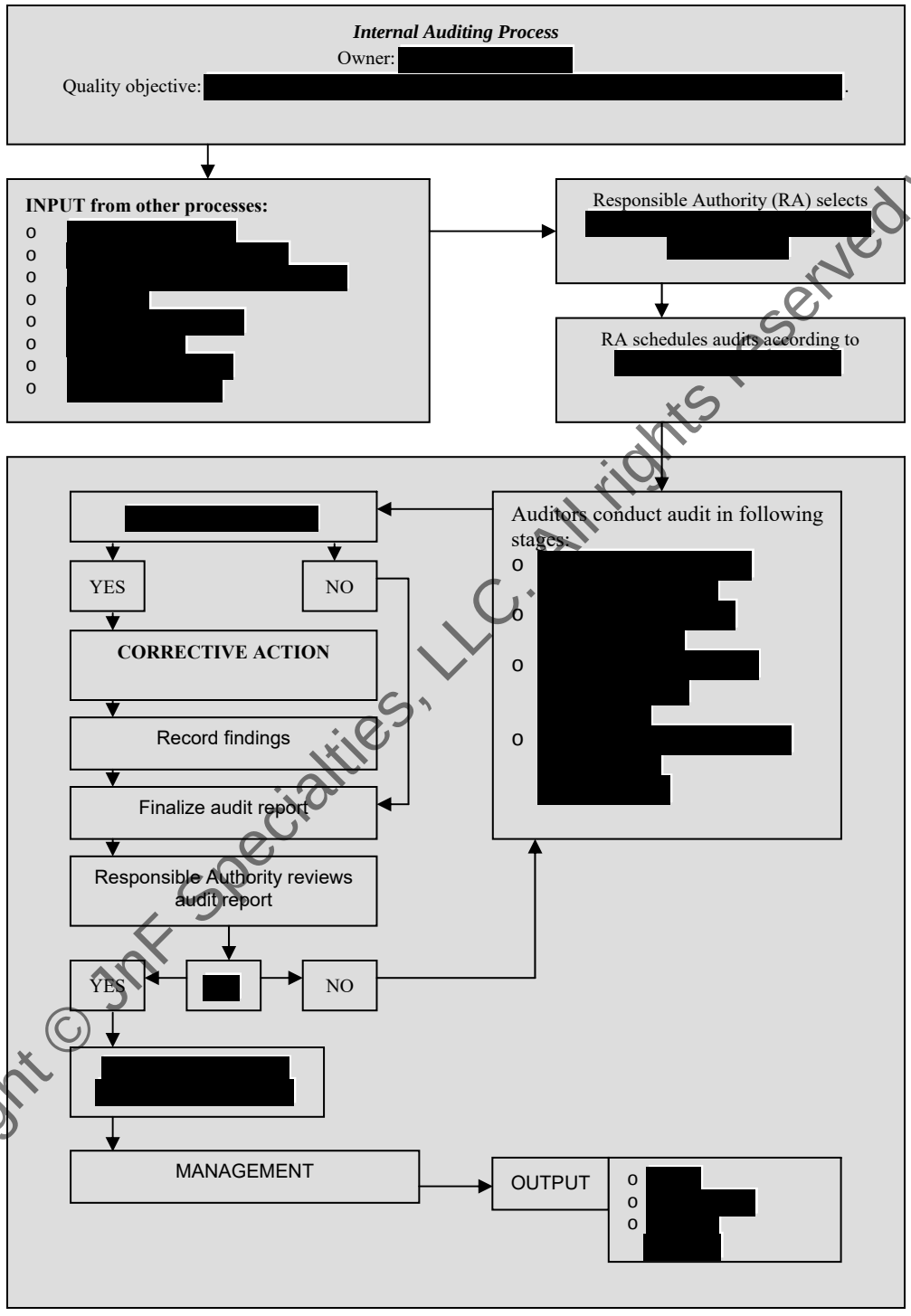
3.12 Copies of the completed audit report are sent to the appropriate managers of the areas audited to report the findings and results. In this way, and in conjunction with the submission of corrective action requests, [redacted]

3.13 The results of internal audits are also gathered and summarized on [redacted]

3.14 In all cases, auditees are expected to cooperate fully with the audit team.

Left blank intentionally

4.0 PROCESS MAP



Your Logo

Your Company Name

CORRECTIVE ACTION PROCEDURE

Origination Date: XXXX

Document Identifier:	QMS-13 Corrective Action Procedure
Date:	Latest Revision Date
Project:	Customer, Unique ID, Part Number
Document Status:	Draft, Redline, Released, Obsolete
Document Link:	Location on Server (if used)

Abstract:
This document describes the procedures used to correct and prevent nonconformities.

REVISION LOG

Issue	Date	Comment	Author
Orig			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

1.0 PURPOSE

This document provides details and procedures for the process governing the discovery, reporting, resolution and recording of actions taken to correct or prevent nonconformities.

2.0 THEORY

Corrective action is taken to correct nonconformities, which could be product defects found during production, errors found in documents, equipment problems or problems related to how the Company performs functions in its processes. "Corrective action" is simply the "fix" that corrects the problem.

Whenever we take corrective action we also attempt to prevent the problem from recurring. Sources for preventive action opportunities include risk management, error proofing, failure mode and effects analysis and reports of product problems by external sources. Having a formal system to record and resolve both existing and potential problems ensures that these problems do not occur or reoccur, thereby improving our products, processes and work environment.

3.0 PROCEDURE: INTERNAL REPORTS

3.1 The Company utilizes a ***Request for Support*** (RFS) form to [redacted]

3.2 ALL employees are empowered with the ability to report sources of problems and nonconformances.

3.3 No disciplinary action may be attached to the submission of RFS's.

3.4 The Quality Manager has been assigned the role of RFS Administrator.

3.5 See Process Map for the processing and routing of RFS's.

3.6 If the responsible manager determines they are not responsible for the issue involved, [redacted]

3.7 Actions taken shall [redacted]

3.8 The Quality Manager shall [redacted]

3.9 In addition to corrective action efforts, management shall [redacted] which shall be used to prevent potential nonconformances. These shall be reported to management for review.

3.10 The management review process shall [redacted]

3.11 Where product is suspected of a nonconformance, the Company [redacted]

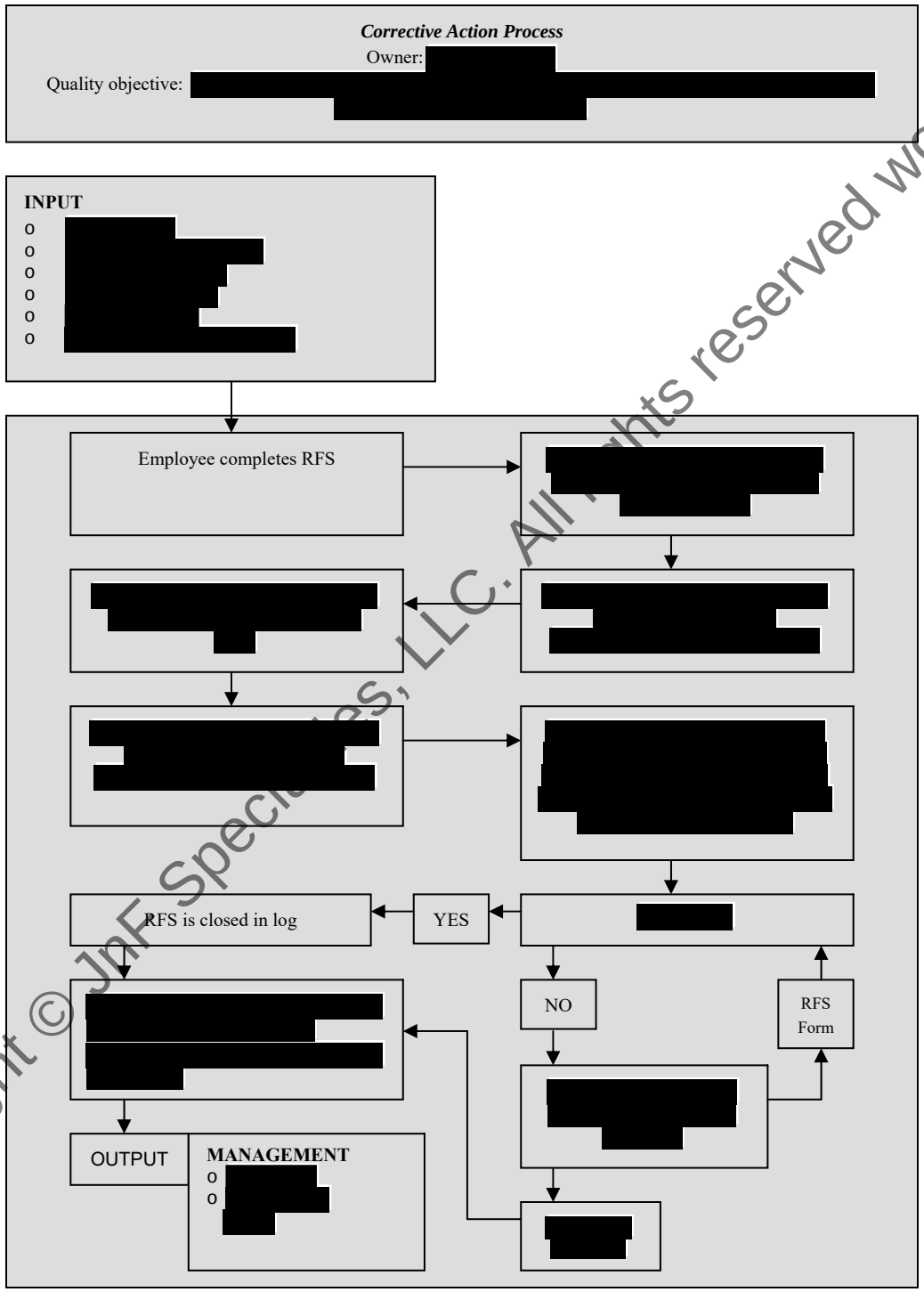
4.0 PROCEDURE: INVESTIGATION & CORRECTIVE ACTION REQUESTS (ICAR's)

4.1 Any purchasing agent may submit an ***Investigation and Corrective Action Request*** (ICAR) to a Supplier that [redacted]

4.2 ICAR's are processed through the same steps as the RFS but are routed to the Supplier for [redacted]

4.3 Failure of a Supplier to respond to an ICAR or to respond with an insufficient action plan may mean [redacted]

5.0 PROCESS MAP



Your Logo

Your Company Name

CONTROL OF NONCONFORMITIES PROCEDURE

Origination Date: XXXX

Document Identifier:	QMS-14 Control of Nonconformities Procedure
Date:	Latest Revision Date
Project:	Customer, Unique ID, Part Number
Document Status:	Draft, Redline, Released, Obsolete
Document Link:	Location on Server (if used)

Abstract:
This document describes procedures for control of nonconformities.

REVISION LOG

Issue	Date	Comment	Author
Orig			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

1.0 PURPOSE

This document defines and makes reference to the procedures necessary for the control of nonconformities.

2.0 THEORY

Product or services that have failed inspections or tests or that in any way do not meet requirements are considered "nonconforming". Nonconformities must be controlled to ensure they are not accidentally delivered or used. The Company's system ensures that nonconformities are identified when found and are segregated, investigated and dispositioned. Corrective actions are taken to ensure nonconformities do not reoccur.

3.0 GENERAL PROCEDURE

3.1 A nonconformity occurs when any service or product made by the Company or raw material used by the Company or returned from the Customer does not meet:

- [redacted]

3.2 Nonconformities must [redacted]

3.3 All employees are empowered to engage this procedure when they discover potential or actual nonconforming product or services. No employee may work on [redacted]

3.4 Upon discovery of a nonconformity, an employee may make an attempt to perform immediate rework if such rework is within that employee's ability. For example, [redacted]

3.5 When an employee cannot bring the item into conformance through immediate rework, the employee shall [redacted]

3.6 [redacted]

3.7 The employee shall complete the top portion of the ***RFS form***, filling in all pertinent spaces, which includes [redacted]

3.8 The employee shall [redacted]

3.9 Upon receipt of the RFS, the Responsible Authority will [redacted]

3.10 The Responsible Authority will [redacted]

3.11 If the nonconformity is ascertained or estimated to be the fault of a Supplier, the Responsible Authority may elect to submit an ***Investigation and Corrective Action Request*** (ICAR) to the supplier. In such cases, the ICAR number shall be referenced on the RFS. For more on the ICAR system see the ***QMS-13 Corrective Action Procedure***.

3.12 If a document supplement is required or if a configuration change is required, the Responsible Authority will [redacted]

3.13 The RFS shall then be submitted to the Material Review Board (MRB) for review and disposition. Necessary actions are taken to [redacted]

3.14 The MRB consists of the following managers, at a minimum:

- [redacted]
- [redacted]
- [redacted]

3.14.1 MRB Qualification

A Material Review Board member must:

1) [redacted], or [redacted]; or

2) [redacted]

3.15 In the event of a non-unanimous decision, [redacted]

3.16 The Company shall provide timely reporting of delivered nonconformities that may affect [redacted]

4.0 DISPOSITIONS

4.1 Dispositions are classified as Major, Minor or None.

4.1.1 Major: [redacted]

4.1.2 Minor: [redacted]

4.1.3 None: [redacted]

4.2 MRB dispositions may include, but are not limited to:

- [redacted]

4.2.1 Clarification

[redacted]

4.2.2 Conditional Acceptance

[redacted]

4.2.3 Non-Deliverable

[redacted]

4.2.4 Notification

[redacted]

4.2.5 Precautionary

[redacted]

4.2.6 Repair (Non-Standard and Standard)

[redacted]

4.2.7 Request for Waiver/Deviation

[redacted]

4.2.8 Return to Supplier (Receiving Inspection)

[redacted]

4.2.9 Rework (Non-Standard and Standard)

[redacted]

4.2.10 Scrap [redacted]

5.0 CUSTOMER DISPOSITION AUTHORITY

5.1 Major: A Waiver/Deviation disposition is [redacted].

5.2 RTV and Scrap dispositions are [redacted]

5.3 Minor: Conditional Accept and Non-Standard Rework/Repair dispositions are [redacted]

5.4 Scrap, RTV or Standard Rework dispositions are [redacted].

5.5 None: [redacted]

6.0 PROCESSING SCRAP

6.1 Items dispositioned as scrap are physically segregated into an appropriate scrap area.

6.2 Such scrap is [redacted]

6.3 Identifying scrap with markings is unacceptable unless [redacted]

6.4 Scrap is controlled internally so as not to be made available for possible theft, which precludes the use of outdoor scrap bins or other storage areas generally accessible to non-employees.

Your Logo

Your Company Name

CALIBRATION PROCEDURE

Origination Date: XXXX

Document Identifier:	QMS-15 Calibration Procedure
Date:	Latest Revision Date
Project:	Customer, Unique ID, Part Number
Document Status:	Draft, Redline, Released, Obsolete
Document Link:	Location on Server (if used)

Abstract:
This document describes calibration procedures.

REVISION LOG

Issue	Date	Comment	Author
Orig			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

1.0 PURPOSE

This document defines the procedures necessary for calibration of measuring equipment.

2.0 THEORY

Measurement results are only valid when M&TE of known accuracy is used. This calibration procedure ensures M&TE is properly verified for accuracy against known standards. Measurement devices that are used to indicate process feedback are not subject to calibration, such as short-circuit or open-circuit, hot or cold, off or on, etc; however, when a measurement device is used to determine conformance to a Customer requirement, then the device should be properly verified for accuracy.

3.0 DEFINITIONS

- Accuracy Ratio –
- Adequacy -
- Calibration:
- Gages –
- Inspection Aid –
- M&TE -
- Procurement of M&TE -
- Recall –
- Significantly out-of-tolerance -
- Special Equipment -
- Standards -

4.0 GENERAL CALIBRATION PROCEDURE

4.1 Calibration is performed by .

4.2 Measuring instruments are to be calibrated at a temperature of and relative humidity. Sufficient temperature stabilization time is allowed before calibration. For cases where calibration must be conducted in the production area,

4.3 A number is issued when a gage does not provide its own serial number. [redacted]

4.4 All M&TE are kept clean and when not in use are [redacted]

4.5 A ***Recall Log*** is maintained on all M&TE and standards. The log provides [redacted]

4.6 The number of items scheduled for monthly recertification is [redacted]

4.7 In addition to the ***Recall Log***, a ***Calibration Report*** is kept on each Company-owned gage/standard, which includes [redacted]

4.8 Calibration intervals may be established based on one or more of the following criteria: [redacted]

4.9 Adjustable M&TE is periodically recalibrated based upon [redacted]

TABLE I, Calibration Intervals

Calibration Cycle	Recalibration Cycles to Qualify for New Calibration Cycle	New Calibration Cycle
Annual	[redacted]	[redacted]
Bi-Annual	[redacted]	[redacted]
3 - 4 Years	[redacted]	[redacted]
5 Years	[redacted]	[redacted]

4.10 Interval Adjustment: M&TE whose calibration error is recorded as being greater than the last recorded calibration error but not significantly out of tolerance [redacted]

4.11 M&TE calibration intervals may be extended or adjusted [redacted]

4.12 Overdue items should be [redacted]

4.13 A ***Calibration Sticker*** is used to identify individual items of M&TE. The sticker displays [redacted]

4.14 Calibration Standards/Special Equipment

The following is the position of the National Conference of Standards Laboratories (NCSL):

[redacted]

Calibration of standards/special equipment is conducted by checking against laboratory standards available at outside laboratories. Approved calibration laboratories are listed in the ***Approved Supplier's List***.

When calibrations are made for standards/special equipment, the calibration lab is required to submit a report that contains, as appropriate:

- [redacted]

4.15 A ***Calibration Report*** and ***Recall Log*** is maintained on all Transfer Standards, indicating [redacted]

4.16 The calibration department places all Customer furnished inspection gages in the calibration system unless [redacted]

4.17 Traceability: ***Inspection Work Instructions*** and ***Manufacturing Travelers*** specify measurement and test equipment utilized for product conformance inspection.
When specified, [redacted]

4.18 Non-Calibrated M&TE: Upon request, non-calibrated M&TE may be submitted for calibration. Non-calibrated measurement devices may [redacted] under the following conditions:

1) [redacted]
2) [redacted]

A non-calibrated measurement device that is verified accurate [redacted]

4.19 Calibration Not Required M&TE

4.19.1 [redacted] is exempt from calibration, such as but not limited to [redacted]

4.19.2 [redacted] that is checked for accuracy prior to use [redacted]

4.19.3 [redacted] are exempt from calibration, such as but not limited to [redacted]

4.19.4 [redacted] are exempt from shelf life control. NIST traceability is not required for [redacted]

4.19.5 [redacted] are exempt from calibration; however, [redacted]

4.19.6 [redacted] are exempt from calibration; however, [redacted]

4.20 Employee Owned Tools: Personal tooling or gages owned by employees are calibrated prior to use and are placed on a calibration schedule.

4.21 Storage and Handling of M&TE: [redacted]

4.22 M&TE requiring transportation to a calibration laboratory is [redacted]

4.23 M&TE storage areas are [redacted]

4.24 Archive / Long-Term Storage: M&TE does not require accuracy verification prior to archive / long-term storage if it was not:

- [redacted]
- [redacted]
- [redacted]

M&TE that has been calibrated and stored must [redacted]

5.0 OUT-OF-TOLERANCE EQUIPMENT AND TOOLING

5.1 Calibrated M&TE that is found to be significantly out of tolerance, damaged, inoperative, erratic or exhibiting some other form of anomalous condition is [redacted]

5.2 M&TE found significantly out of tolerance at recalibration for 2 interval cycles is [redacted]

5.3 An instrument whose calibration error is significantly out-of-tolerance over a short portion of a specified range may [redacted]

5.4 Any product certified with M&TE subsequently found to be out-of-tolerance is [redacted]

6.0 LOST EQUIPMENT

6.1 Measurement and test equipment that cannot be located is classified as "Lost". [redacted]

7.0 MANAGEMENT REVIEW

7.1 Management Review meetings are conducted according to the ***QMS-04 Management Process Procedure***. During Management Review, [redacted]

APPENDIX 1

Setting and/or selecting a reference standard to calibrate a measurement device.

Requirement:

The measurement range of a device being checked for accuracy must [redacted]

VOLTMETER:

A voltmeter shall be verified for accuracy within an equivalent range on the reference standard:

A voltmeter reference standard may have scales that range from 2-20V, 20-200V, etc.

The voltmeter being checked for accuracy must be set to bracket within a range of the reference standard - or -

[redacted]

OTHER MEASUREMENT DEVICES:

Any reference standard whose maximum measurement range is the same as the device being checked for accuracy must [redacted].

For instance, [redacted]

APPENDIX 2

Nonadjustable M&TE is inherently stable and includes [redacted]

The Operator is only required to check inherently stable M&TE for damage prior to each use because [redacted]

For instance, [redacted]

To control the inventory of inherently stable M&TE, the Responsible Authority [redacted]

Your Logo

Your Company Name

DEFINITIONS AND ABBREVIATIONS PROCEDURE

Origination Date: XXXX

Document Identifier:	QMS-16 Definitions and Abbreviations Procedure
Date:	Latest Revision Date
Project:	Customer, Unique ID, Part Number
Document Status:	Draft, Redline, Released, Obsolete
Document Link:	Location on Server (if used)

Abstract:
This document describes definitions and abbreviations used by the Company.

REVISION LOG

Issue	Date	Comment	Author
Orig			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

1.0 PURPOSE

This document provides the accepted definitions and abbreviations for terms used by the Company.

2.0 ABBREVIATIONS

- ATP: Acceptance Test Procedure
- CCB: Configuration Control Board
- DR: Data Review
- EO: Engineering Order
- ICAR: Investigation and Corrective Action Request (for suppliers, vendors, subcontractors and service providers)
- IHS: Inherently Stable
- IS: “is” or “as found”
- ISO: International Organization for Standardization
- M&TE: Measurement and Test Equipment
- MCD: Manufacturing Control Document
- MRB: Material Review Board
- NCP: Nonconforming Product
- NCR: Nonconformance Report
- QA: Quality Assurance
- QC: Quality Control
- QTP: Qualification Test Procedure
- QTR: Qualification Test Report
- R&D: Research and Development
- RA: Responsible Authority
- REA: Responsible Engineering Authority
- RFCA: Request for Corrective Action
- RFP: Request for Price/Proposal
- RFS: Request for Support
- RQA: Responsible Quality Authority
- RTV: Return to Vendor
- SAE: Society of Automotive Engineers
- SB (also S/B): “should be”

3.0 DEFINITIONS (GLOSSARY)

ACCEPTANCE

[redacted]

ACCESSIBILITY

[redacted]

TRAINING

[redacted]

UNIT (SOFTWARE)

[redacted]

UNIT (HARDWARE)

[redacted]

UNSCHEDULED MAINTENANCE

[redacted]

VALIDATION TESTING

[redacted]

VALIDATION OF A PROCESS

[redacted]

VERIFICATION

[redacted]

VERSION

[redacted]

WAIVER

[redacted]

WORKMANSHIP

[redacted]

Your Logo

Your Company Name

DESIGN AND DEVELOPMENT PROCEDURE

Origination Date: XXXX

Document Identifier:	QMS-17 Design and Development Procedure
Date:	Latest Revision Date
Project:	Customer, Unique ID, Part Number
Document Status:	Draft, Redline, Released, Obsolete
Document Link:	Location on Server (if used)

Abstract:
This document describes the procedures used to design and develop products or services.

REVISION LOG

Issue	Date	Comment	Author
Orig			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

1.0 PURPOSE

This document provides details on the Design and Development process.

2.0 THEORY

The Company performs new product research and development (R&D). Controlling the design and development activity ensures that product designs meet all requirements and that parts produced are adequate as a result of the design.

3.0 DESIGN & DEVELOPMENT PROCEDURE

The responsible engineering authority (REA) for design and development is assigned by the Operations Manager. Design and development personnel from various business groups may include [redacted]

Design and development planning outputs specify [redacted]

The Company defines the data required to enable the product to be identified, manufactured, verified, used and maintained, which may include:

- [redacted]
- [redacted]
- [redacted]

Design and development planning takes into consideration [redacted]

When applicable, the Company considers [redacted]

When appropriate, the Company considers [redacted].

When appropriate, the Company [redacted]

When tests are necessary for verification and validation, these tests are planned, controlled, reviewed and documented to ensure and prove the following:

- [redacted]
- [redacted]
- [redacted]

- [redacted]
- [redacted]

Monitoring and measuring devices used for testing shall [redacted]

At the completion of design and development, the Company ensures [redacted]

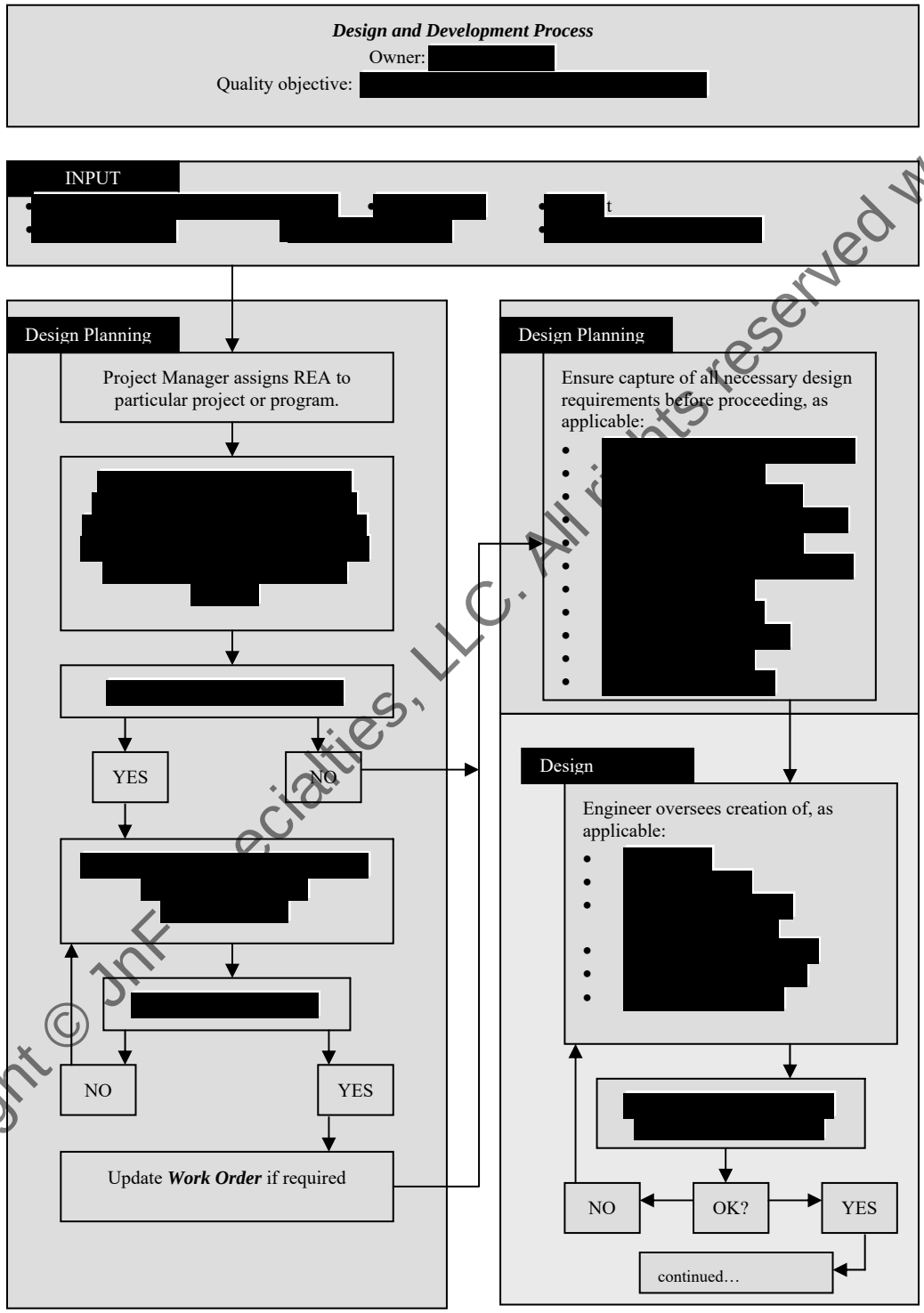
The Company implements a process [redacted]

Design and development changes that affect Customer requirements are approved by the Customer prior to implementation according to the ***QMS-02 Configuration Management Procedure***.

See process map.

Left blank intentionally

4.0 PROCESS MAP



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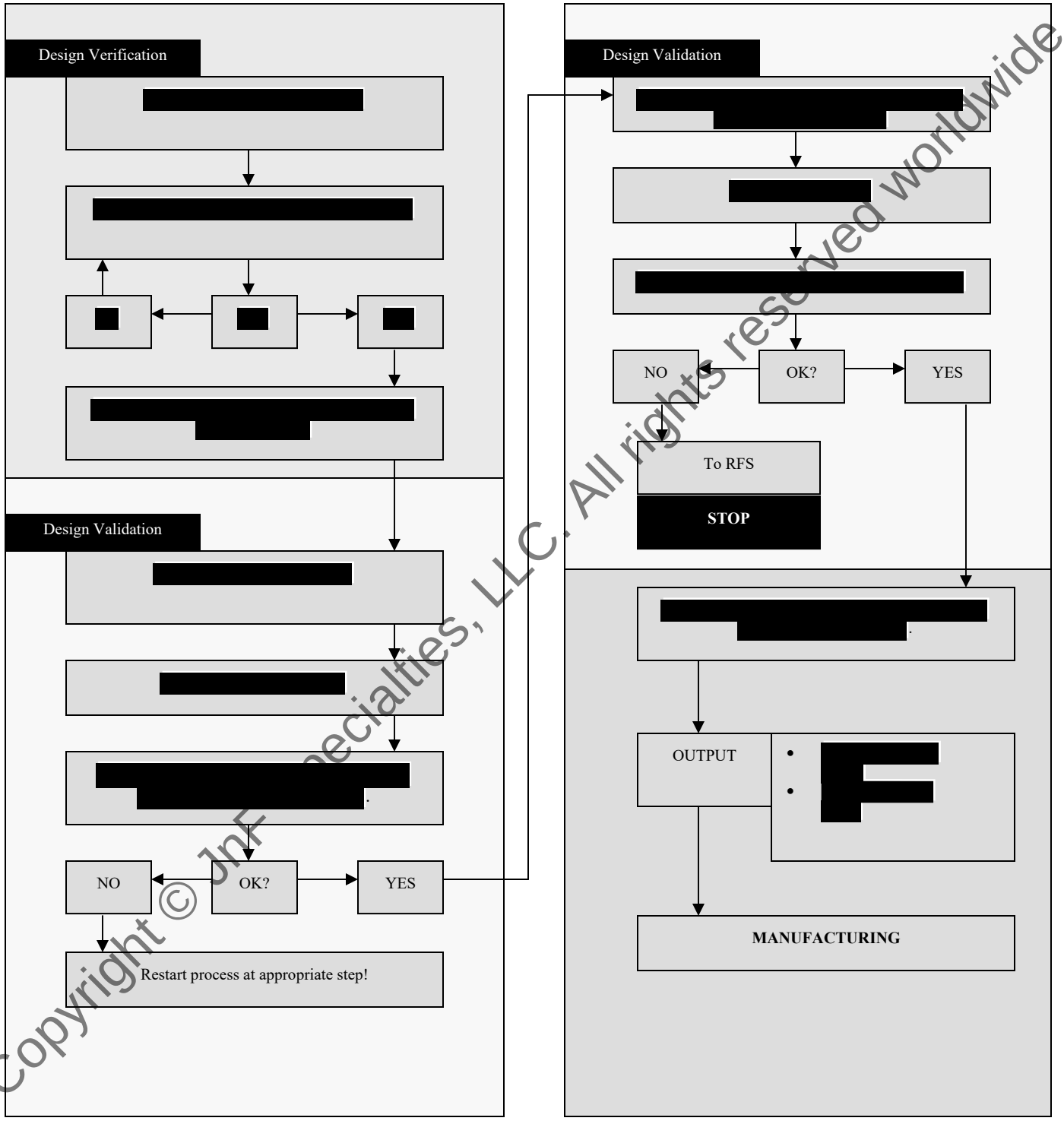


Risk Mitigation and Planning Procedure

Origination Date: (month year)

Document Identifier:	QMS-18 Risk Mitigation and Planning Procedure
Date:	Latest Revision Date
Project:	Customer, Unique ID, Part Number
Document Status:	Draft, Redline, Released, Obsolete

Abstract:
This document describes the requirements for risk mitigation and planning.

REVISION LOG

Issue	Date	Comment	Author
Orig			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

1.0 Purpose

The risk mitigation and planning process uses information from risk identification, assessment and analysis to formulate response strategies for key risks. Common strategies are avoidance, transference and/or mitigation acceptance. The mitigation and planning exercises must be documented in an organized and comprehensive fashion that clearly assigns responsibilities and delineates procedures for mitigation and allocation of risks. Common documentation procedures frequently include the creation of red flag item lists, risk charters and formal risk management planning documentation. Risk mitigation and planning efforts may necessitate that Suppliers set policies, procedures, goals and responsibility standards. Formalizing risk mitigation and planning throughout the Company will help establish a risk culture that should result in better cost management from planning through production and better allocation of project risks that align teams with Customer-oriented performance goals.

2.0 Objectives of Risk Mitigation and Planning

The objectives of risk mitigation and planning are [redacted]

Three key questions can be posed for risk mitigation:

1. [redacted]
2.
3.

An understanding of these three questions is critical to risk mitigation and risk management planning. Question 1 addresses [redacted]

3.0 Risk Response Options

Risk identification, assessment and analysis exercises form the basis for sound risk response options. A series of risk response actions can help to avoid or mitigate the identified risks. A response may be the following:

- [redacted]
-
-
-
-

The above categorization of risk response options [redacted] The strategies and actions include the following:

Acceptance: [redacted]

Avoidance: [redacted]

Mitigation: [redacted]

Transference: [redacted]

Given a clear understanding of the risks, their magnitude and the options for response, an understanding of project risk will emerge. This understanding will include [redacted]

4.0 Risk Planning

Risk planning involves the thoughtful development, implementation and monitoring of appropriate risk response strategies. Risk planning is the detailed formulation of a plan of action for the management of risk:

- [redacted]
- [redacted]
- [redacted]

Risk planning is iterative and includes [redacted]

Planning begins by [redacted]

4.1 Risk Planning Documentation

Each risk plan should be documented but the level of detail will vary with the unique attributes of each project. Large projects or projects with high levels of uncertainty [redacted]

4.2 Red Flag Item Lists

A red flag item list is [redacted]

A red flag item list is [redacted]

See a sample list of risks in Appendix A. While this sample list can be used to create a list of red flag items for a project, it is [redacted]

4.3 Risk Charters

The creation of a risk charter is a more formal identification of risks than the listing of red flag items. Typically, it is [redacted]

A risk charter is [redacted]

[redacted]

A risk charter is [redacted]

The risk charter [redacted] The risk charter may include relevant information such as the following:

- [redacted]

Two examples of risk charters are in Appendix B and C. The first example is a spreadsheet that forms the basis of the risk management plan. The spreadsheet contains columns for identification, analysis, response strategy, monitoring and control. The second example uses the term risk register synonymously with risk charter. The risk register contains more quantitative risk assessment information than the spreadsheet example but the goal of the documentation is similar. The risk register adds issues such as correlation among dependent components, type of distribution used to model the risk and expected value of the risks.

5.0 Formal Risk Management Plan

The strategy to manage risk provides the project team with direction and basis for planning. The risk management plan should [redacted]

The six primary steps in project risk management are the following:

1. [redacted]

The plan is the road map that tells the Company and Supplier how [redacted] The following is a sample risk management plan outline:

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]
7. [redacted]
8. [redacted]
9. [redacted]
10. [redacted]
11. [redacted]

Each risk plan should be documented but the level of detail will vary with the unique attributes of each project. Red flag item lists, risk charters and formal risk management plans provide flexibility in risk management documentation.

6.0 Risk Identification Process

The risk identification process begins with [redacted]

Typical Risk Identification Checklist:

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

The team should examine and identify project events by [redacted]

[redacted]

After the risks are identified, they should be [redacted]

The following table provides a typical list of classifications with alternate identified risks.

CLASSIFICATION OF IDENTIFIED RISKS				
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]
	Inflation			

A number of documents and tools are available to support the risk identification process. The following table provides an example of project-specific documents, program documents and techniques available for risk identification.

6.1 Risk Identification Tools and Techniques

Project risk can be identified multiple ways [redacted]

Risks and opportunities that affect products and services (operational processes) can be determined using tools such as [redacted]

RISK IDENTIFICATION TOOLS AND TECHNIQUES		
[redacted]	[redacted]	[redacted]

The key to success with any risk identification tool or technique is [redacted]

The risk identification process identifies and categorizes risks that could affect the project. It documents these risks and, at a minimum, [redacted]

6.2 Risk Allocation

The rigorous process of risk identification, assessment, analysis and mitigation allows for [redacted]

In theory, best value is achieved by [redacted]

The Company is more likely to accept risks [redacted]

The purchase order is [redacted]

Best practice:

The goal of an optimal allocation of risk is [redacted]

The rigorous process of risk identification, assessment, analysis and mitigation allows for a more transparent and informed understanding of project risk. When risks are understood and their consequences are measured, decisions can be made to allocate risks in a manner that [redacted]

The objectives of risk allocation can vary depending on unique project goals but four fundamental tenets of sound risk allocation should always be followed:

- [redacted]

6.2.1 Allocate Risks to Party Best Able to Manage Them

A fundamental tenet of risk management is [redacted]

Following this principle [redacted]

6.2.2 Risk Allocation in Alignment with Project Objectives

Risks should be allocated in a manner that [redacted]

Allocating risks in alignment with project objectives begins with [redacted]

The importance of clearly understanding and defining project objectives cannot be overemphasized. Project objectives [redacted]

6.2.3 Risk Sharing

The concepts of risk sharing and risk allocation are often used synonymously. Risk allocation is defined as [redacted]

Communication among parties is a key to any sharing of risk allocation. Risk-sharing provisions should [redacted]

6.2.4 Risk Allocation in Alignment with Customer-Oriented Performance Goals

The ultimate goal of risk allocation should [redacted]

6.2.5 Risk Allocation Matrix

Perhaps the most widely used tool for risk allocation is [redacted]

[redacted]

Example of risk allocation matrix for outsourced processes:

RISK	PARTY RECOMMENDED TO ASSUME RISK	HOW RISK IS ASSIGNED OR MANAGED
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Allocation matrices are a fundamental tool in the development of design-produce contracts. Appendix D provides an example design-produce risk allocation matrix. It provides a detailed framework to make risk allocation decisions for each design-produce project. The matrix is also [redacted]

6.2.6 Innovative Contracting Tools and Techniques

The purchase order is [redacted]

The following table provides a list of innovative project delivery, procurement and contracting methods that can be used for risk allocation. [redacted]

Innovative contracting approaches for risk allocation:

Project Delivery Approaches	Procurement Approaches	Purchase order Payment Approaches
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

6.2.7 Contingency Considerations

Any party assuming a risk must be prepared [redacted]

Left blank intentionally

Appendix A - Risk Identification Checklists - Red-Flag List

1. Project Management Risk Document Checklist

Risk management reports vary depending on the size, nature and phase of the project. The following are examples of risk management documents and reports that may be useful:

- [redacted]
- Risk monitoring documentation:
  - [redacted]

2. Sample Red Flag Item List (reduce list as required)

Technical Risks

- [redacted]

External Risks

- [redacted]

- [redacted]

Environmental Risks

- [redacted]

Organizational Risks

- [redacted]

- [redacted]

3. Miscellaneous Checklist

- [redacted]

4. Common Risks

- [redacted]

Environmental

- [redacted]

Other Risks

- [redacted]

Appendix B - Risk Charter

[redacted]

[redacted]

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
1	Active	3c	8/7/xxxx	[redacted]	more time than needed to mitigate NRE	Residents near the proposed equipment location have expressed a desire for	Risk is occurring if the Revised Noise Study indicates the additional wall height is	[redacted]	[redacted]

[redacted]

[redacted]

Appendix C - Risk Register

[redacted]

[redacted]

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Risk 1	Agreements	Permits required from approval agencies could be	[redacted]	Positive between Cost and Schedule (i.e. Duration) of	25% (0.25)	Triangular	[redacted]	Triangular	[redacted]
Risk 2	Regulatory Approval	Grantee documentation of readiness to enter into full funding	B. Regulatory Approval	[redacted]	10%	No Significant Effect	No Significant Effect	[redacted]	2 mos.
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

Appendix D - Design-Produce Risk Allocation Matrix

[redacted]	[redacted]	[redacted]
[redacted]		
[redacted]		
[redacted]		
[redacted]		

Appendix E - Critical Elements Risk Assessment

ACTION ITEM

Date:		Action Item Number:
[redacted]		[redacted]
	[redacted]	
[redacted]		[redacted]
[redacted]		

Form Rev: Orig

Signature: _____

Date: _____

Your Logo

ACTION PLAN

			Page: _____ of _____
			Date: _____
Department:		Responsible Authority:	
Team Designation:			
[redacted]			
	[redacted]		[redacted]

[redacted]	[redacted]	[redacted]		[redacted]		[redacted]

Form Rev: Orig

Your Logo

Approved Supplier List

(mo/yr)

Revisions		Rev:	Orig
Letter	E.O. Number - Description	Date	

			Your Company Name				
Prepared By:							
Approved By:							
			APPROVED SUPPLIER LIST				
			Size:	**A**	CAGE:		Form Rev: Orig 1 of 3

Procedure:

Supplier evaluation:

The Quality or Purchasing Group forwards Supplier Survey for completion by Supplier.

Supplier evaluation **is required** for [redacted]

Supplier evaluation **is *not* required** for [redacted]

A new Supplier is submitted to management for review. Management has discretionary authority to approve or disapprove a Supplier based upon [redacted]

Supplier capability/approval is determined by:

[redacted]

Acceptable Practice:

Suppliers are added bi-annually to this Approved Supplier List or [redacted]

Non-deliverable material Suppliers are added to the Approved Supplier List at the discretion of the Purchasing Manager.

Suppliers that provide process materials that affect production of deliverable items are required to be listed on this Approved Supplier List.

The Purchasing Group may use [redacted]

Glossary:

[redacted]

List of Approved Suppliers

Your Logo	BULLETIN	NUMBER: [redacted] PAGE: 1 of 2

[redacted]		[redacted]	
[redacted]		[redacted]	
[redacted]		[redacted]	
[redacted]		[redacted]	[redacted]

[redacted]

☐ [redacted] ☐ [redacted] ☐ [redacted]

☐ [redacted]

☐ [redacted]

[redacted]

PAGE 2 TEXT BLOCK: Insert page 2 text here

ORIGINA[redacted]

[redacted]

[redacted] [redacted] [redacted] [redacted]

[redacted]

[redacted]

CALCULATED RISK RELEASE

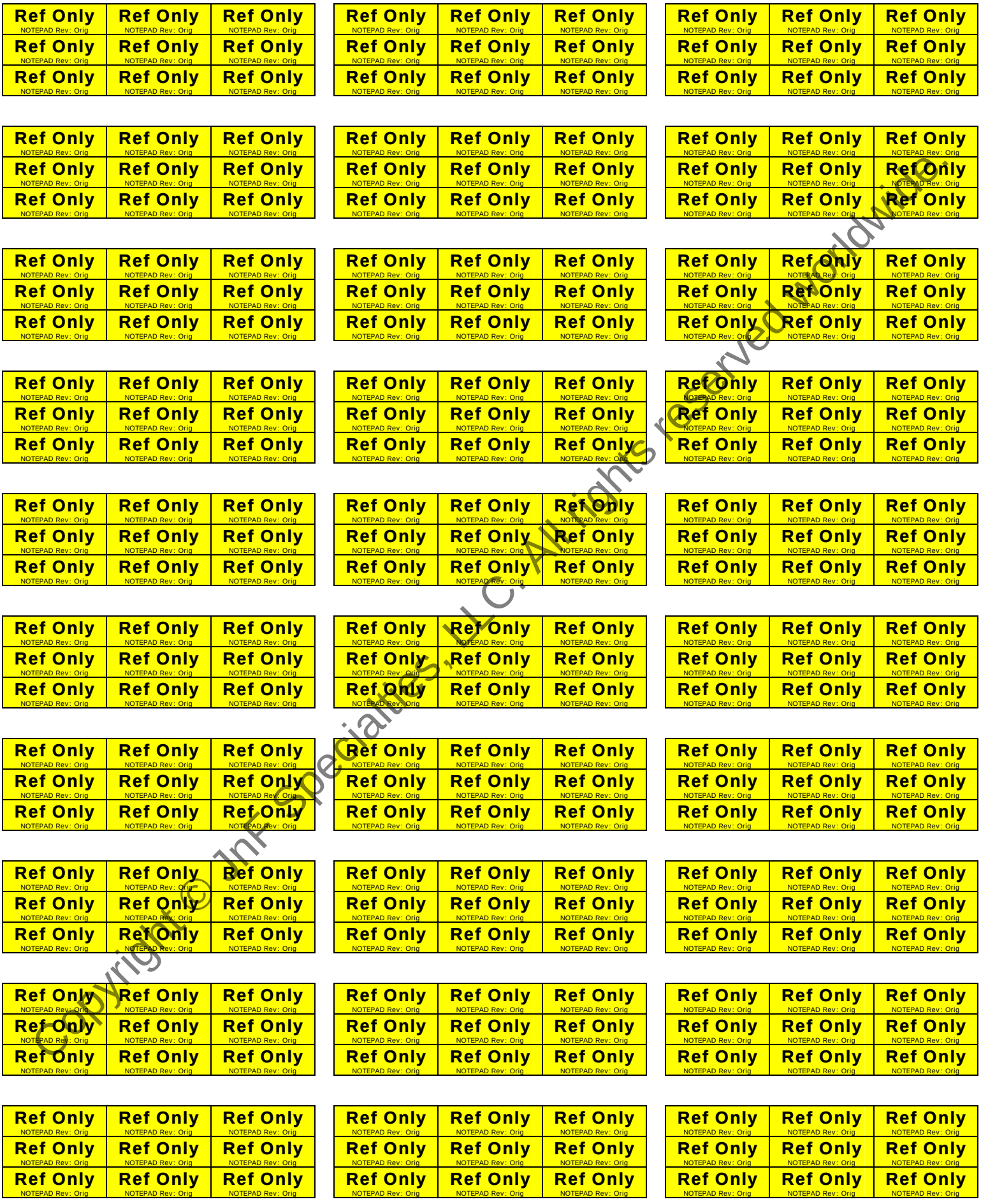
Date:		[redacted]	
[redacted]			

[redacted]

[redacted] ☐ [redacted] ☐ [redacted]

Form Rev: Orig

Your Logo



Calibration Seal
NOTEPAD Rev: Orig

Metrology Recall Card

Description:		Calib Frequency:	
Type:	Model:	S/N:	

Form Rev: Orig

Instrument and Case Identification Tag (shrink to fit)

Tool #:		Tech:	

Form Rev: Orig

Instrument Deviation Tag (shrink to fit)

Tool#:	

Form Rev: Orig

Measuring and Test Equipment Calibration Report

☐ In Tolerance as Received	☐ Out-of-Tolerance as Recv'd	PO# for M&TE:
Department:	Date:	
Equipment:	Location:	

Remarks:

Calib. Manual#:	Rev:	Temp:	% RH:
NIST #:		Calib Due Date:	

Form Rev: Orig

IMPACT ANALYSIS REPORT

Number of parts that may be out-of-spec [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Form Rev: Orig

Your Procedure # Rev: Orig	[Title] Calibration Instruction Sheet	Form Rev: Orig Page 1 of 1
Special Instructions:		[redacted]
		[redacted]
[redacted]		[redacted]

[redacted]	[redacted]	[redacted]	[redacted]

Inherently Stable Measurement Equipment Log

Approved Brands:		Type:	[redacted]
[redacted]		[redacted]	[redacted]
[redacted]	[redacted]		

Form Rev: Orig

Item Name:	
Part Number:	
Lot Number:	
Expiration Date:	

Chemical ID Tag NOTEPAD Form Rev: Orig

Your Logo

Your Company Name

CONFIGURATION AUDIT

Origination Date: XXXX

Document Identifier:	Configuration Audit
Date:	Latest Revision Date
Project:	Customer, Unique ID, Part Number
Document Status:	Draft, Redline, Released, Obsolete
Document Link:	Location on Server (if used)

Abstract:
This document describes how to perform a configuration audit.

REVISION LOG

Issue	Date	Comment	Author
Orig			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

Op#	STEP	ACTION
Steps may be performed before, during or after manufacturing		**(Your) Assembly**
1	QC	Produce Data List, [redacted] complete all fields, particularly the field labeled [redacted]
2	QC	Record the revision level of P/N's recorded on the travelers [redacted]
3	QC	Record the Supplier name and [redacted]
4	QC	Compare the Supplier names on the Data List to the Suppliers listed in the Approved Supplier Listing (Your #)
	IF	THEN
4.1	Revs for [redacted] do not match Revs for [redacted]	Notify the Quality Mgr and Project Engr., then [redacted]
4.1.1	Revs for [redacted] and [redacted] are different	[redacted]
4.2	Supplier name is not [redacted]	Notify the Quality Mgr, then [redacted]
Op#	STEP	ACTION
Steps may be performed before, during or after manufacturing		**(Your) Assembly**
5	QC	Produce [redacted] for each item
6	QC	Record the revision level of [redacted]
7	QC	Record the Supplier name and [redacted]
8	QC	[redacted]
	IF	THEN
8.1	[redacted] does not match [redacted]	Notify the Quality Mgr and Project Engr., then [redacted]
8.2	Supplier name is not [redacted]	Notify the Quality Mgr, then [redacted]

Contract Review

Program Name:				
Program Source:	Internal Customer ☐		External Customer ☐	
RFP#:	Contract Type: Commercial ☐		Gov ☐	R&D ☐
Customer:				
[redacted]				
Understanding of Quality Terms and Contract Requirements				
[redacted]				
Analysis Made By:		Reviewed By:		
	Date:		Date:	

Form Rev: Orig

Your Logo	**INVESTIGATION AND CORRECTIVE ACTION REQUEST**

ICAR Responsible Supplier: _____

Customer: _____ Part# _____ Applicable Customer P.O or Job # _____

Customer CA or corresponding documentation received? Y ☐ N ☐ Number: _____

Date Opened:_____ Step 3. Due: _____ Date ICAR closed: _____ Closed By: _____

[redacted]

5. [redacted]

CUSTOMER SATISFACTION SURVEY Your Logo

Date: (input date)

To: Customer Contact Name
Customer Company Name
Customer Address
Customer City, State, Postal Code

From: Your Name
Your Company Name
Your Address
Your City, State, Zip

Greetings,

[redacted]

please circle the number representing our performance:

[redacted]									
1	2	3	4	5	6	7	8	9	10
[redacted]									
1	2	3	4	5	6	7	8	9	10
[redacted]									
1	2	3	4	5	6	7	8	9	10
[redacted]									
1	2	3	4	5	6	7	8	9	10
[redacted]									
1	2	3	4	5	6	7	8	9	10
[redacted]									
1	2	3	4	5	6	7	8	9	10
[redacted]									
[redacted]									
[redacted]									

Thank you for your participation in our survey - please fax your response to:
Your Name - Phone: Your# - Fax: Your#
Email: Your email

DAILY RECEIVING RECORD

Date:						Page 1 of 1:	
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Form Rev: Orig

(Your Logo)

(Your Co Name) DATA LIST	DATA LIST REVISION:		PROJECT:	Page 1 of
[redacted]		[redacted]		
[redacted]		[redacted]		
[redacted]		[redacted]		

[redacted]	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Use latest revision at the time of contract, or as specified by contract

[redacted]

SUMMARY OF DATA LIST REVISIONS

D/L [redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Form Rev: Orig

DESIGN REVIEW

Program Name:		Job#:	
Part Number:		Rev:	
Chairperson:		Date:	
Attendees:			

Form Rev: Orig

Your Logo

DESIGN REVIEW

Origination Date: xxxxx

Document Identifier:	Design Review Work Instruction
Date:	xxxxx
Project:	
Document Status:	Released

Abstract:
This document describes the work required to perform design review.

REVISION LOG

Issue	Date	Comment	Author
Orig			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

1.0 PURPOSE

This document establishes design review instructions, documentation requirements, scheduling of design reviews, criteria for action item closeout and the items to be defined at each level of review.

2.0 THEORY

Design review is used to enhance the probability of product, software or service success by identifying potential or actual design problems. The solution of identified problems is not attempted at the review but is assigned as an action item. Reviewing a design does not imply a lack of confidence in the designer – it is a normal and necessary part of best engineering practice. Designers of critical items welcome rigorous design reviews for the peace of mind they provide. They help assure that something has not been overlooked because the designer was too close to the work. There is no reflection on a person's competence in having to respond to action items. To serve as a design reviewer indicates that your associates regard you as an expert.

3.0 DESIGN REVIEW

All deliverable hardware and software must undergo at least two levels of design review. [redacted]

3.1 Number and Type of Design Reviews

The number and type of design reviews will depend on [redacted]

3.2 Scheduling Reviews

At the start of a program, responsible authorities must [redacted]

3.3 Heritage Design Review

Designs that are qualified by another program do not require additional review unless [redacted]

3.4 Software and Service Reviews

Computer programs, contents of ROM, PROM and other programmable devices and service operations must be reviewed as carefully as hardware.

3.5 Subcontractor Reviews

Products and services from subcontractors must be design reviewed according to [redacted]

3.6 Interfaces

Reviewers should devote extra attention to [redacted]

3.7 Post Review Design Changes

Changes made to a design subsequent to a successful review should be flagged at the next review. Design changes, even minor ones made after the final design review (CDR) are [redacted].

3.8 Design Review Items

1. Requirements. [redacted]
2. Design. [redacted]
3. Reviewers. [redacted]

4. Design Package. [redacted]
5. Agenda. [redacted]
6. Review Minutes. [redacted]
7. Closeout of Action Items. [redacted]

3.9 Inappropriate Items for a Design Review

[redacted] should be discussed only as they affect [redacted].

3.10 System Review Attendees

System review attendees should include [redacted]

4.0 Types of Design Reviews

4.1 System Level Reviews

4.1.1 Baseline Design Review (BDR)

The BDR is held to assure that the project objective and requirements are [redacted]

The BDR should address the following:

1. [redacted]

2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]

The output of the BDR consists of [redacted]

4.1.2 Preliminary Design Review (PDR)

The PDR is the first review of the preliminary detailed design and is generally [redacted] The PDR should address the following:

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]
7. [redacted]
8. [redacted]

9. [redacted]
10. [redacted]
11. [redacted]
12. [redacted]
13. [redacted]
14. [redacted]

The output of the PDR consists of [redacted]

The development (performance) configuration documents include:

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]

Formal change control procedures are invoked concurrent with the release of the development (performance) configuration documents.

4.1.3 Critical Design Review (CDR)

The system CDR is held immediately prior to design freeze and before significant fabrication activity begins. The CDR presents [redacted]

The CDR should address the following items:

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]
7. [redacted]
8. [redacted]
9. [redacted]
10. [redacted]
11. [redacted]
12. [redacted]

Completion of the CDR and resolution of its action items establishes [redacted]

4.1.4 Environmental Review (ER)

The ER occurs prior to the start of environmental testing of the integrated system or end item. Its purpose is to:

1. [redacted]
2. [redacted]

4.1.5 Buyoff Review

The buyoff review [redacted] addresses:

1. [redacted]
2. [redacted]
3. [redacted]
4. Post-qualification plans.

For programs involving a qualification product, a buyoff review following qualification testing may be used to [redacted]

4.1.6 Operations Review

This review applies to programs that have [redacted]

4.2 Subsystem Level Reviews

Subsystem level reviews are held when the design [redacted]

4.2.1 Hardware Subsystem Reviews

Circuit design reviews are completed [redacted] (as appropriate):

1. [redacted]
2. [redacted]

3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]
7. [redacted]
8. [redacted]

4.2.2 Software Subsystem Reviews

Software reviews should be held [redacted]

4.2.3 Fabrication Pre-release Review (FPR)

Prior to release of a drawing package to the shops for fabrication, an FPR [redacted] should assure that the drawing package:

1. [redacted]
2. [redacted]
3. [redacted]

The review should address the following items:

1. [redacted]
2. [redacted]
3. [redacted]

Upon successful completion of the FPR and closure of action items, the package is released and configuration control begins.

4.3 Other Reviews

Some programs require external reviews. These reviews [redacted]

5.0 Design Review Packages

All design reviews require a review package. For all but the FPR, the package must [redacted]

5.1 System Level Design Review Data Package (BDR, PDR, CDR)

System level review packages typically contain:

[redacted]		

[redacted]

5.2 Circuit Design Review Data Package

Circuit design review packages typically contain:

[redacted]

5.3 Software Review Data Package

Software review packages typically contain:

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

6.0 Responsibilities

6.1 Program Manager

The program manager is responsible for [redacted]

6.2 Chief Engineer

The chief engineer is responsible for [redacted]

[redacted]

6.3 Chief Scientist

The chief scientist is responsible for [redacted]

6.4 Presenter

The presenter is responsible for [redacted]

6.5 Reviewers

Independent reviewers should [redacted]

6.6 Chairperson

The Chairperson [redacted]

The Chairperson [redacted]

The Chairperson [redacted]

The Chairperson [redacted]

6.7 Section, Group and Department Supervisors

Line supervisors are responsible for [redacted]

DIMENSIONAL ANALYSIS REPORT

Date:		Supplier:	
Part#:		PO No:	
P/N Rev:		Job#:	

[redacted]				
[redacted]				
	[redacted]	[redacted]		[redacted]
[redacted]				

[redacted]							
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	

Inspector:		Date:	

Form Rev: Orig

Your Logo

EO NUMBER:	DATE:	RFS#:
ENGINEERING ORDER Page of	CLASS I☐ II☐	PERSON REQUESTING ENGINEERING ORDER: PERSON WRITING ENGINEERING ORDER:

CUSTOMER APPROVAL/CONCURRENCE:

	☐	☐		
	☐	☐		
	☐	☐		
	☐	☐		

Form Rev: Orig

Your Logo

EO NUMBER: 101	DATE: your date	RFS#: N/A	
ENGINEERING ORDER Page 1 of 1	CLASS I☒ II☐	PERSON REQUESTING ENGINEERING ORDER:	Your Name
		PERSON WRITING ENGINEERING ORDER:	Your Name

REASON FOR CHANGE:

Create and release new quality management system based on AS9100

DESIGN STAGES - ELEMENTS:

when applicable, define the task sequence, mandatory steps, significant stages, responsible person, design content, input data, planning constraints, performance conditions and required baselines

N/A

CUSTOMER / REGULATORY AUTHORITY'S SAFETY / FUNCTIONAL OBJECTIVES:

NA

KEY CHARACTERISTICS:

when applicable according to design or contract requirements

N/A

DESCRIPTION OF CHANGE - DESCRIBE WAS AND IS CONDITION

WAS: (list your existing quality management system)

IS: **Create and release the following list of QMS policies and procedures for compliance with AS9100D:**

Calibration Procedure
Configuration Management Procedure
Control of Documented Information Procedure
Control of Nonconforming Product Procedure
Corrective Action Procedure
Counterfeit Parts Prevention Procedure
Definitions and Abbreviations Procedure
Design and Development Procedure
Internal Auditing Procedure
Management Process Procedure
Manufacturing Procedure
Proposal Development and Contract Review Procedure
Purchasing Procedure
Quality Handbook
Receiving Procedure
Responsibilities & Authorities Procedure
Risk Mitigation and Planning Procedure
Shipping Procedure
Training Procedure

Create and release the following list of QMS support documents:

AS9100 Quality Systems Assessment Checklist

Collect and revise all forms that affect quality as defined by the QMS Audit Team. Display the title and form revision level on each form and if possible, display the latest Company logo.

First Piece Inspection Report

Date:		Supplier:	
Part No:		PO No:	
[redacted]		[redacted]	
[redacted]			
[redacted]			
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]			
[redacted]			
[redacted]			
[redacted]			
[redacted]			
[redacted]			
[redacted]			
[redacted]			

[redacted]

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	

Inspector:		Date:	

Form Rev: Orig

(Your Logo)

Quality System Impact Analysis		
Auditor(s):	Procedure Name and # under Audit:	
Date:	Supervisor Affected:	Areas Audited:
Brief Description of Practice:	[redacted]	
[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		

Form Rev: Orig

Your Address
Your Phone – Fax – Email

Your Company Name

Information Request

Date:		Phone:	
Subject:		Email:	
By:		Date:	

Form Rev: Orig

INSPECTION FORM

Part No:		Process:		Final QC:		Sheet:	of	
Part Name:				In-Process:		Date:		
[redacted]								
[redacted]								

Form Rev: Orig

(Your Logo)

Your Logo	Inspection Instructions	Form Rev: Orig	Page 1 of 1
	Special Instructions: [redacted]	[redacted]	
		[redacted]	
		[redacted]	

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Drawing No:						INSPECTION RECORD													Form Rev: Orig
Item Name:						(Your Company Name)													Front
						(Description of Your Inspection Process)													
Use ANSI [redacted]						[redacted]													
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Form Rev: Orig Back

(Description of Your Inspection Operation) continued...

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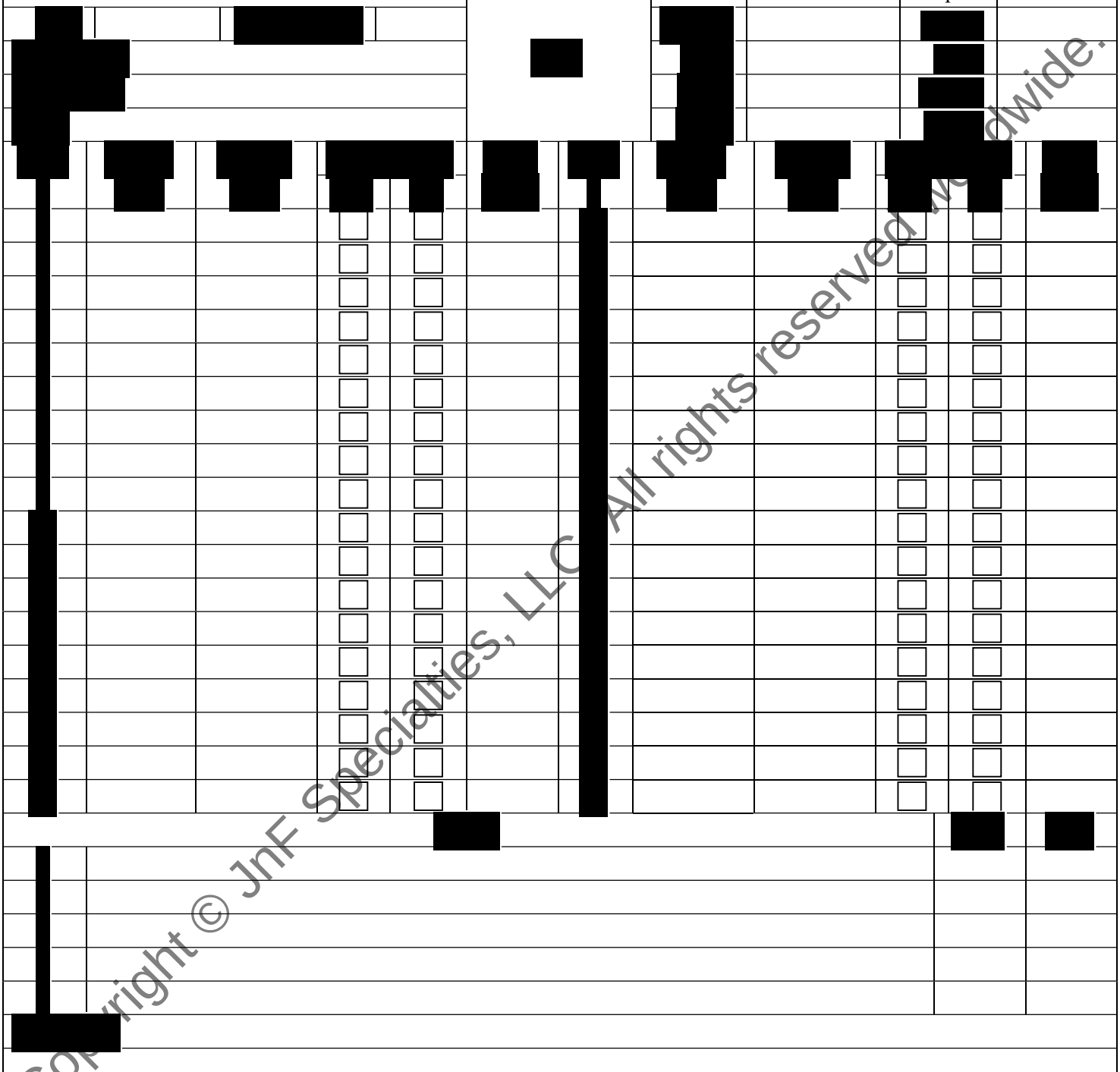
Your Company Name

First Article ☐	Other ☐	**INSPECTION REPORT**	Date:	
Item #:		Item Revision	Previous Report #	RW:
Item Name:			Date:	Repair:



INSPECTION SUMMARY

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]
[redacted]										

Form Rev: Orig

Your Logo

INSPECTOR STAMP LOG

[redacted]	[redacted]	[redacted]	[redacted]	

Form Rev: Orig

(Your Logo)

PLAN - STEP ONE: Audit Preparation & Planning

Process to Audit (Audit Scope):	
Audit Date(s):	Lead Auditor:
[redacted]	[redacted]
[redacted]	
[redacted]	
[redacted]	

[redacted]	
[redacted]	[redacted]

DO - STEP TWO: Compare Documentation vs. Requirements

[redacted]		
[redacted]	[redacted]	[redacted]
[redacted]		
[redacted]		
[redacted]		

[redacted]

CHECK - STEP THREE: Compare Actual Practice vs. Requirements

[redacted]			
[redacted]	[redacted]	[redacted]	[redacted]

[redacted]			
[redacted]	[redacted]	[redacted]	[redacted]

[redacted]			
[redacted]	[redacted]	[redacted]	[redacted]

ACT - STEP FOUR: Verify the Effectiveness of the Process

[redacted]		
[redacted]	[redacted]	[redacted]
[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		
Provide brief details on any areas that you found were well-implemented, particularly effective or worth noting as positive traits of the process.		

STEP FIVE: Summarize Your Findings for Nonconformance System

NONCONFORMITIES	
[redacted]	[redacted]
[redacted]	
[redacted]	
[redacted]	
[redacted]	

OPPORTUNITIES FOR IMPROVEMENT	
[redacted]	
[redacted]	
[redacted]	
[redacted]	

STEP SIX: Review Audit Report and Submit

All auditors on the audit team must submit their audit reports for summary and review by the Lead Auditor. Lead Auditor: [redacted]

Signature of Lead Auditor

Audit report reviewed and ready for submission:

Date

STEP SEVEN: Submit Audit Report to Appropriate Managers

The completed audit report must be submitted to the managers responsible for the areas audited, as well as any other appropriate persons.

Audit report sent to:

☐ Quality Manager (for logging)	☐ Manager	☐ Manager
☐ Manager	☐ Manager	☐ Manager
☐ Manager	☐ Manager	☐ Manager
☐ Manager	☐ Manager	☐ Manager

☐ Other:

NOTES PAGE

Your Note [redacted]	[redacted]

MANAGEMENT REVIEW REPORT

Origination Date: XXXX

Document Identifier:	Name, Number, Unique ID
Date:	Latest Revision Date
Document Status:	Draft, Redline, Released, Obsolete
Document Link:	Location on Server (if used)

Abstract:
This document provides the management review report.

CREATION LOG

Issue	Date	Comment	Author
0-0			

REVISION RECORD

Issue	Item	Reason for Change

Please complete each section - this form may be used as the final report or used as [redacted]

Date of Review: **Recorded by:**

In Attendance:

NAME	TITLE

Absent:

NAME	TITLE

ITEM 1: Review of the Quality Policy for current adequacy and the need for changes to it. *Review* [redacted]

- ☐ [redacted]
- ☐ [redacted]

ITEM 2: Internal audit results. *Report* [redacted]

ITEM 3: Status of corrective actions. *Review* [redacted]

ITEM 4: Review of resources needed to maintain and improve the effectiveness of the quality management system. *Discuss* [redacted]

ITEM 5: Review the effectiveness of current training programs and the effectiveness of additional training for designated individuals. *Include* [redacted]

ITEM 6: Review of Suppliers and Subcontractors. *Discuss* [redacted]

ITEM 7: Review of quality objectives, data and goals. *Review* [redacted]

Process	Quality Objective	Data Metric	Current Standing	Goal
Management	[redacted]			
Corrective Action				
Internal Auditing				
Proposal Development and Contract Review				
Purchasing				
Receiving				

ITEM 8: Discuss Customer feedback and complaints not already discussed as part of the corrective action review. *Develop and implement* [redacted]

ITEM 9: Discuss the overall performance of the quality system, any changes to the Company that may affect the quality system or vice-versa. *Include* [redacted]. *IMPORTANT:* [redacted]

ITEM 10: Note other recommendations for management to [redacted]

ITEM 11. Note follow-up activities from prior Management Review issues.

ITEM 12. Set date for next Management Review:

ITEM 13. RFS's FILED AT THIS MEETING:

[redacted]	[redacted]	[redacted]
[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		

ITEM 14. OTHER ACTION ITEMS ASSIGNED:

[redacted]	[redacted]	[redacted]

ITEM 15. ITEMS FOR FOLLOW-UP AT NEXT MEETING:

METRICS

Origination Date: XXXX

Document Identifier:	Defining Metrics
Date:	Latest Revision Date
Document Status:	Draft, Redline, Released, Obsolete
Document Link:	Location on Server (if used)

Abstract:
This document describes the process to develop a useable metric.

REVISION LOG

Issue	Date	Comment	Author
0-0			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

1.0 SCOPE

Explain the relationship between organizational objectives and metrics and provide some examples of the tools and techniques for collecting metric data.

2.0 THEORY

Nothing gets improved unless it is measured and a metric that is not [redacted]

3.0 OBJECTIVES

3.1 [redacted]

3.2 [redacted]

3.3 [redacted]

3.4 [redacted]

3.5 [redacted]

4.0 OVERVIEW

4.1 [redacted]

4.2 [redacted]

4.3 Attributes of a metric

4.4 Example of a metric

4.5 Metrics development worksheet

5.0 DEFINITIONS

5.1 Measurement

The act or process of quantitatively comparing results to requirements to arrive at a quantitative estimate of performance.

5.2 Metric

A measurement [redacted]

6.0 TOOLS

6.1 Sampling

Sampling instead of 100% measurement is useful when there are too many items to check, destruction of the item is necessary, data is needed quickly or data collection is expensive. Acceptable sampling plans are based on Society Standards such as ANSI Z 1.4 for Attributes or ANSI Z1.9 for Variables. Administrative costs and difficulties can be avoided by restricting the number of sampling plans. Data used to establish a metric should be economical to collect.

6.2 Check Sheet

The results of a measurement sample can be presented on a check sheet to establish a trend.
The check sheet can list attributes or variables type data:

Attributes type data		
Standard	Quantity	
[redacted]	[redacted]	
[redacted]	[redacted]	
[redacted]	[redacted]	
[redacted]		
[redacted]		
[redacted]	[redacted]	

Variables type data		
Time Study	Quantity	
[redacted]	[redacted]	
[redacted]	[redacted]	
[redacted]	[redacted]	
[redacted]	[redacted]	
[redacted]	[redacted]	
[redacted]	[redacted]	

6.3 Frequency Table

The check sheet is useful as a snapshot of the counts of an activity but it is [redacted]
The check sheet can be improved by converting it to a frequency table:

Attributes type data		
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]		[redacted]
[redacted]		[redacted]
[redacted]	[redacted]	[redacted]

Variables type data		
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

6.4 Histogram

The frequency table helps to quantify the cumulative number of recurring events but it is [redacted] Converting the frequency data to a Histogram is useful to display the central tendency of the data:

6.5 Pareto Analysis

The frequency table helps to quantify the cumulative number of recurring events but it is [redacted] Converting the frequency data to a Pareto Chart is useful to display the most recurring event to the least recurring event:

Pareto Analysis of Attributes Data

6.6 Miscellaneous Charts, Diagrams and Statistics

Trend and control charts accumulate data over time so they are more than a snapshot of events but they are [redacted]

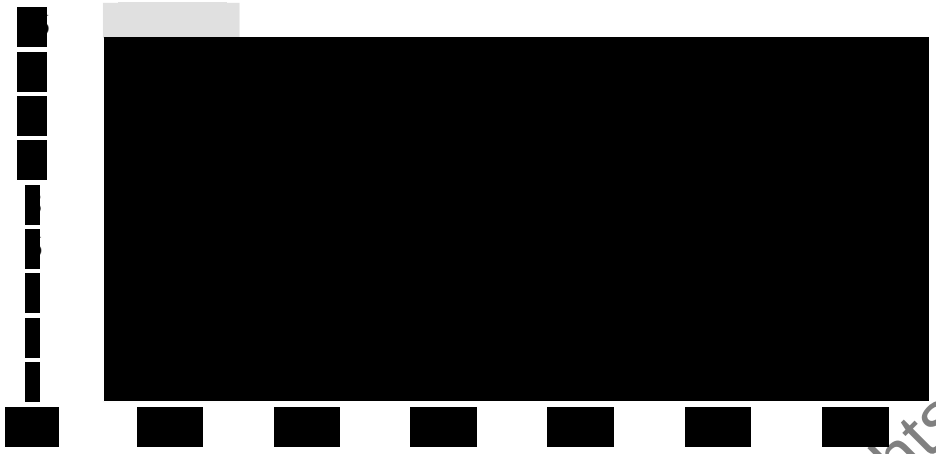
A process flowchart defines the sequence of operations that supports a system of activities but by itself it is not a metric. Parametric and non-parametric statistics are powerful tools to understand the interaction of process variables but they do not [redacted]

7.0 ATTRIBUTES OF A METRIC

7.1 [redacted]
7.2
7.3
7.4
7.5
7.6
7.7
7.8
7.9

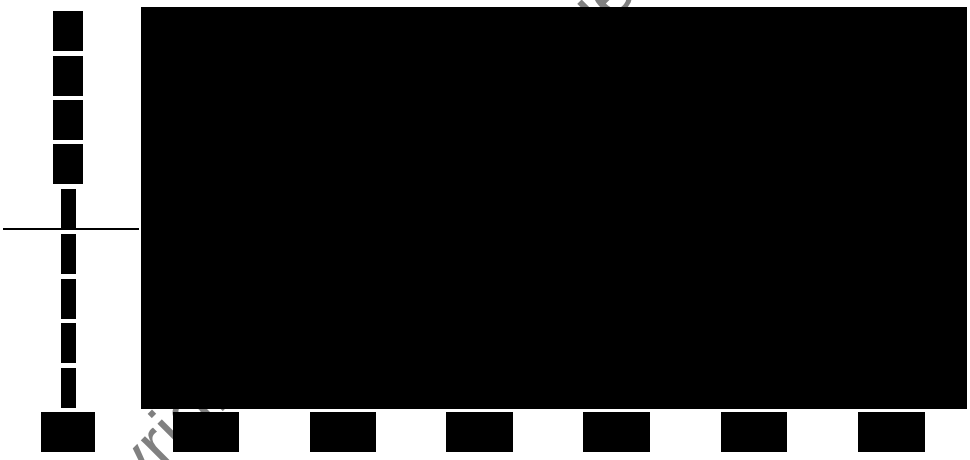
8.0 EXAMPLE OF A METRIC

Lets examine the Pareto Analysis of the Attributes Data



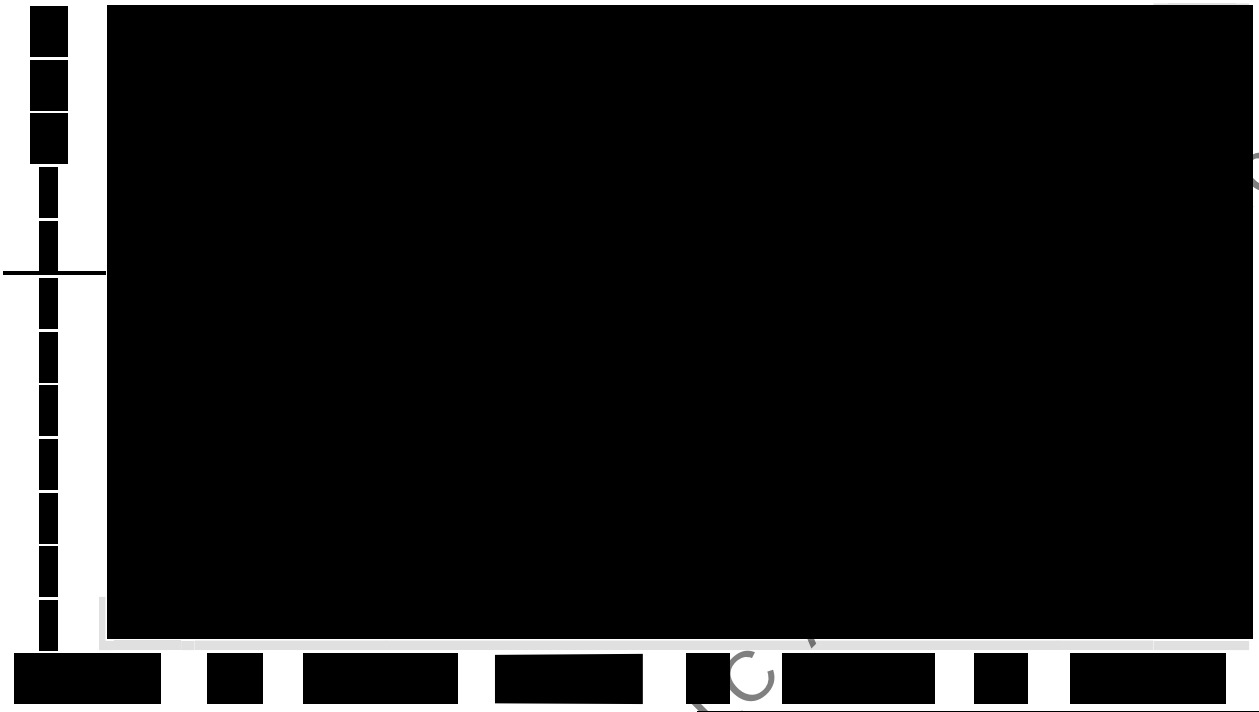
The chart has value because it identifies the <few> from the <many> but it is not a metric by itself unless it is

The chart has been modified to



The modified chart is still not a metric because

The following chart is the best representation of a metric:



The chart now meets the objectives of a metric because [redacted]

METRICS DEVELOPMENT WORKSHEET

[redacted]

REQUEST FOR SUPPORT

☐**Nonconformance** ☐**Continuous Improvement Opportunity** ☐**Calculated Risk Release**

SUBCONTRACTOR: _____ DATE RECEIVED: _____

RFS#: SHEET _____ OF _____

Traveler#:		Op#:		Quantity Received:		Job Number:	
Item Name:		**Description: ID S/B Spec#, Para# & IS Condition w/Quantity &Dimension Affected**					**# Discrepant**
Dwg/Spec:							
Part#:							
[redacted]							

ACN Orientation: ☐Yes ☐No	Suppl.: ☐Yes ☐No	ICAR: ☐Yes # ☐No	EO: ☐Yes # ☐No

CLASSIFICATION	Disposition - check all that apply
MAJOR	[redacted]

Approvals and Effectivity Verification

[redacted]

Request for Support (RFS) Log

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Form Rev: Orig

REQUEST FOR SUPPORT LOG

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Form Rev: Orig

Abbreviations:

[redacted]

PACKING SLIP

(Your Company Name)
Your Address

[redacted]

We hereby certif[redacted]

By: Date:

Form Rev: Orig

(Your Logo)

(Your Logo)

(Your Company Name)

DOCUMENT NAME

Origination Date: XXXX

Document Identifier:	Name
Date:	Latest Revision Date
Project:	Customer, Unique ID, Part Number
Document Status:	Draft, Redline, Released, Obsolete

Abstract:
This document describes xxxxxx.

REVISION LOG

Issue	Date	Comment	Author
0-0			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

1.0 PROCESS MAP

2.0 PURPOSE

3.0 REFERENCES

4.0 EQUIPMENT

5.0 MATERIALS

6.0 OPERATING PROCEDURES

7.0 WORKMANSHIP

Your Logo

Your Company Name

PROCESS ORIENTATION CHECKLIST

Origination Date: XXXX

Document Identifier:	Name, Number, Unique ID
Date:	Latest Revision Date
Project:	Customer, Unique ID, Part Number
Document Status:	Draft, Redline, Released, Obsolete
Document Link:	Location on Server (if used)

Abstract:
This document describes an orientation checklist to understand a process.

REVISION LOG

Issue	Date	Comment	Author
0-0			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

Defined properly, a quality management system is viewed as [redacted]

The traditional approach to quality management has confused practitioners that are used to "compliance to requirements". The traditional standards-based approach will prevent proper application of the quality system and diminish the return on investment in the PDCA cycle to continuously improve the QMS and its processes. Once processes are properly identified and defined, the PDCA cycle can then be effectively applied to drive improvement in the processes and in the QMS.

Process Name:	
Question	**Answer** (N/A if not applicable)
Process Characteristics	
Who owns the process?	
Who is responsible for performing and overseeing the process?	
[redacted]	
Support Process Question With Who - training, knowledge, skills	
[redacted]	
Support Process Questions With What - equipment, installations	
What machines, materials, safety equipment, test equipment, computer systems and software are used in the process?	
[redacted]	
Support Process Questions With What Key Criteria - measurements, assessments	
What in-process/final verification criteria are associated with the output?	
[redacted]	
Input - what should be received	
Upon what inputs does the process operate, e.g., document(s), materials, tooling, schedule, etc?	
[redacted]	

Process Name:	
Question	**Answer** (N/A if not applicable)
[redacted]	
Output - what should be delivered	
What output does the process produce?	
[redacted]	
Support Process Questions **Performance indicators**	
How is the process identified throughout the process?	
How is inspection status identified throughout the process?	
[redacted]	
Support Process Question **How - instructions, procedures, methods**	
What instructions are available to Operators?	
Are documents/work instructions approved?	
[redacted]	
Workmanship	
Process Map Step 1: (name)	
Is this a key characteristic in the process?	
If so, [redacted]	
Process Map Step 2: (name)	
Is this a key characteristic in the process?	
If so, [redacted]	

Process Name:	
Question	**Answer** (N/A if not applicable)
What function should be observed in this process step?	
[redacted]	
Process Map Step 3: (name)	
Is this a key characteristic in the process?	
If so, [redacted]	
Process Map Step 4: (name)	
Is this a key characteristic in the process?	
If so, [redacted]	
Repeat questions listed above for each remaining Steps in the process map	

Improvement Resources	
[redacted]	[redacted]

Drawing No:		PRODUCTION INSPECTION RECORD-1	Form Rev: Orig
Item Name:		(Your Company Name)	
[redacted]			
[redacted]		[redacted]	

[redacted]																			[redacted]	[redacted]
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5																				
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33																				

(Your Logo)

Form Rev: Orig

Use additional space to record inspection tool numbers, product serial numbers, lot numbers, etc

Inspection Operations continued...

#	[redacted]
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32	
33	

(Your Logo)

Your Company Name, etc and logo

Date:

Attention:
Company:
Address:
City, State:
Zip Code:

Subject: Customer/Government Property located at your facility

Dear (insert your appropriate name)

Our records show the Customer/Government property listed below is currently located at your facility. If you have knowledge of other property that should be included, please let us know by including the item(s) on your response.

[redacted]

Supplier/Subcontractor Certification:
I certify the Customer/Government property listed above is physically controlled by our facility.

Signed: _____ Date: _____

PROPERTY CONTROL	Your Logo		
CUSTOMER SUPPLIED / CUSTOMER OWNED			
Customer Name:			
PO#:		Qty:	
ID#:			
Initials:			

NOTEPAD Form Rev: Orig

PROPERTY CONTROL	Your Logo		
CUSTOMER SUPPLIED / CUSTOMER OWNED			
Customer Name:			
PO#:		Qty:	
ID#:			
Initials:			

NOTEPAD Form Rev: Orig

PROPERTY CONTROL	Your Logo		
CUSTOMER SUPPLIED / CUSTOMER OWNED			
Customer Name:			
PO#:		Qty:	
ID#:			
Initials:			

NOTEPAD Form Rev: Orig

PROPERTY CONTROL	Your Logo		
CUSTOMER SUPPLIED / CUSTOMER OWNED			
Customer Name:			
PO#:		Qty:	
ID#:			
Initials:			

NOTEPAD Form Rev: Orig

PROPERTY CONTROL	Your Logo		
CUSTOMER SUPPLIED / CUSTOMER OWNED			
Customer Name:			
PO#:		Qty:	
ID#:			
Initials:			

NOTEPAD Form Rev: Orig

PROPERTY CONTROL	Your Logo		
CUSTOMER SUPPLIED / CUSTOMER OWNED			
Customer Name:			
PO#:		Qty:	
ID#:			
Initials:			

NOTEPAD Form Rev: Orig

PROPERTY CONTROL	Your Logo		
CUSTOMER SUPPLIED / CUSTOMER OWNED			
Customer Name:			
PO#:		Qty:	
ID#:			
Initials:			

NOTEPAD Form Rev: Orig

PROPERTY CONTROL	Your Logo		
CUSTOMER SUPPLIED / CUSTOMER OWNED			
Customer Name:			
PO#:		Qty:	
ID#:			
Initials:			

NOTEPAD Form Rev: Orig

PROPERTY CONTROL	Your Logo		
CUSTOMER SUPPLIED / CUSTOMER OWNED			
Customer Name:			
PO#:		Qty:	
ID#:			
Initials:			

NOTEPAD Form Rev: Orig

PROPERTY CONTROL	Your Logo		
CUSTOMER SUPPLIED / CUSTOMER OWNED			
Customer Name:			
PO#:		Qty:	
ID#:			
Initials:			

NOTEPAD Form Rev: Orig

Property Management Log

	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
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24							
25							

Form Rev: Orig

Your Logo

Property Record

Contract Number:		
Customer Name:		
Property Description:		
Quantity:	Date Received:	Value:
[redacted]	[redacted]	[redacted]

Form Rev: Orig

Your Logo

PURCHASE ORDER

(Your Company Name)
Your Address
Your City, State, Zip
Phone
Fax

Date	
Purchase Order #	Page:

This order number must appear on all bills of lading, packing slips and invoices. Send 2 copies of invoice to:
Attention: Accounts Payable

Terms	Net 45	FOB: Shipping Point
Taxable		

[redacted]

Sign Acknowledgement Copy and Return Immediately
Note: A contract does not exist until receipt of this acknowledgement

Buyer:		Date:

Form Rev: Orig

(Your Company Name)

Terms and Conditions of Purchase

1) WARRANTIES

2) CHANGES

3) INFRINGEMENT INDEMNITY

4) DOCUMENT MARKING AND USE

5) PROPRIETARY INFORMATION, DUPLICATION AND DISCLOSURE

6) ASSIGNMENTS AND SUBCONTRACTING

7) GENERAL

8) PRICES

9) SPECIAL PROVISIONS FOR U.S. GOVERNMENT WORK

10) INSOLVENCY

11) FAIR LABOR STANDARDS ACT

12) INSPECTION

13) VARIATION IN QUANTITY

14) DISPUTES

15) EQUAL EMPLOYMENT OPPORTUNITY/AFFIRMATIVE ACTION PROVISIONS

Contractor and Subcontractor Listing Requirement

1)

2)

Form Rev: Orig

Inspection Tags
Green = Good, Yellow = Withhold, Red = Bad
Use standard, colored card stock – size approximately 3.5" tall by 5.75" wide or use stock size

GOOD TAG			Your Logo		
P/N:		PO #:		Date:	
Dwg #:		Rev:		Lot #:	
[redacted]		[redacted]		[redacted]	
[redacted]		[redacted]		[redacted]	
[redacted]			[redacted]		
[redacted]					
[redacted]					

Form Rev: Orig

GOOD TAG			Your Logo		
P/N:		PO #:		Date:	
Dwg #:		Rev:		Your Lot #:	
[redacted]		[redacted]		[redacted]	
[redacted]		[redacted]		[redacted]	
[redacted]		[redacted]		[redacted]	
[redacted]		[redacted]		[redacted]	
[redacted]			[redacted]		
[redacted]					
[redacted]					
[redacted]					
[redacted]					

Form Rev: Orig

WITHHOLD TAG		Your Logo	
Date:		Item Name:	
[redacted]		[redacted]	
[redacted]		[redacted]	
[redacted]			

Form Rev: Orig

BAD TAG		Your Logo	
Date:		Item Name:	
[redacted]		[redacted]	
[redacted]		[redacted]	
[redacted]			

Form Rev: Orig

GOOD TAG		Your Logo		
P/N:		Rev:		Date:
PO#:		Lot#:		
MR#:		Qty Ok:		
Ready For:				
Initials:				

Form Rev: Orig

GOOD TAG		Your Logo		
P/N:		Rev:		Date:
PO#:		Lot#:		
MR#:		Qty Ok:		
Ready For:				
Initials:				

Form Rev: Orig

GOOD TAG		Your Logo		
P/N:		Rev:		Date:
PO#:		Lot#:		
MR#:		Qty Ok:		
Ready For:				
Initials:				

Form Rev: Orig

GOOD TAG		Your Logo		
P/N:		Rev:		Date:
PO#:		Lot#:		
MR#:		Qty Ok:		
Ready For:				
Initials:				

Form Rev: Orig

GOOD TAG		Your Logo		
P/N:		Rev:		Date:
PO#:		Lot#:		
MR#:		Qty Ok:		
Ready For:				
Initials:				

Form Rev: Orig

GOOD TAG		Your Logo		
P/N:		Rev:		Date:
PO#:		Lot#:		
MR#:		Qty Ok:		
Ready For:				
Initials:				

Form Rev: Orig

GOOD TAG		Your Logo		
P/N:		Rev:		Date:
PO#:		Lot#:		
MR#:		Qty Ok:		
Ready For:				
Initials:				

Form Rev: Orig

GOOD TAG		Your Logo		
P/N:		Rev:		Date:
PO#:		Lot#:		
MR#:		Qty Ok:		
Ready For:				
Initials:				

Form Rev: Orig

GOOD TAG		Your Logo		
P/N:		Rev:		Date:
PO#:		Lot#:		
MR#:		Qty Ok:		
Ready For:				
Initials:				

Form Rev: Orig

WITHHOLD TAG		Your Logo	
Date:		Item Name:	
PO #:		Item Part Number:	
Lot #:		Material Report #:	
S/N:		Initials:	
Reason for Withholding:			

Form Rev: Orig

WITHHOLD TAG		Your Logo	
Date:		Item Name:	
PO #:		Item Part Number:	
Lot #:		Material Report #:	
S/N:		Initials:	
Reason for Withholding:			

Form Rev: Orig

WITHHOLD TAG		Your Logo	
Date:		Item Name:	
PO #:		Item Part Number:	
Lot #:		Material Report #:	
S/N:		Initials:	
Reason for Withholding:			

Form Rev: Orig

WITHHOLD TAG		Your Logo	
Date:		Item Name:	
PO #:		Item Part Number:	
Lot #:		Material Report #:	
S/N:		Initials:	
Reason for Withholding:			

Form Rev: Orig

WITHHOLD TAG		Your Logo	
Date:		Item Name:	
PO #:		Item Part Number:	
Lot #:		Material Report #:	
S/N:		Initials:	
Reason for Withholding:			

Form Rev: Orig

WITHHOLD TAG		Your Logo	
Date:		Item Name:	
PO #:		Item Part Number:	
Lot #:		Material Report #:	
S/N:		Initials:	
Reason for Withholding:			

Form Rev: Orig

Helpful Hint:
Purchase green “presentation” paper for the Good Material Tag and yellow “presentation” paper for the Withhold Tag, then print and cut whenever you need…

ACCEPTED TAG		Your Logo		
THIS MATERIAL HAS BEEN INSPECTED AND ACCEPTED				
P/N:		Rev:		Date:
PO#:		Lot#:		
MR#:		Qty Ok:		
Initials:				

Form Rev: Orig

ACCEPTED TAG		Your Logo		
THIS MATERIAL HAS BEEN INSPECTED AND ACCEPTED				
P/N:		Rev:		Date:
PO#:		Lot#:		
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Initials:				

Form Rev: Orig

ACCEPTED TAG		Your Logo		
THIS MATERIAL HAS BEEN INSPECTED AND ACCEPTED				
P/N:		Rev:		Date:
PO#:		Lot#:		
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Form Rev: Orig

ACCEPTED TAG		Your Logo		
THIS MATERIAL HAS BEEN INSPECTED AND ACCEPTED				
P/N:		Rev:		Date:
PO#:		Lot#:		
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Form Rev: Orig

ACCEPTED TAG		Your Logo		
THIS MATERIAL HAS BEEN INSPECTED AND ACCEPTED				
P/N:		Rev:		Date:
PO#:		Lot#:		
MR#:		Qty Ok:		
Initials:				

Form Rev: Orig

ACCEPTED TAG		Your Logo		
THIS MATERIAL HAS BEEN INSPECTED AND ACCEPTED				
P/N:		Rev:		Date:
PO#:		Lot#:		
MR#:		Qty Ok:		
Initials:				

Form Rev: Orig

ACCEPTED TAG		Your Logo		
THIS MATERIAL HAS BEEN INSPECTED AND ACCEPTED				
P/N:		Rev:		Date:
PO#:		Lot#:		
MR#:		Qty Ok:		
Initials:				

Form Rev: Orig

ACCEPTED TAG		Your Logo		
THIS MATERIAL HAS BEEN INSPECTED AND ACCEPTED				
P/N:		Rev:		Date:
PO#:		Lot#:		
MR#:		Qty Ok:		
Initials:				

Form Rev: Orig

ACCEPTED TAG		Your Logo		
THIS MATERIAL HAS BEEN INSPECTED AND ACCEPTED				
P/N:		Rev:		Date:
PO#:		Lot#:		
MR#:		Qty Ok:		
Initials:				

Form Rev: Orig

ACCEPTED TAG		Your Logo		
THIS MATERIAL HAS BEEN INSPECTED AND ACCEPTED				
P/N:		Rev:		Date:
PO#:		Lot#:		
MR#:		Qty Ok:		
Initials:				

Form Rev: Orig

FINAL INSPECTION
PERFORMED BY _____
YOUR LOGO

Form Rev: Orig

FINAL INSPECTION
PERFORMED BY _____
YOUR LOGO

Form Rev: Orig

FINAL INSPECTION
PERFORMED BY _____
YOUR LOGO

Form Rev: Orig

FINAL INSPECTION
PERFORMED BY _____
YOUR LOGO

Form Rev: Orig

FINAL INSPECTION
PERFORMED BY _____
YOUR LOGO

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FINAL INSPECTION
PERFORMED BY _____
YOUR LOGO

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FINAL INSPECTION
PERFORMED BY _____
YOUR LOGO

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FINAL INSPECTION
PERFORMED BY _____
YOUR LOGO

Form Rev: Orig

FINAL INSPECTION
PERFORMED BY _____
YOUR LOGO

Form Rev: Orig

FINAL INSPECTION
PERFORMED BY _____
YOUR LOGO

Form Rev: Orig

Helpful Hints:

Purchase “presentation” paper in your choice of color and then print and cut labels whenever you need.

Purchase peel-and-stick labels of the correct size and then print whenever you need.

Your Logo	Receiving Inspection Instructions	Form Rev: Orig Page 1 of 1
	Special Instructions: [redacted]	

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
R&I	---	Op 1: [redacted]		
		Op 2: [redacted]		
		Op 3: [redacted]		
		Op 4: [redacted]		
		Op 5: [redacted]		
		Op 6: [redacted]		
		Op 7: [redacted]		
		Op 8: [redacted]		
		Op 9: [redacted]		
		Op 10: [redacted]		
		Op 11: [redacted]		
		Op 12: [redacted]		
		Op 13: [redacted]		
		Op 14: [redacted]		
		Op 15 [redacted]		
		Op 16: [redacted]		
		Op 17: [redacted]		

Drawing No: [redacted]					**RECEIVING INSPECTION RECORD** [redacted]					
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
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35										

Form Rev: Orig

Your Logo

Receiving Log

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Form Rev: Orig

REQUEST FOR CHANGE

Desired Change:			
Preparer Name:		Submittal Date:	
[redacted]		[redacted]	
[redacted]		[redacted]	
[redacted]		[redacted]	
[redacted]		[redacted]	
[redacted]			

(Your Logo)

Purchase Requisition	#	Quote Number	(Your Logo)
Date:		Date Matl Required:		To be used for Project:

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]		

[redacted]	[redacted] ☐ [redacted] ☐	[redacted] ☐	[redacted] ☐	[redacted] ☐	[redacted] ☐

[redacted]	[redacted] ☐ [redacted] ☐	[redacted] ☐ [redacted] ☐	[redacted] ☐ [redacted] ☐

[redacted]		[redacted]	[redacted]	[redacted]	[redacted]

Vendor Information	Purchase Order	Date
	[redacted]	
	[redacted]	
[redacted]		

Form Rev: Orig

RISK ANALYSIS

General			
Project Name:	[redacted]	Customer Name:	[redacted]
Risk Identification			
[redacted]			
Risk Assessment			
[redacted]			
Risk Planning			
[redacted]			
Risk Response			
[redacted]			

Form Rev: Orig

RISK ANALYSIS

Origination Date: (month year)

Document Identifier:	Risk Analysis Work Instruction
Date:	Orig
Project:	
Document Status:	Released

Abstract:
This document describes methods to easily identify and manage risks.

REVISION LOG

Issue	Date	Comment	Author
0-0			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

1.0 Scope

Identify the risks associated with products, activities or services that can be controlled and influenced and prioritize mitigation of the risk.

2.0 Objective

The identification of risks is a key element of the business operation, as these determine those issues and areas that should be the primary focus for monitoring, control and improvement. Risks associated with products, activities or services should be evaluated and scored in terms of opportunity, probability and severity according to their risk. A risk can be defined as an effect between any product, activity or service on any functional area of the business operation; such as, employee health and safety, environment, property, resources, products, outsourcing, cost and schedule. A risk priority number (RPN) is calculated for each risk and graphed as a Pareto Distribution by sorting in descending order to prioritize risk mitigation efforts.

3.0 Process Steps

[redacted]

4.0 Requirements

4.1 Definitions

Opportunity Score

[redacted]

Probability Score

[redacted]

Severity Score

[redacted]

4.2 Identification of Functional Area Risks

The management team should use their best judgment regarding the level of detail required to conduct a comprehensive review. Once the management team has identified potential risk categories then a cross-functional team of representatives from affected functional areas should be established to perform a risk analysis.

The team should document [redacted]

4.3 Ranking Potential Risks

The management team should rate the significance of each risk using a numerical ranking scale from [redacted]

4.4 Calculating the Risk Priority Number

The risk priority number (RPN) that is used in the Pareto Distribution chart is calculated by [redacted] see Figure 1 and Figure 2 examples.

Typical Risk Categories and Potential Risks:

Risk Categories

[redacted]

A guidance list of potential risks for functional areas is provided in the following tables. The management team should identify risk categories that are appropriate to the targeted functional area. The following risks are for illustrative purposes only - the risk assessment team should brainstorm to generate a detailed list of potential risks that are appropriate to the selected risk categories.

FUNCTIONAL AREA: EMPLOYEE HEALTH & SAFETY	
PHYSICAL RISKS	HEALTH RISKS
[redacted]	[redacted]

FUNCTIONAL AREA: EMPLOYEE HEALTH & SAFETY	
PHYSICAL RISKS	HEALTH RISKS
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

FUNCTIONAL AREA: ENVIRONMENT			
[redacted]	[redacted]	[redacted]	[redacted]

FUNCTIONAL AREA: PROPERTY		
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

FUNCTIONAL AREA: PROPERTY		
[redacted]	[redacted]	[redacted]
[redacted]		Spills and releases

FUNCTIONAL AREA: RESOURCE	
[redacted]	[redacted]
[redacted]	[redacted]

FUNCTIONAL AREA: PRODUCT		
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

FUNCTIONAL AREA: OUTSOURCING		
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

4.5 Significance Analysis

After potential risks have been identified for a functional area, the significance ranking process will evaluate and score each risk according to the following criteria:

[redacted]

4.6 Example Functional Area: Employee Health & Safety

4.6.1 **Opportunity or frequency of occurrence of the risk** – defined as the frequency of occurrence of safety related employee accidents or incidents or the frequency of employee accidents occurring compared to the facility as a whole. Another point of view for this evaluation would be [redacted]

Opportunity or Frequency of Occurrence of the Risk	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	

4.6.2 **Probability or likelihood of occurrence of the risk** – defined as the expected likelihood of occurrence of safety related employee accidents or incidents.

Probability or Likelihood of Occurrence of the Risk	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	

4.6.3 **Severity of the risk** – defined as the actual or potential risk or seriousness of an employee accident.

Severity of the Risk	
[redacted]	
[redacted]	
[redacted]	

Severity of the Risk	
	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

4.6.4 **Scale of use of the risk** – defined as the actual or potential size, volume or magnitude of the resulting employee safety risk. This should be evaluated as to the number of employees that work in the functional area compared to the facility; obviously, [redacted]

Scale of Use of the Risk	
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

4.6.5 **Legal or regulatory concern** – defined as regulatory exposure of employee safety as related to applicable federal, state and local laws. If the functional area is subject to general safety regulations, the rating would [redacted]

Examples of specific regulations include:

SPECIFIC SAFETY MANAGEMENT PROGRAMS		
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Legal or Regulatory Concern of the Risk	
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

4.6.6 **Degree of control or influence of the risk** – defined as the level of control that the functional area has over employee health and safety; for instance, [redacted]

Degree of Control or Influence of the Risk	
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

4.6.7 **Stakeholder concern of the risk** – defined as the actual or potential risk to employees and the surrounding community as perceived by internal or external groups.

Stakeholder Concern of the Risk	
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Using the above sample functional area for Employee Health and Safety, the management team [redacted]

Example of Combining Functional Areas on One Worksheet

Figure 1: Risk Analysis Worksheet

Date:	
Risk Category Potential Risk	
[redacted]	[redacted]

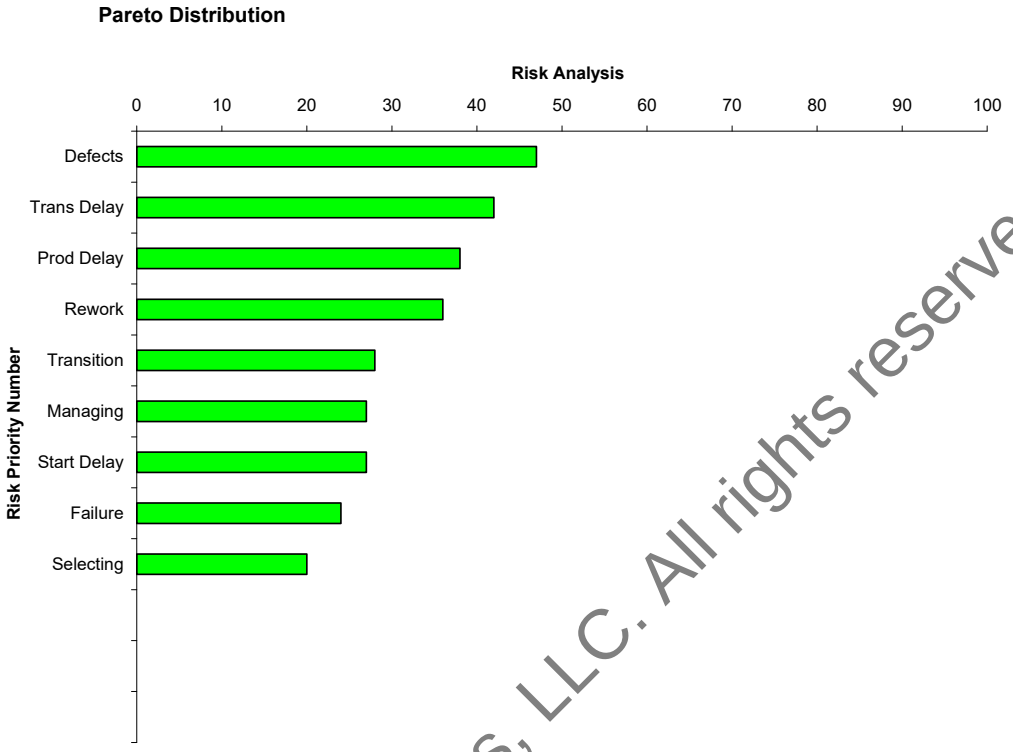
Form Rev: Orig

Example of Completed Form for One Functional Area with 3 Risk Categories

Figure 2: Outsourcing Risk Assessment

Date:	
Risk Category Potential Risk	---
[redacted]	[redacted]

Example of Completed Pareto Distribution Chart for Potential Risks of Outsourcing to New Supplier



Date: _____

Your Co Name

Typical Functional Areas to Consider for Potential Risks

[redacted]

Critical Elements Risk Assessment

Form Rev: Orig

Your Logo

RISK STATUS REPORT

[redacted]		[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	
	[redacted]		
	[redacted]		
[redacted]			
[redacted]	[redacted]		
	[redacted]		
[redacted]			
[redacted]	[redacted]		
1			
2			
3			
4			
5			
6			
7			
8			
9			
[redacted]			
[redacted]	Low Medium High	[redacted]	[redacted]
[redacted]			

Form Rev: Orig

Your Logo

ROUTING TICKET		(Your Company)	
P/N:		Initial	Date
Short Description	☐		
Short Description	☐		
Short Description	☐		
Short Description	☐		
Short Description	☐		
Short Description	☐		

Form Rev: Orig

ROUTING TICKET		(Your Company)	
P/N:		Initial	Date
Short Description	☐		
Short Description	☐		
Short Description	☐		
Short Description	☐		
Short Description	☐		
Short Description	☐		

Form Rev: Orig

ROUTING TICKET		(Your Company)	
P/N:		Initial	Date
Short Description	☐		
Short Description	☐		
Short Description	☐		
Short Description	☐		
Short Description	☐		
Short Description	☐		

Form Rev: Orig

ROUTING TICKET		(Your Company)	
P/N:		Initial	Date
Short Description	☐		
Short Description	☐		
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Short Description	☐		
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Short Description	☐		

Form Rev: Orig

ROUTING TICKET		(Your Company)	
P/N:		Initial	Date
Short Description	☐		
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Short Description	☐		

Form Rev: Orig

ROUTING TICKET		(Your Company)	
P/N:		Initial	Date
Short Description	☐		
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Short Description	☐		

Form Rev: Orig

ROUTING TICKET		(Your Company)	
P/N:		Initial	Date
Short Description	☐		
Short Description	☐		
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Short Description	☐		
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Form Rev: Orig

ROUTING TICKET		(Your Company)	
P/N:		Initial	Date
Short Description	☐		
Short Description	☐		
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Form Rev: Orig

ROUTING TICKET		(Your Company)	
P/N:		Initial	Date
Short Description	☐		
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Short Description	☐		
Short Description	☐		

Form Rev: Orig

ROUTING TICKET		(Your Company)	
P/N:		Initial	Date
Short Description	☐		
Short Description	☐		
Short Description	☐		
Short Description	☐		
Short Description	☐		
Short Description	☐		

Form Rev: Orig

Avery Label 2"x4" Peel-&-Stick Label #5163 8½"x11"

(Your Logo)

ROUTING TICKET

ACCOUNT#:

Operator:		Date:	
XXX Lot#:		XXX Lot#:	
[redacted]			

Form Rev: Orig

Shelf Life Expiration Log

Description:					Date Received:				
P/N:			Rev:			PO#:			
Supplier Lot#:									
[redacted]									
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	y

Form Rev: Orig

Shipping Log

[redacted]	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	[redacted]

Form Rev: Orig

(Your Logo)

Your Logo **Supplier Evaluation**

Supplier: **Commodity:**

If Part I criteria is met, Supplier is approved without further evaluation.

Part I

☐ [redacted] ☐ [redacted]

☐ [redacted] ☐ [redacted]

If Part I criteria is NOT met, Supplier must be evaluated under Part II.

Part II

[redacted]

☐ [redacted]
☐
☐
☐
☐
☐

[redacted]
☐ [redacted]
☐ [redacted] ____

RESULTS OF INITIAL EVALUATION

(Ref. Purchasing Procedure)

☐ [redacted] ☐ [redacted] ☐ [redacted]

[redacted] ____ [redacted] ____

RESULTS OF RECEIVING INSPECTION OR SERVICE FEEDBACK

Purchase Order Number **Request for Support Number**

☐ [redacted] ☐ [redacted]

[redacted]

NOTES

SUPPLIER PERFORMANCE RATING REPORT

Job #: Performance Reporting Dates:

Supplier:

OVERALL PERFORMANCE RATING **100**

[redacted]
Excellent
Good
Improvement Expected
Improvement Required

	Points (100 Max)	Weight %
Quality.....	100	[redacted]
Delivery.....	100	[redacted]
Documentation.....	100	[redacted]
Cooperation.....	100	[redacted]

Quality: The number of items accepted divided by the number of items that should have been received times 100.

Delivery: The grace period is [redacted] If items are damaged in shipping the Supplier has earned zero (0) points.

Documentation: [redacted]

Cooperation: [redacted]

Purchasing Agent_____ Date_____

Form Rev: Orig

SUPPLIER RATING WORKSHEET

Supplier:
P/N:

QUALITY

[redacted]			

DELIVERY

[redacted]	[redacted]	[redacted]	[redacted]

DOCUMENTATION

[redacted]	[redacted]	[redacted]

COOPERATION

[redacted]	[redacted]	[redacted]

Quality: [redacted]

Delivery: [redacted]

Documentation: [redacted]

Cooperation: [redacted]

[redacted]	

Form Rev: Orig

Supplier Overall Performance Rating

Supplier:	Overall Performance Rating				Month:
[redacted]	[redacted]	[redacted]			[redacted]
		☐	☐	☐	☐
		☐	☐	☐	☐
		☐	☐	☐	☐
		☐	☐	☐	☐
		☐	☐	☐	☐
		☐	☐	☐	☐
[redacted]					

Supplier Monthly Rating Report

[redacted]	[redacted]	Monthly [redacted]

Form Rev: Orig

Prepared by: _____ Date: _____

Your Logo

Your Company Name

SUPPLIER QUALITY REQUIREMENTS

Origination Date: XXXX

Document Identifier:	Supplier Quality Requirements
Date:	Latest Revision Date
Project:	Customer, Unique ID, Part Number
Document Status:	Draft, Redline, Released, Obsolete
Document Link:	Location on Server (if used)

Abstract:
This document describes flowdown requirements for Suppliers.

REVISION LOG

Issue	Date	Comment	Author
0-0			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

☐PURPOSE and SCOPE

To establish the minimum requirements for supplier Quality Systems necessary to ensure that materials, parts, components, and services meet the requirements of the Contract. Procedures used to implement the provisions of this requirement shall be subject to Buyer approval upon request.

☐APPLICABILITY

These requirements shall apply to all supplies and services when referenced on the Purchase Order and amendments thereto.

When Buyer's Purchase Order includes Seller's Inspection System Level I, as a requirement, Seller's contractual commitment for an Inspection System shall be defined by all paragraphs of this specification. When Buyer's Purchase Order indicates Level II as a requirement then the Seller's contractual commitment for an Inspection System shall be defined only by those paragraphs of this specification which are checked-off.

☐DEFINITIONS and ABBREVIATIONS

A. The term 'Buyer' or 'Buyer' means Buyer.

B. The term 'Seller' means the legal entity that is the contracting party with the Buyer with respect to the Purchase Order.

C. 'IAW' means in accordance with.

D. 'MRB' means Material Review Board

☐SELLER's QUALITY SYSTEM, GENERAL

[redacted]

☐NEGOTIATIONS

[redacted]

☐PROPRIETARY INFORMATION

[redacted]

[redacted]

☐**PROCESS CONTROL**

[redacted]

[redacted]

☐**SUBCONTRACTOR CONTROL**

[redacted]

☐**DRAWING and CHANGE CONTROL**

[redacted]

☐**RECEIVING INSPECTION**

[redacted]

☐**STOCK CONTROL**

[redacted]

☐SAMPLING INSPECTION

Acceptance sampling procedures, if other than ANSI Z 1.4, must have Buyer approval prior to use; sampling to permit defects is not allowed.

☐TOOL, GAGE, and TEST EQUIPMENT

[redacted]

☐MATERIAL CONTROL

[redacted]

[redacted]

☐**TECHNICAL REQUIREMENTS**

[redacted]

Ref: Page 1 / of /	Your Company Name SURVEY REPORT

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]

[redacted]	[redacted]
[redacted] ☐	
[redacted] ☐	
[redacted] ☐	
[redacted] ☐	

[redacted]

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]				
[redacted]				
[redacted]				

[redacted]

Ref: Page 2 / of /	Your Company Name SURVEY REPORT Continuation…

Ref: Page 3 / of /	Your Company Name SURVEY REPORT Continuation…

Your Production Area
Training Certificate

awarded to

Your Employee Name

Your Specification
Your Details

Your Date

Training Supervisor ***Quality Manager***

YOUR PRODUCTION AREA TRAINING CERTIFICATE

Awarded to

Your Employee Name

For successful completion of
Your Specification
Your Details

Your Date

Training Supervisor

Quality Manager

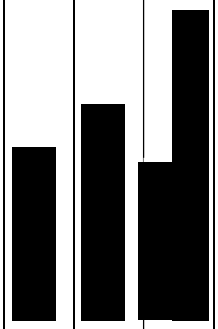
TRAINING LOG

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Form Rev: Orig

Your Logo

QMS Procedure Training Matrix for (Your Company)

Name																		
B. eQMS			X	X	X	X	X			X	X			X		X		X
Br. eQMS			X	X	X	X	X			X	X			X		X		X
C. eQMS	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Ch. eQMS			X		X	X				X	X			X		X		X
Chr. eQMS			X		X	X				X	X			X		X		X
D. eQMS			X		X	X				X	X			X		X		X
Da. eQMS	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Dav. eQMS			X			X								X		X		X
E. eQMS			X			X			X					X	X	X		X
F. eQMS	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
J. eQMS			X	X	X	X			X		X		X	X	X	X	X	X
Je. eQMS		X	X	X	X	X	X			X	X	X	X	X		X	X	X
Jef. eQMS	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Jo. eQMS			X		X	X				X	X			X		X		X
K. eQMS			X			X	X		X	X	X			X		X		X
L. eQMS			X			X								X		X		X
P. eQMS			X			X			X					X		X		X
R. eQMS			X			X								X		X		X
Ri. eQMS		X	X			X	X			X	X		X	X	X	X	X	X
S. eQMS			X			X								X		X		X
Sh. eQMS			X		X	X				X	X			X		X		X
St. eQMS		X	X	X	X	X	X			X	X	X	X	X		X		X
Su. eQMS	X	X	X	X	X	X				X	X		X	X	X	X	X	X
T. eQMS		X	X	X	X	X	X			X	X	X	X	X		X	X	X
W. eQMS	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Y. eQMS			X		X	X				X	X			X		X		X
Yo. eQMS			X		X	X				X	X			X		X		X
Z. eQMS		X	X			X	X		X			X		X		X		X

X = Applicable QMS Procedure record of orientation training for each Employee.
The Company must [redacted]

Note - Optional Multi-Purpose Form:
Change title of form to "Work Instruction Training Matrix" and change column headings to applicable title of job-related work instruction to establish a record of orientation for each Employee's work-related activity.

ORIENTATION/TRAINING REQUEST

To:	
Dept:	Date:

You have been scheduled to attend the next orientation

[redacted]

Form Rev: Orig

Your Logo

[redacted]		[redacted]		[redacted]		[redacted]		[redacted]		[redacted]	[redacted]
TRAVELER [redacted]										[redacted]	[redacted]
[redacted]				[redacted]						[redacted]	
[redacted]											
[redacted]										[redacted]	
[redacted]										[redacted]	

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Form Rev: Orig

Your Logo

VERIFICATION AND VALIDATION

Program Name:		Job Number:	
[redacted]		[redacted]	

DESIGN STAGE

☐ [redacted] ☐ [redacted] ☐ [redacted] ☐ [redacted] ☐ [redacted]

VERIFICATION INPUTS

VERIFICATION ACTIVITIES

☐ [redacted] ☐ [redacted] ☐ [redacted] ☐ [redacted]

Comments:

VALIDATION ACTIVITIES

☐ [redacted] ☐ [redacted] ☐ [redacted]

INTENDED USE OF PRODUCT

TEST-DEMONSTRATION REVIEW

☐ [redacted] ☐ [redacted] ☐ [redacted] ☐ [redacted] ☐ [redacted]

VERIFICATION AND VALIDATION
APPROVED PROCESSES, EQUIPMENT, M&TE and PERSONNEL
ACTION ITEMS – RESPONSIBILITY – DUE DATE

Form Rev: Orig

DOCUMENT NAME

Origination Date: (month year)

Document Identifier:	Name, Number, Unique ID
Date:	Your Date
Document Status:	Released

Abstract:
This document describes xxxxxx.

REVISION LOG

Issue	Date	Comment	Author
Orig	Mo/Yr	Original Release	

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

1.0 SCOPE

2.0 THEORY

3.0 REFERENCES

4.0 EQUIPMENT

5.0 MATERIALS

6.0 OPERATING PROCEDURES

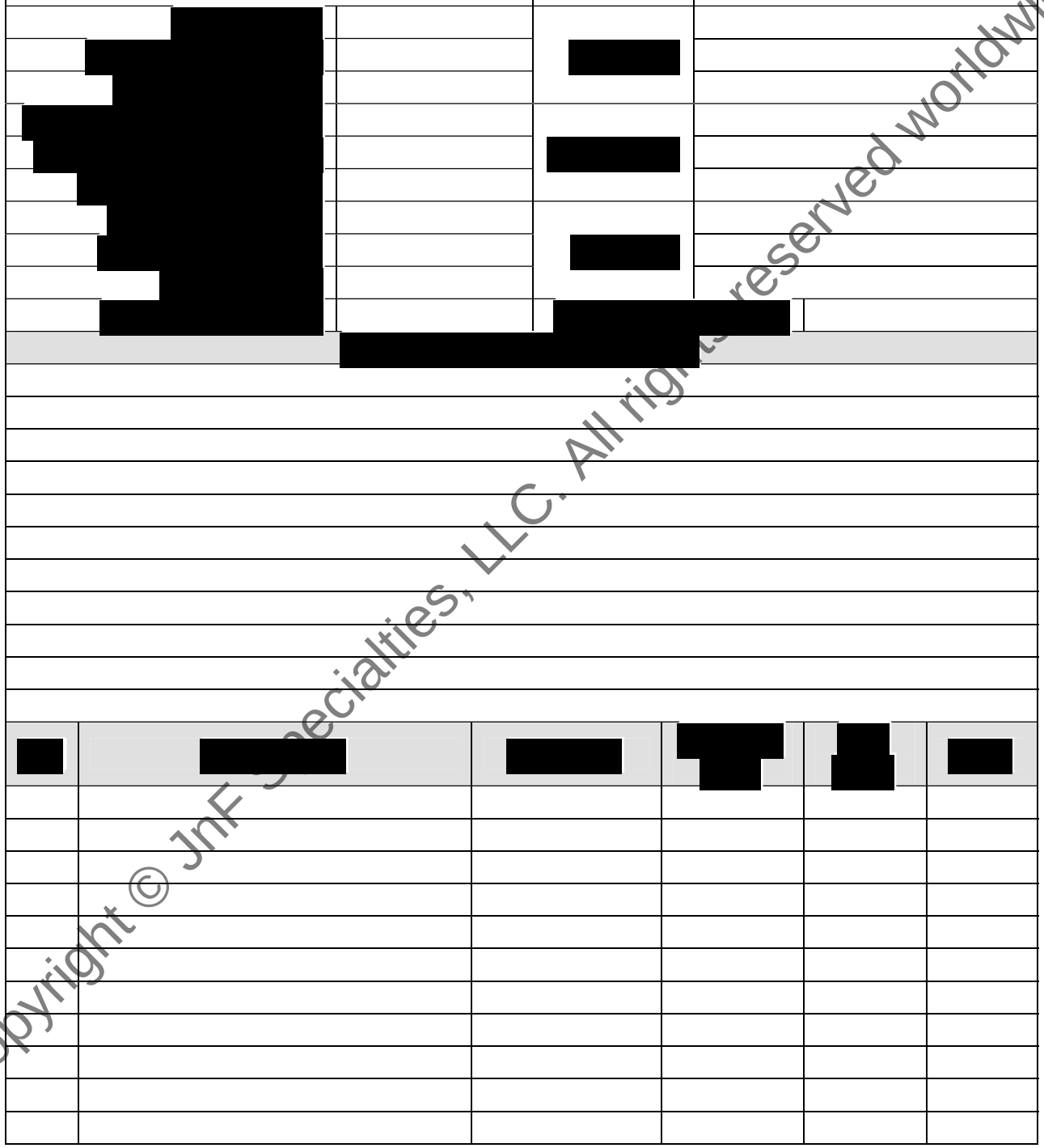
7.0 WORKMANSHIP

(Your Logo)

WORK ORDER

Job #: Rev:

(Your Company Name) Your Address City, State, Zip	Customer:	



Form Rev: Orig

Add to Cart