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QUALITY POLICIES HANDBOOK

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Abstract:

This document summarizes the Company's quality policies, procedures and forms.

REVISION LOG

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DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

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Paragraph numbers in parentheses (x.x.x) refer to related content in the quality handbook.

1.0 Scope and Objective

1.1 Scope

The Company's quality policies handbook applies to all business operations and production activities required to produce deliverable goods (products, components and activities).

1.2 Objective

The objective of the quality management system is to implement and maintain a management system that [redacted]

The following principles have been identified to facilitate the achievement of this goal:

a) [redacted]

b)

c)

d)

e)

f)

g)

2.0 Normative References

2.1 Internal Normative References

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

2.2 External Normative References

a) ***API Specification Q1, 10th Edition*** - Specification for quality management system Requirements for Manufacturing Organizations for the Petroleum and Natural Gas Industry

3.0 Terms and Definitions

Terms and definitions apply as defined in ***QMS-16 Definitions and Abbreviations Procedure***, ***ISO 9001:2015*** and ***API Spec Q1***.

3.1 ISO / API / QMS Correlation

The Company's Quality Policies Handbook is designed to correspond to paragraph numbering in the ***API Spec Q1***.

4.0 Quality Management System Requirements

4.1 Quality Management System

4.1.1 General

To ensure that products, services and processes conform to specified requirements, the Company has [redacted] according to requirements in QMS standard ***API Spec Q1***.

The quality management system (QMS):

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]
e) [redacted]
f) [redacted]
g) [redacted]

The type and extent of outside processes are [redacted] Annual management planning outlines [redacted] according to the ***QMS-04 Management Process Procedure***. Plans are established by the Company and teams are assigned to [redacted] The quality management system and policies are reviewed in annual Management Reviews according to the ***QMS-04 Management Process Procedure***.

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The following diagram illustrates the processes of the quality management system, [redacted]

Figure 4.1.1: Process-Based Quality Management System

4.1.2 Quality Policy

The Company is dedicated to providing high quality and high value products, components, activities and services to Customers, [redacted] to meet or exceed applicable [redacted] The Company is committed to [redacted] that are established, [redacted] the Company.

The Company's quality management system is designed to comply with ***API Spec Q1***.

The Quality Policy is defined, documented, approved and reviewed by Top Management according to the ***QMS-04 Management Process Procedure*** to ensure:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]
e) [redacted]

Department managers (Your titles, e.g., [redacted] are responsible for [redacted] within their respective organizations.

4.1.3 Quality Objectives

Management ensures that quality objectives are compatible with [redacted] according to

QMS-04 Management Process Procedure, including those needed to meet [redacted] requirements.

Quality Objectives:

a) [redacted]
b)
c)
d)
e)

4.1.4 Planning the Quality Management System

4.1.4.1 General

The Company has defined and documented methods needed for the operation, management and control of all quality management system processes according to the ***QMS-04 Management Process Procedure***. Activities include requirements [redacted] according to ***API Spec Q1***. Quality procedures describe [redacted] affecting quality activities. Management ensures that quality processes that impact [redacted] and specific quality goals.

The Company defines:

a) [redacted]
b)
c)
d)
e)
f)
g) ies
h)
i)

4.1.4.2 Exclusions

a) The Company cites [redacted]

4.1.5 Communications

Management ensures appropriate communication processes are established within the Company and communication takes place regarding [redacted] according to the ***QMS-04 Management Process Procedure***.

4.1.5.1 Internal

Management ensures internal communication is executed through the use of [redacted]

[redacted] Results of the analysis of data (6.3) are [redacted] within the Company.

The Company has established processes to ensure:

a) [redacted]

b) [redacted]

4.1.5.2 External

The Company's external communication process is used to [redacted]

External communication is applied through [redacted] The communication process provides information required by [redacted] Subsequent changes to [redacted] are processed according to the ***QMS-07 Proposal Development and Contract Review Procedure*** and the ***QMS-02 Configuration Management Procedure***.

The Company has established processes to ensure:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]
e) [redacted]
f) [redacted]

4.2 Management Responsibility

4.2.1 General

Management demonstrates its commitment to the development and implementation of the QMS and the continual improvement of its effectiveness by:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]

4.2.1.1 Customer Focus - Value Added

Management has established Customer care and satisfaction as a core function in the Quality Policy that is supported by:

a) [redacted]
b) [redacted]

4.2.2 Responsibility and Authority

The responsibility, authority and interrelation of all personnel that manage, perform or verify work affecting product and component quality and delivery has [redacted]

All personnel [redacted]

a) [redacted]
b)
c)

4.2.3 Management Representative

The Company has appointed a Management Representative to facilitate the quality management system. The Quality Manager has been assigned the role of [redacted]

The Quality Manager is responsible for:

a) [redacted]
b)
c)
d)
e)
f)
g)

The Quality Manager has the responsibility and authority to [redacted] The Quality Manager has the authority to [redacted] on an expedited, high priority basis. The Quality Manager reports directly to [redacted]

4.3 Organization Capability

4.3.1 Resources and Knowledge

4.3.1.1 Resources

Management and supervisory personnel identify and provide [redacted] involved in [redacted]

Resources include those required to [redacted] the quality management system.

4.3.1.2 Knowledge

The Company uses, maintains, determines and internally shares knowledge that is required to [redacted] The Company considers the need [redacted] according to the ***QMS-07 Proposal Development and Contract Review Procedure***. The Company integrates [redacted] into [redacted] using the ***QMS-02 Configuration Management Procedure***.

4.3.2 Human Resources

Personnel performing work affecting conformity to product and component requirements are competent on the basis of [redacted]

4.3.2.1 Personnel Competence

The Company defines personnel competency and identifies training requirements or other actions [redacted] according to the ***QMS-06 Training Procedure***. Responsible Authorities pay particular attention [redacted] to ensure [redacted] according to the ***QMS-01 Control of Documented Information Procedure*** (4.5).

The training procedure:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]
e) [redacted]

4.3.2.2 Training

Training is provided to achieve [redacted] Required qualifications for specific tasks are documented according to the ***QMS-06 Training Program***. Where education and/or experience are required by the job description, the Company [redacted] Evidence of the determination of competence of personnel and appropriate [redacted] in applicable ***Training Logs***. Training records are retained and maintained according to the ***QMS-01 Control of Documented Information Procedure***.

The training procedure:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]
e) [redacted]
f) [redacted]

g) [redacted]
h) [redacted]

4.3.2.3 Awareness - Value Added

When an employee is accepted into a position, their [redacted] New training requirements are identified and training is scheduled on a timely basis. Periodic re-training is conducted to [redacted] When training requirements for a position require [redacted] such training is [redacted] Records [redacted] are retained and maintained according to the ***QMS-01 Control of Documented Information Procedure***.

4.3.3 Work Environment

The Company determines and manages the work environment [redacted] and environmental factors.

The Company determines and maintains the infrastructure needed to [redacted] by providing:

a) [redacted]
b)
c)
d)

4.4 Documentation Requirements

4.4.1 General

The quality management system includes:

a) Quality Policies Handbook that includes:
   i. [redacted]
   ii.
   iii.
   iv.
b) [redacted]
c)
d) [redacted] ***1***
e)

4.4.2 Procedures

Procedures are controlled so that the information on them is [redacted]
Procedures are reviewed and approved [redacted]

Procedures are controlled to:

- [redacted]

Top-Down Structure of Documented Information:

a) [redacted]
b)
c)
d)
e)
f)

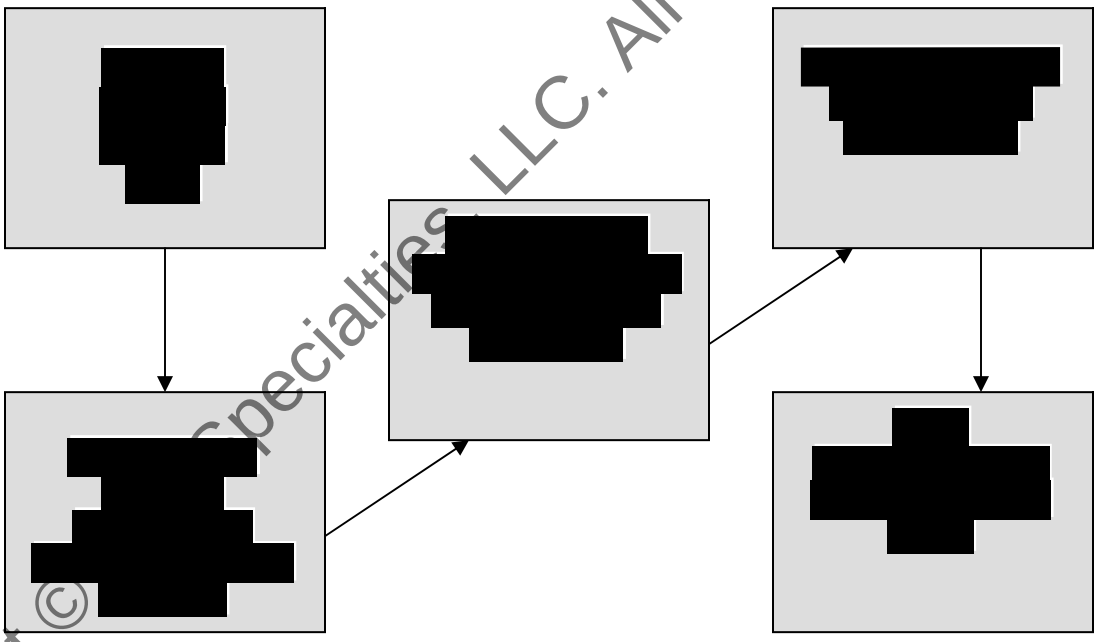


Figure 4.4.2: QMS Document Structure

The Company reviews and approves procedures [redacted] according to the ***QMS-02 Configuration Management Procedure***. ***Work Instructions*** and ***Forms*** that are specific to a department may be [redacted] according to the ***QMS-01 Control of Documented Information Procedure***.

4.4.3 Control of Internal Documents

To prevent unintended alterations of documented information that is retained and maintained as evidence of conformity, the Company [redacted] according to the ***QMS-01 Control of Documented Information Procedure***. Changes and translations [redacted] according to the ***QMS-02 Configuration Management Procedure***.

Obsolete documents are [redacted] Superseded and/or obsolete documents may [redacted]

Management provides guidelines for managing electronic data processes according to the ***QMS-04 Management Process Procedure***. The ***Master Document List*** identifies [redacted] The applicable issues of appropriate internal documents are [redacted] of the Quality System. Illegible printed copies of controlled documents are [redacted]

4.4.4 Control and Use of External Documents

External documents used for planning and operation of the QMS are [redacted] according to the ***QMS-02 Configuration Management Procedure***. When [redacted] the Company applies the ***QMS-02 Configuration Management Procedure*** to [redacted] and other affected processes.

4.5 Control of Records

Records that provide evidence [redacted] according to the ***QMS-01 Control of Documented Information Procedure***. The procedure identifies [redacted] and disposition of records. Unless otherwise stated and where required [redacted] records are retained for a period of ten (10) years [redacted]

5.0 Product Realization

5.1 Contract Review

5.1.1 General

The Company has established the ***QMS-07 Proposal Development and Contract Review Procedure*** to control [redacted]

5.1.2 Determination of Requirements

The Contract Review process is performed to [redacted] and to record [redacted]
The Company considers a contract to be [redacted] according to Customer requirements with [redacted]

Determinations include requirements specified by the Customer, and:

a) [redacted]
b)
c)
d)

These requirements are defined in:

a) [redacted]
b)
c)
d)
e)

5.1.3 Review of Requirements

Responsible Authorities perform contract reviews according to the ***QMS-07 Proposal Development and Contract Review Procedure*** that includes:

a) [redacted]
b)
c)

Written or verbal orders are [redacted]

Contract reviews ensure that:

a) [redacted]
b)
c)

Contract changes are identified in the contract or purchase documents according to the ***QMS-07 Proposal Development and Contract Review Procedure*** and Responsible Authorities are [redacted]
Contract review documentation is retained and maintained according to the ***QMS-01 Control of Documented Information Procedure***.

5.2 Planning

The Company's design and development process is conducted [redacted] according to the ***QMS-17 Design and Development Procedure***, which addresses [redacted]

Design inputs relating to product and component requirements are [redacted] which includes:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]
e) [redacted]
f) [redacted]
g) [redacted]
h) [redacted]

Each product and component design is translated [redacted] prior to the release of the design. Design requirements, [redacted] are documented according to the ***QMS-17 Design and Development Procedure***. Changes in design outputs are documented according to the ***QMS-02 Configuration Management Procedure***.

5.3 Risk Management

5.3.1 General

Risk management for product delivery/quality is conducted according to ***QMS-03 Risk Mitigation and Planning Procedure***. The procedure identifies [redacted] Proportionate actions are taken [redacted] according to the ***QMS-04 Management Process Procedure*** and ***QMS-13 Corrective Action Procedure***. The Company integrates and implements [redacted] and evaluates their [redacted] Records of actions, risk assessment and mitigation are retained and maintained according to the ***QMS-01 Control of Documented Information Procedure*** (4.5). Risk assessment considers [redacted] and includes [redacted] when applicable.

5.3.2 Risk Assessment

5.3.2.1 Product Delivery

Risk assessment associated with product and component delivery includes:

a) [redacted]
b) [redacted]

5.3.2.2 Product Quality

Risk assessment associated with product and component quality includes, as applicable:

c) [redacted]
d) [redacted]

5.3.2.3 Changes Impacting Product Quality

The Company pays particular attention to internal/external changes that [redacted] which include but are not limited to:

a) [redacted]
b)
c)
d)
e)

A risk assessment is performed (5.3.2.2) for [redacted]

5.3.3 Contingency Planning

The Company has established and maintains a ***Contingency Plan Work Instruction*** for planning that is based on assessed risks (5.3) that impact [redacted]

Contingency planning includes:

- [redacted]
-
-
-

5.3.4 Records

Records for the management of risk assessment and required actions are retained and maintained (4.5) according to the ***QMS-01 Control of Documented Information Procedure***.

5.4 Design

5.4.1 General

To ensure that specified requirements are met for deliverable goods and services, the Company has established the ***QMS-17 Design and Development Procedure***.

5.4.2 Design Planning

Design and development responsibilities and authority are [redacted] When design and development activities are performed [redacted] When design and development is [redacted] according to the ***QMS-08 Purchasing Procedure***. Planning output is [redacted] according to the ***QMS-02 Configuration Management Procedure***.

The ***QMS-17 Design and Development Procedure*** controls:

a) [redacted]
b)
c)
d)

e) [redacted]
f) [redacted]

5.4.3 Design Inputs

Design inputs for deliverable goods are [redacted] and include:

a) [redacted]
b)
c)
d)
e)
f)
g)
h)

Design requirements, [redacted] and records are retained and maintained according to the ***QMS-01 Control of Documented Information Procedure***.

5.4.4 Design Outputs

The design and development outputs [redacted] according to the ***QMS-02 Configuration Management Procedure***. Outputs are in a form suitable for [redacted]

Outputs:

a) [redacted]
b)
c)
d)
e)
f)

Design output is reviewed at suitable stages according [redacted]:

a) [redacted]
b)

Reviews are attended by [redacted] according to the ***Design Review Work Instruction***. Records of the review [redacted] according to the ***QMS-01 Control of Documented Information Procedure***.

5.4.5 Design Review

To propose actions for [redacted] and to evaluate [redacted] final review and verification functions are [redacted]

[redacted] according to the ***Design Review Work Instruction***. Records of the design verification [redacted] are retained and maintained according to the ***QMS-01 Control of Documented Information Procedure*** (4.5).

5.4.6 Design Verification and Final Review

To ensure the outputs of the design and development meet [redacted] final review and verification functions are [redacted] according to the ***Design Review Work Instruction***. Records of required actions, design verification and final review are retained and maintained according to the ***QMS-01 Control of Documented Information Procedure*** (4.5).

5.4.7 Design Validation and Approval

Validation functions are planned to [redacted] Where possible, validation is performed using [redacted] and if practical, [redacted] Records of validation results are retained and maintained in [redacted]

Each new design is validated by one or more of the following:

a) [redacted]
b) [redacted]
c) [redacted]

The completed design is approved after [redacted] Final design approval is provided by [redacted] Records of required actions, design validation and approval are retained and maintained according to the ***QMS-01 Control of Documented Information Procedure*** (4.5).

5.4.8 Design Changes

Design and development changes, including changes [redacted] according to the ***QMS-02 Configuration Management Procedure***.

All changes are:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]
e) [redacted]

The review includes [redacted] and the [redacted] Records of the results of the review and any necessary changes, including [redacted] according to the ***QMS-01 Control of Documented Information Procedure***.

5.5 Purchasing

5.5.1 Purchasing Control

5.5.1.1 Procedure

The Company has established the ***QMS-08 Purchasing Procedure*** to ensure [redacted] which addresses the following requirements:

a) [redacted]
b)
c)
d)
e)
f)
g)
h)

5.5.1.2 Initial Supplier Evaluation - Critical Purchases

When the purchased product, component or activity is defined as critical [redacted] the criteria for the initial evaluation of Suppliers [redacted] Re-evaluation is required when [redacted]

The initial evaluation of Suppliers of critical products, components or activities includes:

a) [redacted]
b)
c)
i.
ii.
iii.

5.5.1.3 Initial Supplier Evaluation - Critical Purchases - Customer Specified, Proprietary, and/or Legal Limited

The Company performs an initial evaluation of Suppliers [redacted] and when [redacted]

Initial evaluation under these conditions does not extend beyond the current contract, and includes:

a) [redacted]

b) [redacted]

5.5.1.4 Initial Supplier Evaluation - Noncritical Purchases

The Company performs an initial evaluation of Suppliers that includes one or more of the following activities:

a) [redacted]
b)
c)

5.5.1.5 Supplier Re-Evaluation

The Company determines the frequency of approved Supplier re-evaluation [redacted] according to the ***QMS-08 Purchasing Procedure***. Re-evaluation of suppliers of critical and non-critical products, components or activities is performed according to [redacted]

5.5.1.6 Records

Results of evaluations, re-evaluations and necessary actions are recorded that include [redacted] The Company retains and maintains an ***Approved Supplier List*** and records of ***Supplier Evaluations*** with [redacted] Records are retained and maintained according to the ***QMS-01 Control of Documented Information Procedure***.

5.5.1.7 Outsourcing

The Company ensures [redacted] according to the ***QMS-08 Purchasing Procedure*** for [redacted] within the scope of [redacted] The Company maintains responsibility [redacted] including applicable [redacted] and ***API Product Specifications***. Records are retained and maintained according to the ***QMS-01 Control of Documented Information Procedure*** for outsourced activities that includes [redacted]

5.5.2 Purchasing Information

The Company ensures the adequacy of specified purchasing information [redacted] according to the ***QMS-08 Purchasing Procedure***.

Purchasing information is documented [redacted] according to the ***QMS-08 Purchasing Procedure***, including [redacted] and the following:

a) [redacted]
b)
c)
d)

e) [redacted]
f) [redacted]

5.5.3 Verification of Purchased Products, Components or Activities

5.5.3.1 General

The Company has established the ***QMS-09 Receiving Procedure*** for verification [redacted] to ensure and provide [redacted] The Company maintains records of verification activities according to the ***QMS-01 Control of Documented Information Procedure***.

5.5.3.2 Critical Purchases

Verification activities for critical products, components and activities include:

a) [redacted]
b)
c)

5.5.3.3 Noncritical Purchases

The Company determines conformance of noncritical products, components or activities according to the ***QMS-09 Receiving Procedure***.

5.5.3.4 Records

Records of verification activities and applicable evidence of conformance are retained and maintained according to the ***QMS-01 Control of Documented Information Procedure*** (see 4.5).

5.6 Control of Product Realization

5.6.1 General

The Company has established the ***QMS-10 Production Procedure*** for product realization, which provides for:

a) [redacted]
b)
c)
d)
e)
f)
g)
h)
i)
j)
k)

5.6.2 Quality Plan

The Company has established the [redacted] to describe the processes of the [redacted] (including [redacted]) and the resources [redacted]

As required by Customer contract, the plan addresses each of the following when combined with [redacted]:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]
e) [redacted]

The [redacted] and revisions are [redacted] and each configuration change is [redacted]

5.6.3 Process Control Documents

Process controls are documented in [redacted] that include requirements for [redacted] API product specifications, [redacted] and [redacted] The process controls establish [redacted] for processes, [redacted]

5.6.4 Validation of Processes

The Company validates processes for production and servicing [redacted] by subsequent [redacted] When the Company chooses to outsource a process [redacted]

The Company has established the ***QMS-10 Production Procedure*** to address methods for review and approval of the processes, including:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]
e) [redacted]
f) [redacted]

The Company validates processes that are [redacted] If processes that require validation are not specified, [redacted] validation include, as a minimum:

a. [redacted]
b. [redacted]

c. [redacted]
d. [redacted]

5.6.5 Identification and Traceability

The Company has established the ***Traceability Work Instruction*** to identify and trace [redacted] including [redacted] The ***Traceability Work Instruction*** includes [redacted] Records of identification and traceability are retained and maintained (4.5) according to the ***QMS-01 Control of Documented Information Procedure***.

5.6.6 Inspection/Test Status

The Company has established the ***QMS-10 Production Procedure*** to [redacted] that indicates [redacted] The Company ensures that only [redacted]

5.6.7 Externally Owned Property

The Company has established the ***QMS-10 Production Procedure*** for [redacted] including [redacted] The ***QMS-10 Production Procedure*** includes requirements for [redacted] Records for the control and disposition of Customer-Supplied property are retained and maintained (see 4.5) according to the ***QMS-01 Control of Documented Information Procedure***.

5.6.8 Preservation of Product

The Company has established procedures to [redacted] The procedures are [redacted] As applicable, preservation includes [redacted] and required [redacted] according to the ***QMS-10 Production Procedure*** and the ***QMS-11 Shipping Procedure***.

5.6.8.1 Storage and Assessment

The Company identifies the requirements for [redacted] The Company uses designated [redacted] To detect damage and/or deterioration, [redacted] are assessed [redacted] according to the ***QMS-10 Production Procedure*** using the ***Storage and Assessment Internal Audit Report Form***. Records of the results of assessments are retained and maintained (4.5) according to the ***QMS-01 Control of Documented Information Procedure***.

5.6.9 Inspection, Testing, and Verification

5.6.9.1 General

The Company has established the ***QMS-10 Production Procedure*** for inspection, testing and verification methods to [redacted] The procedure includes [redacted]

Records of required inspections and testing are retained and maintained (5.6.9.4) according to the ***QMS-01 Control of Documented Information Procedure***.

5.6.9.2 In-Process Inspection, Testing, and Verification

The Company inspects, tests, and verifies [redacted] according to the applicable ***Quaiity Plan*** (5.6.2) and/or the ***QMS-10 Production Procedure*** (5.6.3) Evidence of conformity with the acceptance criteria is retained and maintained according to the ***QMS-01 Control of Documented Information Procedure***.

5.6.9.3 Final Inspection, Testing, and Verification

The Company performs product and component final inspection and testing according to the applicable ***Quality Plan*** (5.6.2) and/or the ***QMS-10 Production Procedure*** (5.6.3) to [redacted] Personnel other than [redacted] In-process and final inspection and testing may [redacted] such as [redacted] Evidence of conformity with the acceptance criteria is retained and maintained according to the ***QMS-01 Control of Documented Information Procedure***.

5.6.9.4 Records

Records of required inspection, testing, verification methods and final acceptance are retained and maintained (4.5) according to the ***QMS-01 Control of Documented Information Procedure***.

5.6.10 Preventive Maintenance

The Company has established a ***Maintenance Procedure*** for preventive maintenance of equipment used in product realization, including TMMDE.

Preventive maintenance is based on one or more of the following:

a) [redacted]
b)
c)
d)
e)
f)
g)
h)

The procedure identifies requirements for:

a) [redacted]
b)

c) [redacted]

Records of preventive maintenance are retained and maintained (see 4.5) according to the ***QMS-01 Control of Documented Information Procedure***.

5.7 Product Release

The Company has established the ***QMS-10 Production Procedure*** to ensure [redacted] unless otherwise [redacted] and, where applicable, [redacted] Records are retained and maintained (4.5) according to the ***QMS-01 Control of Documented Information Procedure*** to enable [redacted]

5.8 Testing, Measuring, Monitoring, and Detection Equipment (TMMDE)

5.8.1 General

The Company determines the use of testing, monitoring and measurement requirements [redacted] according to the ***QMS-10 Production Procedure***.

The Company has established the ***QMS-15 Calibration Procedure*** to ensure [redacted]

Equipment that is provided from [redacted] is also controlled according to the ***QMS-15 Calibration Procedure*** and [redacted]

5.8.2 Procedure

The Company has established the ***QMS-15 Calibration Procedure*** to ensure [redacted] Suitability of TMMDE [redacted] is determined by the ***QMS-10 Production Procedure***. Maintenance of TMMDE is determined according to the ***Maintenance Procedure*** and [redacted]

The procedure includes requirements for the specific equipment type that addresses:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]
e) [redacted]
f) [redacted]
g) [redacted]
i) [redacted]
j) [redacted]

5.8.3 Equipment

Testing, measuring and monitoring equipment are to:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]
e) [redacted]

Computer software [redacted] of specified requirements.

5.8.4 TMMDE Equipment from Other Sources

When the equipment is provided from a source external to the Company, [redacted]

When control of TMMDE is [redacted] apply the following requirements from ***API Spec Q1***:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]
e) [redacted]
f) [redacted]

5.8.5 Records

The Company maintains a registry of TMMDE that includes [redacted] When control of TMMDE is limited [redacted] according to the ***QMS-01 Control of Documented Information Procedure***. Records of results of calibration and accuracy verification are retained and maintained (4.5) according to the ***QMS-01 Control of Documented Information Procedure***.

5.9 Control of Nonconforming Product

5.9.1 Procedure

5.9.1.1 General

The Company has established the ***QMS-14 Control of Nonconformities Procedure*** to [redacted]

5.9.1.2 Nonconforming Product During Product Realization

The procedure addresses nonconforming products, components and activities identified during product realization that includes controls for:

a) [redacted]
b)
c)
d)

5.9.1.3 Nonconforming Product After Delivery

The procedure also addresses nonconforming products and components that are identified after delivery, which includes controls for:

1. [redacted]
2.
3.
4.

5.9.2 Nonconforming Product

The Company addresses nonconforming products, components or activities by performing one or more of the following:

a) [redacted]
b)
c)
d)

5.9.3 Release of Nonconforming Product Under Concession

The Company has established the ***QMS-14 Control of Nonconformities Procedure*** to include release of product/component under concession. The evaluation and release under concession of nonconforming [redacted] that do not satisfy [redacted] is permitted when [redacted] provided that:

a) [redacted]
b)
c)

5.9.4 Customer Notification of Nonconforming Product

The Company notifies Customers of products and components that [redacted] The Company maintains records of notifications (4.5) according to the ***QMS-01 Control of Documented Information Procedure***.

5.9.5 Records

Records of the nature of nonconformities, consessions and subsequent actions are retained and maintained (4.5) according to the ***QMS-01 Control of Documented Information Procedure***, that include [redacted]

5.10 Management of Change (MOC)

5.10.1 General

The quality management system is maintained at its authorized revision level [redacted] according to the ***QMS-01 Control of Documented Information Procedure*** (5.10.2). For each quality management system change, the Company applies [redacted] the ***QMS-02 Configuration Management Procedure***, which considers:

a) [redacted]
b)
c)
d)
e)
f)

5.10.2 MOC Application

The Company uses the Management of Change (MOC) process that is defined in the ***QMS-02 Configuration Management Procedure*** for changes that [redacted]

5.10.3 MOC Notification

The Company documents change orientation [redacted] using the applicable ***Engineering Order***, which includes [redacted]

5.10.4 Records

The Company retains and maintains records of Management of Change (MOC) activities (4.5) according to the ***QMS-01 Control of Documented Information Procedure***.

6.0 Quality Management System Monitoring, Measurement, Analysis, and Improvement

6.1 General

The Company has established the ***QMS-04 Management Process Procedure*** to [redacted] that are needed to [redacted] according to the requirements of ***API Spec Q1***, and to [redacted] Quality management system monitoring, measurement, analysis and improvement include [redacted]

6.2 Monitoring, Measuring, and Improving

6.2.1 Customer Satisfaction

The Company has established the ***QMS-04 Management Process Procedure*** to [redacted] which addresses:

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

Records of the results of Customer satisfaction information are retained and maintained (4.5) according to the ***QMS-01 Control of Documented Information Procedure***.

6.2.2 Internal Audit

6.2.2.1 General

The Company has established the ***QMS-12 Internal Auditing Procedure*** to [redacted] At least every 12 months, the Company [redacted] and conforms to the requirements of ***API Spec Q1***.

The planning of internal audits takes into consideration [redacted] Processes defined as critical to product realization are [redacted]

All processes of the quality management system are audited [redacted] The Company identifies [redacted] to [redacted] conform to the requirements of ***API Spec Q1***. Outsourced activities that impact [redacted] are included as part of the internal audit.

6.2.2.2 Performance of Internal Audit

Audits are performed by [redacted]

[redacted] is implemented [redacted] are retained and maintained according to the ***QMS-01 Control of Documented Information Procedure*** (4.5). When applicable, [redacted] are audited in conjunction with [redacted] All processes of the quality management system are audited prior to [redacted]

6.2.2.3 Audit Review and Closure

The Company processes nonconformities on an [redacted] The Responsible Authorities for the area being audited [redacted] according to the ***QMS-13 Corrective Action Procedure*** (6.4.2). The results of internal audits and [redacted] are reported [redacted] according to the ***QMS-04 Management Process Procedure*** (6.5). Records of internal audits are retained and maintained (4.5) according to the ***QMS-01 Control of Documented Information Procedure***.

6.2.3 Process Evaluation - Value-Added

The Company performs internal audits and management reviews [redacted] according to the ***QMS-12 Internal Auditing Procedure***. When planned results [redacted] according to the ***QMS-14 Control of Nonconformities Procedure*** and the ***QMS-13 Corrective Action Procedure***.

6.3 Analysis of Data

The Company has established the ***QMS-04 Management Process Procedure*** [redacted] to demonstrate [redacted] The analysis includes [redacted]

The data analysis output provides information relating to:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]
e) [redacted]
f) [redacted]

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

6.4 Improvement

6.4.1 General

The Company continually improves the effectiveness of the quality management system through the use of [redacted] according to the ***QMS-04 Management Process Procedure***.

6.4.2 Corrective Action

The Company has established the ***QMS-14 Control of Nonconformities Procedure*** and the ***QMS-13 Corrective Action Procedure*** to address [redacted] and to apply [redacted] Corrective actions are appropriate [redacted]

The procedure identifies requirements for:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]
e) [redacted]
f) [redacted]
g) [redacted]
h) [redacted]
i) [redacted]
j) [redacted]

Records of the activities for corrective actions and their effectiveness are retained and maintained (4.5) according to the ***QMS-01 Control of Documented Information Procedure***.

6.5 Management Review

6.5.1 General

The Company's quality management system is reviewed at least every 12 months to [redacted] The review includes [redacted] including the [redacted].

6.5.2 Input Requirements

The input to management review includes:

a) [redacted]
b) [redacted]
c) [redacted]

d) [redacted]s
e) [redacted]
f) [redacted]
g) [redacted]
h) [redacted]
i) [redacted]
j) [redacted]
k) [redacted]
l) [redacted]

6.5.3 Output Requirements

The output from the management review includes [redacted]

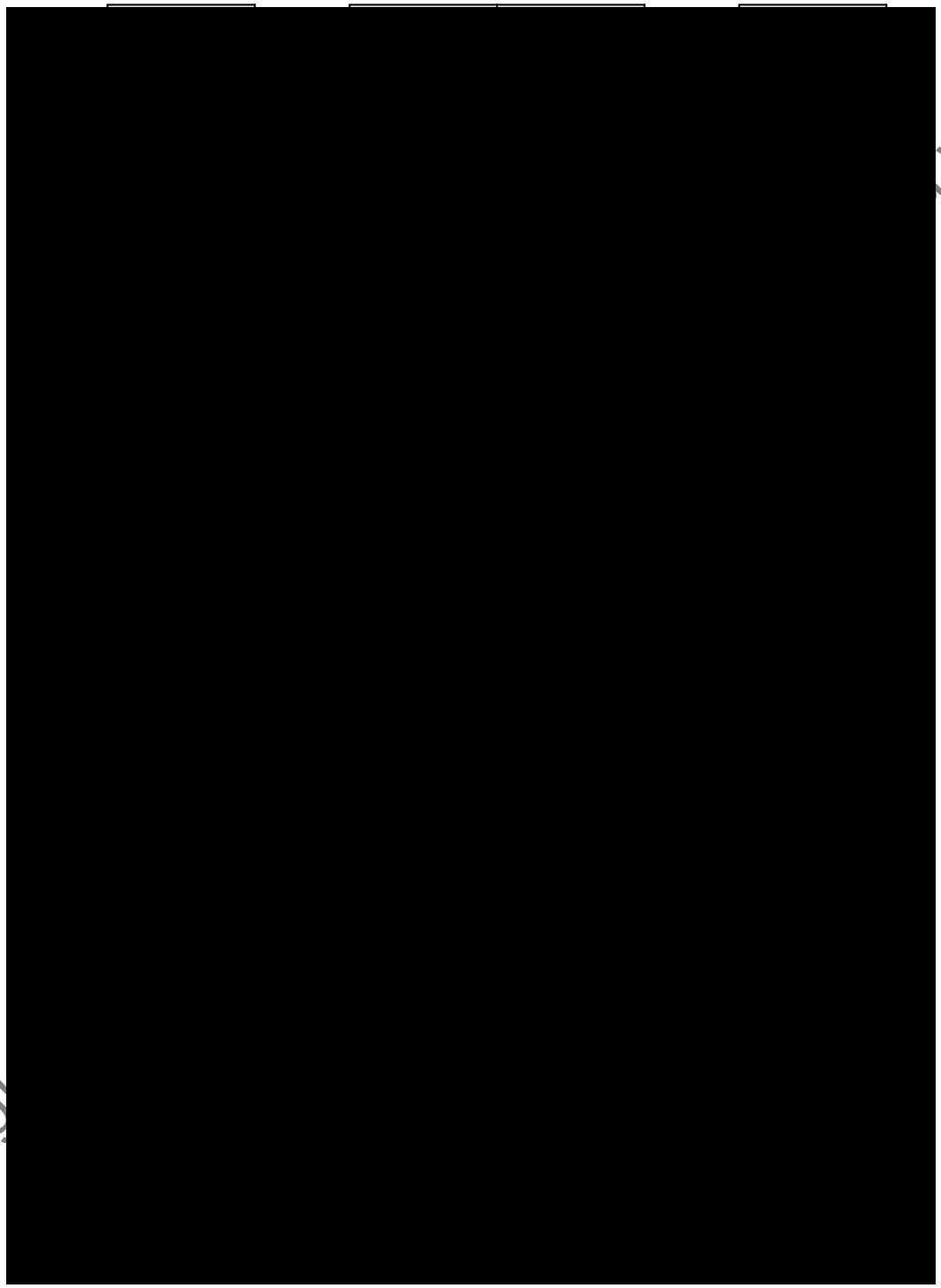
The summary assessment includes:

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

Top management reviews and approves [redacted] Records of management reviews are retained and maintained (4.5) according to the ***QMS-01 Control of Documented Information Procedure***.

Left blank intentionally

7.0 Key Realization Processes/Interactions



8.0 Quality Objectives

Your Logo

Your Company Name

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 procedure describes methods for controlling documented information.

REVISION LOG

Issue	Date	Comment	Author
Orig			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

1.0 PURPOSE OF DOCUMENT AND RECORD CONTROL

This procedure defines the requirements for [redacted]

The following documents are not subject to this procedure:

- [redacted]

2.0 THEORY

Documents must be controlled [redacted] This ensures [redacted]

3.0 DOCUMENT TYPES

3.1. Quality Handbook: this document provides [redacted] It also defines [redacted] and defines how [redacted]

3.2. QMS Procedures: these documents provide [redacted] The Quality Handbook includes references to the applicable QMS procedures.

3.3. Inspection Instructions: these documents are [redacted] using requirements from [redacted]

3.4. Forms: these documents are [redacted]

3.5. Records that are created for [redacted]

4.0 QUALITY HANDBOOK

4.1. Establishing the Quality Handbook

The Quality Handbook is established [redacted]

4.2. Review and Approval of the Quality Handbook

The Quality Handbook is [redacted]

4.3. Distribution of the Quality Handbook

The Quality Handbook is [redacted]

The Document Control Center may [redacted]

In some cases, a hardcopy of the Quality Handbook [redacted]

Each employee must [redacted]

4.4. Change Control of the Quality Handbook

Changes to the Quality Handbook are not subject to [redacted] Any employee may [redacted] Requests for changes may [redacted]

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

IMPORTANT:

The quality management system shall [redacted]

5.0 QUALITY MANAGEMENT SYSTEM PROCEDURES

5.1. Creating New QMS Procedures

QMS procedures should [redacted]

5.2. Review and Approval

QMS Procedures are [redacted] Approval is indicated by [redacted]

5.3. Distribution

QMS procedures are distributed [redacted] The Document Control Center may [redacted]

In some cases, a hardcopy of the procedure may [redacted]

5.4. Change Control

Changes to QMS procedures are [redacted]

6.0 GENERAL WORK INSTRUCTIONS

6.1. Creating New Work Instructions

Where necessary, work affecting quality is described by [redacted]

Typically, new work instructions are [redacted] Work instructions should be created as soft files (i.e., MS Word, etc) and then [redacted]

Work instructions should include, [redacted]

NOTE REGARDING JOB SPECIFIC WORK INSTRUCTIONS:

Engineering may develop work instructions that are [redacted]

6.2. Review and Approval

Work instructions must be reviewed and approved by [redacted] Approval is indicated by [redacted]

6.3. Distribution

General work instructions are distributed [redacted] The Document Control Center may [redacted]

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

6.4. Change Control

Changes to general work instructions are [redacted]

7.0 INSPECTION INSTRUCTIONS

7.1. Creating New Inspection Instructions

New inspection instructions are [redacted] Inspection instructions should be created as soft files (i.e., MS Word, etc) and then [redacted]

NOTE REGARDING JOB SPECIFIC INSPECTION INSTRUCTIONS:

Engineering may develop inspection instructions that [redacted]

7.2. Review and Approval

Approval is indicated by [redacted].

7.3. Distribution

Inspection instructions are distributed [redacted] The Document Control Center may [redacted]

In some cases, a hardcopy of the inspection instruction may [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 develop a new form for use in their area. The form should be created in software format (MS word, Excel, etc) and then [redacted] Forms are [redacted]

8.2. Review and Approval

Forms may be reviewed and approved by [redacted] It is the appropriate manager's responsibility to [redacted]

8.3. Distribution

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

8.4. Change Control

Any employee may submit a ***Request for Change*** to [redacted] Revised forms go through [redacted]

9.0 EXTERNAL DOCUMENTS

9.1. Some external (third party) standards or specifications may be maintained on file without [redacted] This is necessary because [redacted] To maintain control, [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 deemed necessary, they shall [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

A record is [redacted] Records must remain legible, identifiable, retrievable and be retained and maintained for a minimum of [redacted] Records that originate from internal and external activites must [redacted]

See below for the controls and responsibilities needed for identification, collection, storage, protection, retrieval, retention time and disposition of records.

11.1 [redacted]

11.2 [redacted]

11.3 [redacted]

11.4 [redacted]

11.5 [redacted]

11.6 [redacted]

11.7 [redacted]

11.8 [redacted]

11.9 [redacted]

11.10 [redacted]

11.11 [redacted]

11.12 [redacted]

11.13 [redacted]

APPENDIX A: RECORD RETENTION MATRIX

Required Record or Document Type	Company Record	Controller	Type	Location	Minimum Retention
Calibration records					
Contract review records					
Control of nonconformities					
Corrective actions					
Design change records					
Design input records					
Design review records					
Design validation records					
Design verification records					
First Article Inspection					
Internal audit records					
Lost, damaged or unsuitable Customer property					
Management review meeting reports					
Record of realization process					
Record of release of product/component					
Supplier evaluation					
Traceability records					
Training records					

Your Logo

Your Company Name

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 and components produced by the Company's configuration management activities include the following:

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

2.0 THEORY

Part configuration includes a variety of aspects of a given part, including [redacted] Because a given product or component may change over its life, typically due to [redacted] it is important to [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]
- [redacted]

3.2. All such technical documents are developed by Engineering and approved by the CCB. (See section 4.0) They are then controlled according to this procedure.

3.3. The baseline documentation is entered into a database that maintains current data for every configuration item. As new configuration items are generated, approved and placed in the release system, they are [redacted] The database may be used to generate breakdown lists that may be a

[redacted]
Configuration accounting lists and reports may be generated by [redacted]

3.4. Configuration documents, Customer data and intellectual property and external documents received by the Company are [redacted]
Project personnel are responsible for [redacted]

4.0 CONFIGURATION CONTROL BOARD (CCB)

4.1. The Responsible Engineering Authority (REA) and Quality Manager serve [redacted] which has full authority and responsibility for [redacted] MRB actions approved by the CCB that affect configuration [redacted]

4.2. The Chairperson of the CCB is any specified member dependent upon the circumstance.
The Customer may be invited to attend CCB meetings.

4.3. The CCB serves as the point of authority to [redacted]

4.4. CCB responsibilities include:

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

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

4.2.1 As-Built vs. As-Designed Configuration

The 'as-designed' configuration for each integrated system is contained in a database. For each serialized subassembly or assembly a listing of the current 'as-designed' configuration is prepared at the time a release to build is processed. This configuration listing is used as [redacted] Responsible Authority acceptance of the ***As-Built Parts List*** is a pre-requisite to [redacted] Any subsequent changes or rework [redacted]

5.0 BASELINE MANAGEMENT

5.1. The Company may establish a configuration baseline to identify [redacted] The baselines provide [redacted]

5.2. All descriptions of the baselines used to state product and component performance and design requirements are contained in configuration documents.

5.3. For configuration management purposes, four major baselines may be required as discussed below.

5.3.1. Pre-Release Baseline: [redacted]

5.3.2. Functional Baseline: [redacted]

At the Functional Baseline, the configuration management system is operating and the released documents have described the following:

- [redacted]

5.3.3. Allocated Baseline: [redacted] These include:

- [redacted]

5.3.4. Deliverable Goods Baseline: [redacted]

This baseline prescribes:

- [redacted]

This baseline and approved changes serve as [redacted] The CCB must prepare an ***Engineering Order*** according to the Change Processing section herein to integrate [redacted]

5.4. Baseline Maintenance

Once established, the baselines serve as the approved departure points for updating by incorporation of changes that have been approved by the CCB. The baselines plus the approved changes represent [redacted] The Document Control Center may [redacted]

[redacted]

The release of a technical document requires that it be placed into the normal control system for configuration documents. The release system is shown in Figure 1, which…,

- [redacted]

Figure 1: Release System Flowchart

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

- [redacted]

5.6. The Document Control Center prepares the release package after insuring [redacted] Documents are controlled so that the information on them is [redacted]

6.0 CONFIGURATION CHANGE CONTROL

6.1. Configuration change control is the process of [redacted]

6.2. Change control is vested in the Configuration Control Board. Any employee may request [redacted] Approval of the CCB is mandatory to permit further action on a proposed change.

6.3. Joint change control authority is established [redacted]

6.4. Evaluations of changes include [redacted] The need for the change is justified if [redacted]

6.5. The evaluation will take into consideration [redacted] Typically, this will include [redacted]

6.6. All associated changes and affected hardware items or computer programs are included on the ***Engineering Order***, ***Engineering Change Proposal*** or ***Request for Support*** (RFS) form. The evaluation by the CCB includes [redacted] Redlined technical documents may be used if [redacted]

6.7. 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:

6.7.1. Engineering Change: [redacted]

6.7.2. Deviation: [redacted]

6.7.3. Waiver: [redacted]

6.8. 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]

6.8.1. Class I Changes

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

- [redacted]

6.8.2. Class II Changes

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

6.9. Change Implementation

The CCB provides a complete description of the effort required to accomplish the approved change. The definition of the actual tasks required is [redacted] Engineering changes are fully documented on an ***Engineering Order*** (EO) or [redacted] All proposed changes are evaluated by the CCB prior to implementation and the signature approved ***EO*** or [redacted]

6.9.1. All approved changes are implemented under the guidance of the configuration management function.

6.9.2. Configuration Management maintains approval records for all configuration changes. These records identify [redacted]

6.9.3. The Responsible Authority that originally approved applicable documents verifies [redacted] The Responsible Authority asserts [redacted]

6.9.4. The Document Control Center may retain older hardcopies or softcopies for historical purposes, but these are not [redacted] Superseded documents may [redacted] The Responsible Authority monitors, controls and records [redacted]

6.9.5. During the evaluation of the ***ECP***, ***EO*** or ***RFS***, the CCB determines [redacted]

6.9.6. The CCB provides a complete description of the effort required to [redacted] Engineering changes are fully documented on an ***Engineering Order*** (EO) or [redacted] All proposed changes are evaluated by the CCB prior to implementation and the signature approved ***EO*** or [redacted]

6.9.7. Deviation: [redacted]

6.9.8. Waiver: [redacted] When a request for waiver is [redacted] Once approved, the configuration [redacted]

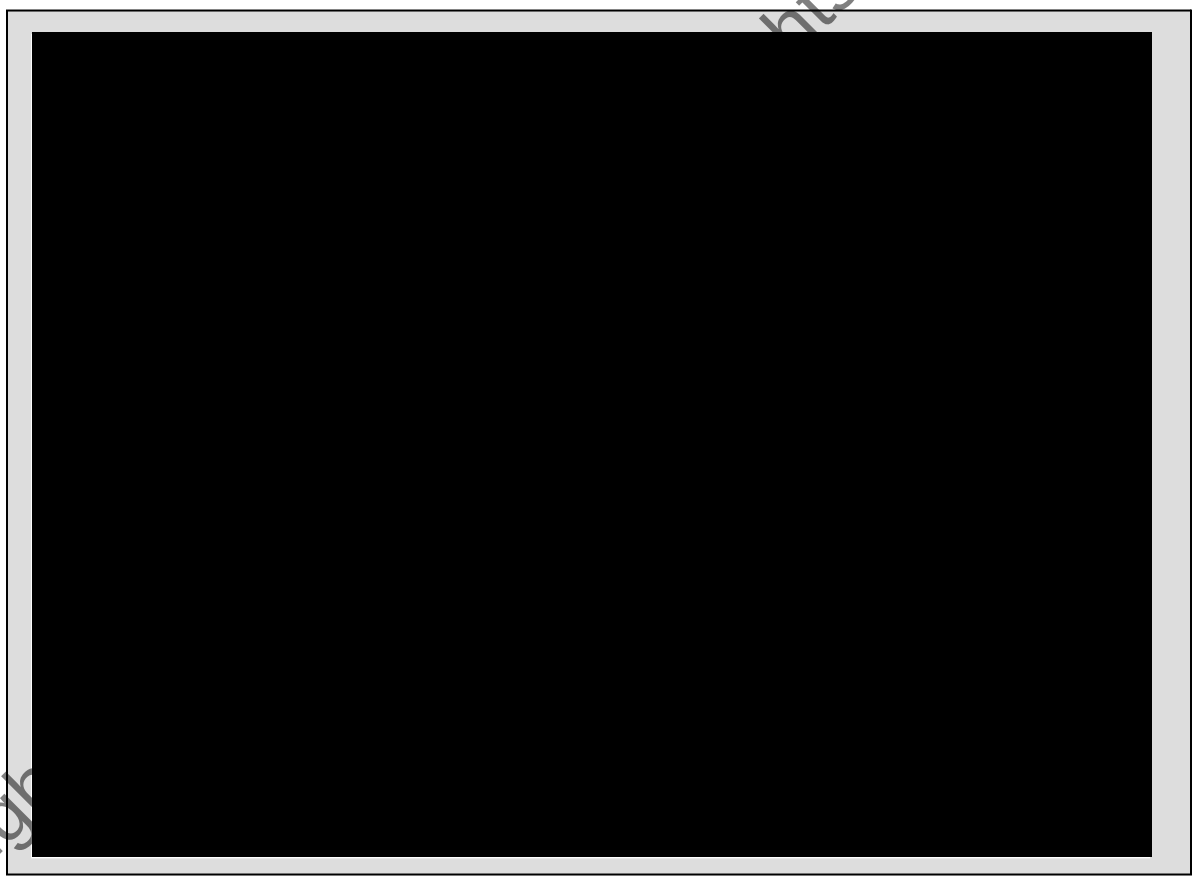
6.9.9. Supplement Releases: All changes require the processing of an ***Engineering Order*** [redacted] Supplements to existing documents are [redacted]

6.9.10. Upon accumulation of five [redacted]

6.9.11. Proposed Class I engineering changes are approved by the CCB and are [redacted] A Class I Engineering Change is not implemented until [redacted]

A summary of the change control flow and resulting actions is shown in Figure 2.

Figure 2: Change Control Flow



6.9.12. Re-identification Practices

Part numbers are changed whenever [redacted] a new part number is created or

[redacted]

6.9.13. All deliverable items are fabricated and assembled according to the configuration defined by the appropriate engineering drawing and its authorized changes.

6.9.14. No oral instruction or other random or unwritten authority is accepted in place of [redacted] Redlined technical documents may [redacted]

7.0 SUBCONTRACTOR AND VENDOR CHANGES

7.1. Only those subcontractors having a funded design effort are permitted [redacted]

7.2. For all vendors used by suppliers, [redacted]

7.3. Suppliers and vendors are controlled according to the Purchasing Procedure.

8.0 MANAGEMENT DIRECTIVES

8.1. Management members of the CCB/MRB issue their binding policies, procedures and directives to personnel within their exclusive organization in the form of a ***Bulletin***.

8.2. The ***Bulletin*** is completed as required by individual format. The ***Bulletin*** is the only accepted form of correspondence for [redacted] A ***Bulletin*** cannot cause [redacted]

9.0 CONFIGURATION RECORDS AND REPORTS

The following lists are revised as required to include the latest configuration status of listed documents. Dependent upon contract requirements, records and reports may include:

9.1. Numerical lists: [redacted]

9.2. Indentured Lists: [redacted]

9.3. As-Built Parts List: [redacted]

9.4. EO Status: [redacted]

9.5. Data Lists: [redacted]

9.6. Configuration Account Record for Integrated Systems: A configuration account record is produced for integrated systems that are assembled and tested by the Company. The record identifies [redacted] Prior to environmental testing and prior to final acceptance, the integrating activity [redacted] Starting with the integration of the first component, the configuration account record is maintained by [redacted]

9.6.1. Configuration Item Identification Report: As part of acceptance for an integrated system, for each configuration item, a review of the 'as-designed' configuration is made and compared with the 'as-built' configuration. All differences are [redacted] This report precisely identifies the configuration item and is part of the ***Configuration Item Data Package***.

9.6.2. As-Built vs. As-Designed Configuration: The 'as-designed' configuration for each integrated system is [redacted] This configuration listing is used as the '***As-Designed Parts List***' baseline document to record the initial CCB approved configuration. During the workflow, [redacted] Responsible Authority acceptance of the ***As-Built Parts List*** is [redacted] Any subsequent changes or rework affecting the completed item, even during [redacted]

10.0 PRODUCT/COMPONENT AND TEST SOFTWARE CONTROL

Production of software for integration into deliverable goods is controlled according to [redacted] Revision control is applicable to software programs that are used to [redacted]

Your Logo

Your Company Name

CONFIGURATION MANAGEMENT PROCEDURE

Origination Date: XXXX

Document Identifier:	QMS-03 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
0-0			

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 deliverable goods produced by the Company's configuration management activities include the following:

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

2.0 THEORY

Part configuration includes a variety of [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 [redacted]

3.3. Configuration documents, Customer data and intellectual property and external documents received by 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] Typically, this includes [redacted]

5.2. All associated changes and affected hardware items or computer programs are included on [redacted] The evaluation by the CCB includes [redacted] Redlined technical documents may [redacted]

5.3. Types of Configuration Change

Changes to the configuration are implemented after [redacted] 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 [redacted] Proposed Class I engineering changes are [redacted] Implementation is withheld [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]

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 implemented [redacted]

5.5. Change Implementation

5.5.1. The Responsible Authority that originally approved applicable documents verifies that changes have been [redacted] The Responsible Authority asserts [redacted]

5.5.2. Superseded revision levels of electronic documents are [redacted] Superseded documents may [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 [redacted] The determination of need for all Class I Engineering Changes is [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/COMPONENT AND TEST SOFTWARE CONTROL

Revision control is applicable to software programs that are used for operation of production and test equipment.

RISK MITIGATION AND PLANNING PROCEDURE

Origination Date: (month year)

Document Identifier:	QMS-03 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
0-0			

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 [redacted] 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 [redacted] Risk mitigation and planning efforts may necessitate [redacted] Formalizing risk mitigation and planning throughout the Company will [redacted]

2.0 Objectives of Risk Mitigation and Planning

The objectives of risk mitigation and planning are to [redacted] The process identifies [redacted] It ensures [redacted] The owner of the risk could be [redacted] Three key questions can be posed for risk mitigation:

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

An understanding of these three questions is critical to risk mitigation and risk management planning. Question 1 addresses [redacted] An understanding of questions 2 and 3 is necessary for [redacted]

[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 [redacted] A response may be the following:

- [redacted]

The above categorization of risk response options helps [redacted] The project development team must identify [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 [redacted]

[redacted]
The understanding will [redacted]

4.0 Risk Planning

Risk planning involves [redacted] Risk planning is [redacted] for the management of risk:

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

Risk planning is iterative and includes [redacted] For large projects or projects with a high degree of uncertainty, the result [redacted] For smaller repetitive projects, risk planning [redacted]

Planning begins by developing and documenting a risk management strategy. Early efforts establish [redacted] This planning should also address [redacted]

4.1 Risk Planning Documentation

Each risk plan should [redacted] Large projects or projects with high levels of uncertainty will benefit from [redacted]

Projects that are smaller or contain minimal uncertainties may require [redacted]

4.2 Red Flag Item Lists

A red flag item list is created at the earliest stages of project development and maintained as a checklist during project development. It is [redacted] Not all projects will require a comprehensive and quantitative risk management process. A red flag item list can [redacted]

Red flag items specific to API Spec Q1 requirements include:

[redacted]

a) [redacted]
b) [redacted]

Risk assessment associated with product and component quality includes, as applicable:

c) [redacted]
d) [redacted]

A red flag item list is a technique to identify risks and focus attention on [redacted] Issues and items that can potentially impact [redacted] are identified in a list or red flagged and the list is [redacted] By listing items that can [redacted] Occasionally, items considered risky are [redacted] The red flag item list facilitates [redacted] By maintaining a running list, these items will [redacted]

See a sample list of risks in Appendix A. While this sample list can be used to [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] The risk charter provides [redacted] It also helps by [redacted]

A risk charter is a document containing [redacted] It is similar to [redacted] The risk charter contains [redacted] It may contain [redacted] It may also include [redacted] This method may [redacted] The terms "risk charter" and "risk register" have the same meaning.

A risk charter is used as a management tool to [redacted] It provides assistance in [redacted] As part of a comprehensive risk management plan, the risk charter can [redacted]

The risk charter organizes [redacted] A risk charter is typically [redacted] The identified risks are listed with [redacted] The risk charter may include relevant information such as the following:

- [redacted]

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

Two examples of risk charters are in Appendix B and C. The first example is [redacted] The second example uses [redacted] The risk register contains [redacted] The risk register adds [redacted]

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] Since the Company resources and applicable Supplier's ability to plan and work the project affects risks, additional [redacted]

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

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

The plan is the road map that tells the Company [redacted] how to [redacted] Since it is [redacted] and be [redacted] in other areas to [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 [redacted] Red flag item lists, risk charters and formal risk management plans provide [redacted]

6.0 Risk Identification Process

The risk identification process begins with [redacted] but most identification processes begin with [redacted] These issues and concerns can [redacted] Appendix A contains examples of risk checklists and the following provides a typical checklist. Checklists and databases can be created for [redacted]

Typical Risk Identification Checklist:

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

- [redacted]
- [redacted]

The team should examine and identify [redacted] This is a practical way of [redacted] Risks are those events that [redacted]

After the risks are identified, they should be [redacted] Classification of risks helps [redacted] Classifying risks also [redacted] The typical risk identification checklist shown above is [redacted] which is provided in detail in Appendix A. The following table provides a typical list of classifications with alternate identified risks.

CLASSIFICATION OF IDENTIFIED RISKS				
[redacted]				

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. At a minimum, the team should start by [redacted] Numerous techniques are available to facilitate risk identification after [redacted]

[redacted] afterward, these risks [redacted] also serve as good tools for risk assessment, which is often [redacted]

Risk identification tools and techniques		
PROJECT-SPECIFIC DOCUMENTS	**PROGRAM DOCUMENTS**	**TECHNIQUES**
[redacted]	[redacted]	[redacted]

The key to success with any risk identification tool or technique is [redacted] The documents and techniques should only [redacted] and never [redacted]

The risk identification process identifies and categorizes risks that [redacted] It documents these risks and, at a minimum, produces [redacted] Risk identification is [redacted] The tools and techniques outlined

herein should support the risk identification process, but [redacted]

6.2 Risk Allocation

The rigorous process of risk identification, assessment, analysis and mitigation allows for a more transparent and informed allocation of project risk. When risks are understood and their consequences are measured, [redacted]

In theory, best value is achieved by [redacted] However, [redacted] The judgment required by the Company is how [redacted]

The Company is more likely to accept risks where [redacted]

The contract is the vehicle for [redacted] Whether the contract is for [redacted] it defines the roles and responsibilities for risks. Risk allocation in any contract affects [redacted]

Best practice:

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

However, if the Company [redacted] they will realize [redacted]

The rigorous process of risk identification, assessment, analysis and mitigation allows for [redacted]
When risks are understood and their consequences are measured, [redacted]

[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 [redacted]

A fundamental tenet of risk management is to allocate the risks to [redacted] For example, the risk of [redacted] is best borne by [redacted]

Following this principle of allocating the risks to [redacted]

Because of the advantages and disadvantages associated with efficient and equitable allocation of risk, [redacted]

6.2.2 Risk Allocation in Alignment with [redacted]

Risks should be allocated in a manner that [redacted] The definition of a clear and concise set of [redacted] is essential to [redacted] and these [redacted] For instance, if the Customer [redacted]

[redacted]

Allocating risks in alignment with [redacted] While this idea seems simple, in practice it is [redacted]

The importance of clearly understanding and defining [redacted] directly determine optimum [redacted] In addition, [redacted] should be understood early in the project process and referred to for any important [redacted]

6.2.3 Risk Sharing

The concepts of risk sharing [redacted] However, the term risk sharing can be somewhat misleading. In reality, [redacted] instead, exposure to the risk is [redacted] Risk sharing is clearly [redacted] For example, a risk that is commonly shared is [redacted] In this situation, the Company is [redacted]

Communication among parties is a key to any sharing [redacted] Risk-sharing provisions should be [redacted]

6.2.4 Risk Allocation in Alignment with [redacted]

The ultimate goal of risk allocation should be [redacted] For example, [redacted]

6.2.5 Risk Allocation Matrix

Perhaps the most widely used tool for risk allocation is [redacted] It is useful to compile the list of project risks in the form of a project risk allocation matrix. The matrix is intended [redacted] The matrix can be [redacted] It provides clear [redacted] The following example is [redacted] The table intentionally does not contain [redacted]

Example of risk allocation matrix:

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

Allocation matrices are [redacted] Appendix D provides an example [redacted] risk allocation matrix. It provides [redacted] The matrix is also applicable to [redacted]

6.2.6 Innovative Contracting Tools and Techniques

The contract is the vehicle for risk allocation. The contract provisions determine risk allocation, which in turn affects [redacted]

[redacted] Innovative contracting techniques provide a means to [redacted]

The following table provides a list of innovative [redacted] The Company can develop these non-traditional techniques and [redacted]

Innovative contracting approaches for risk allocation:

[redacted]	[redacted]	[redacted]

6.2.7 Contingency Considerations

Any party assuming a risk must be prepared for [redacted] Prudent companies use [redacted] to complete a project - see Appendix E.

When a Company requires a Supplier [redacted] An option that is not often exercised is [redacted]

In an example, the Company could [redacted]

This incentive would [redacted]

Left blank intentionally

Appendix A - Risk Identification Checklists - Red-Flag List

1. Project Management Risk Document Checklist

Risk management reports vary depending on [redacted] The following are examples of risk management documents and reports that may be useful:

- [redacted]
  - [redacted]

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

[redacted] Risks

- [redacted]

[redacted] Risks

- [redacted]

- [redacted]

[redacted] Risks

- [redacted]

[redacted] Risks

- [redacted]

[redacted] Risks

- [redacted]

- [redacted]

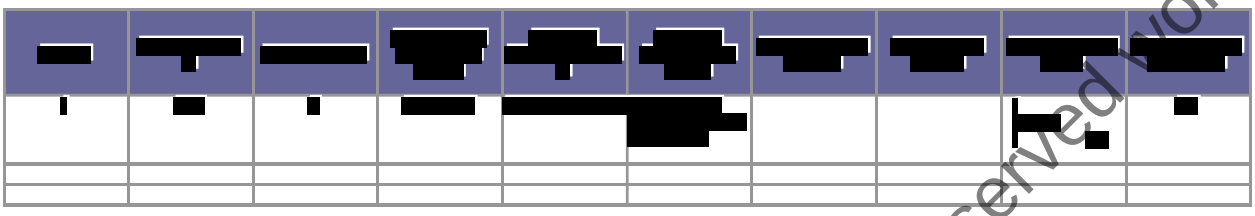
3. Miscellaneous Checklist

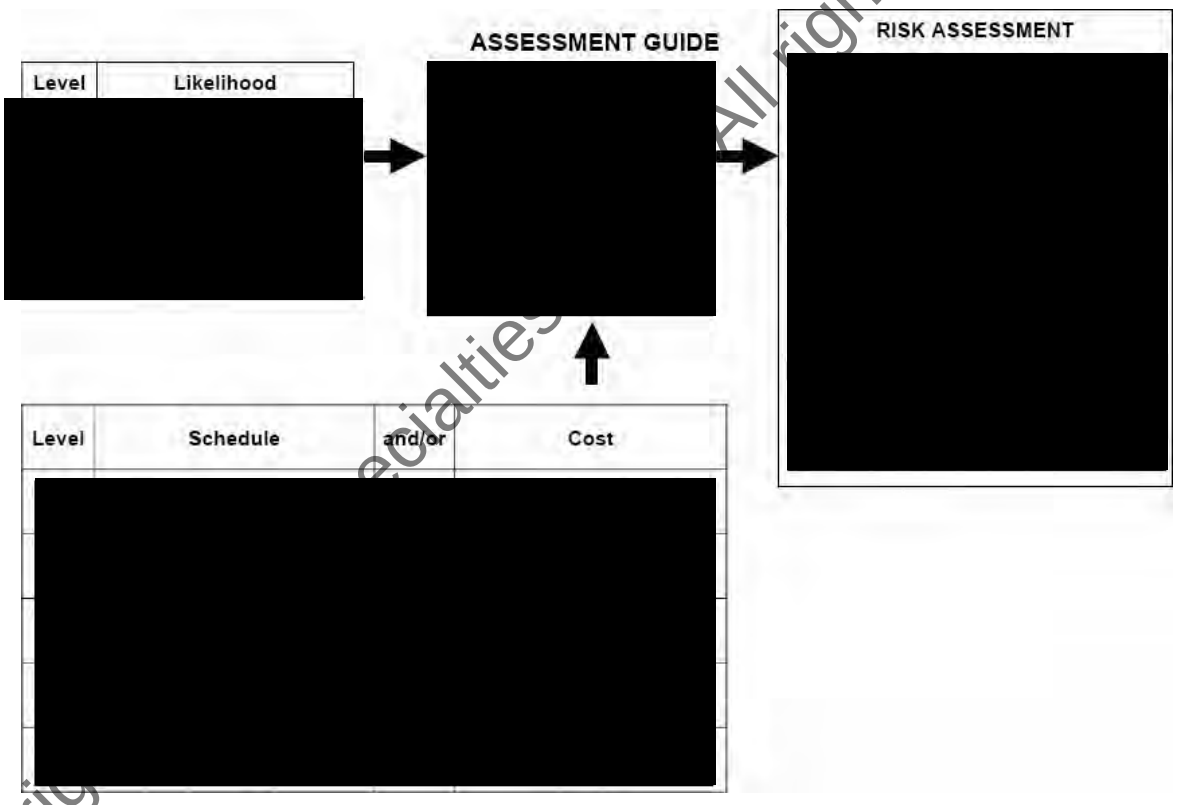
- [redacted]

Appendix B - Risk Charter

Project Risk Charter Management Plan (Example)

Double-click to browse Excel spreadsheet





See legend below...

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Appendix C - Risk Register

Project Risk Register Management Plan (Examples)

Double-click to browse Excel spreadsheet

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Risk 1				Positive between Cost and Schedule (i.e.	25% (0.25)	Triangular		Triangular	
Risk 2	Legal or Regulatory Approval				10%	No Significant Effect	No Significant Effect		2 mos.
[redacted]									
[redacted]									

[redacted]

Left blank intentionally

Appendix D - [redacted] Risk [redacted] Matrix

[redacted] RISKS	OWNER	[redacted]
[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		
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[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		

[redacted] RISKS	OWNER	[redacted]
[redacted]		
[redacted]		
[redacted]		
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[redacted]		
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[redacted]		
[redacted]		
[redacted]		
[redacted]		

[redacted] RISKS	OWNER	[redacted]
[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		
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[redacted]		

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Appendix E - Critical Elements Risk Assessment

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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
Document Link:	Location on Server (if used)

Abstract:
This document describes the management process procedure.

REVISION LOG

Issue	Date	Comment	Author
0-0			

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 must also be treated as a process. This means that management activities must have [redacted] The Company must consider the results of [redacted] to determine if [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]
  - o [redacted]
  - o [redacted]
  - o [redacted]

4.0 PROCEDURE: MANAGEMENT REVIEW

4.1 The management of the Company performs formal management review of the Quality Management System a minimum of [redacted] to ensure [redacted] The minimum attendance for Management Review [redacted]

4.2 This review shall include [redacted] Pay particular attention to [redacted]

4.3 Minutes of the meetings are taken and maintained. The ***Management Meeting Report Template*** may be used as a guide for the records or may be completed and retained as the record.

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

- [redacted]

4.5 Management shall use action items or the corrective action system to [redacted] This includes [redacted] See the ***QMS-13 Corrective Action Procedure***.

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

- [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]

4.7 Management shall determine external issues that affect its ability to achieve intended results, which may include, but are not limited to:

[redacted]

4.8 The Management Review meeting outputs are approved by top management and include the following topics in a summary assessment of the effectiveness of the quality management system:

- [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 must be [redacted]

5.3 Top management will assign [redacted]

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

5.5 During Management Review, the data [redacted]

5.6 When a process does not [redacted] according to the ***QMS-13 Corrective Action Procedure***. Such action may [redacted]

5.7 The current [redacted] recorded in the management meeting report. (See section 4.0 above.)

5.8 Over time, management shall assess [redacted] If not, corrective action shall be taken according to the ***QMS-13 Corrective Action Procedure***.

6.0 PROCEDURE: INTERNAL and EXTERNAL COMMUNICATION

6.1 Internal communication is an important facet of the way the Company does business. By this we mean that information must be able to flow in all directions, from top management throughout the Company and from all employees back to top management.

The following methods are used for internal and/or external communications:

- [redacted]

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

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

6.2.1 Confidential Company Information

Company Employees must not [redacted] All such communications must [redacted] This policy supplements but does not replace [redacted]

6.2.1.1 Basic Company Information

Company Employees must not [redacted] For example, [redacted] but engineering personnel generally would not [redacted] This is not intended to [redacted] it is intended to [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]

- [redacted]

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

6.2.1.2 Written Company Information

All Written Company Information must conform to [redacted]

All Written Company Information must [redacted]

With respect to any Written Company Information regarding [redacted] care must be exercised to [redacted]

Written Company Information regarding [redacted] must also be approved by [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]
  - [redacted]
  - [redacted]

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

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

7.3 To manage resources, top management must [redacted]

7.4 During Management Review, managers [redacted]

7.5 [redacted]

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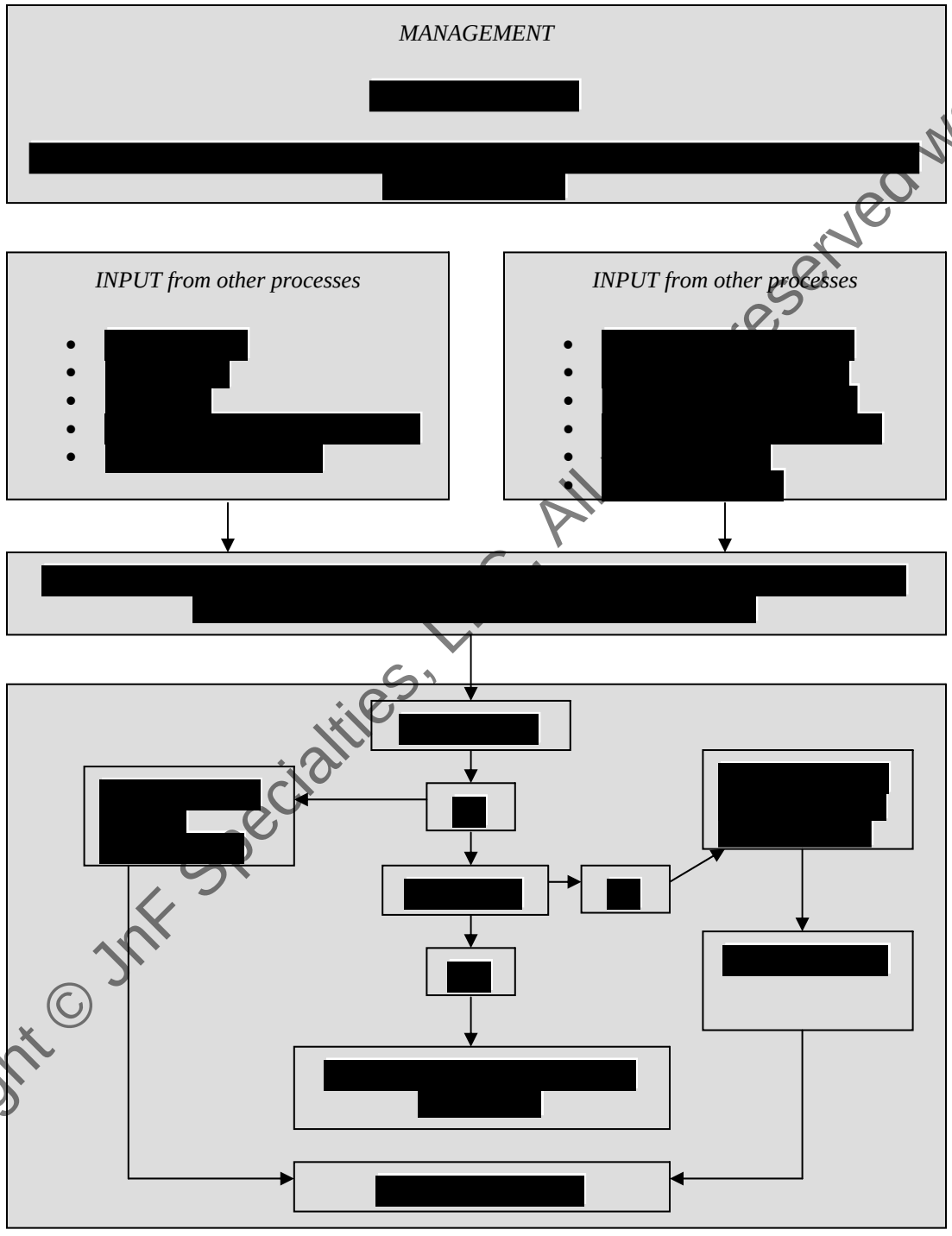
APPENDIX A: PROCESS MAP



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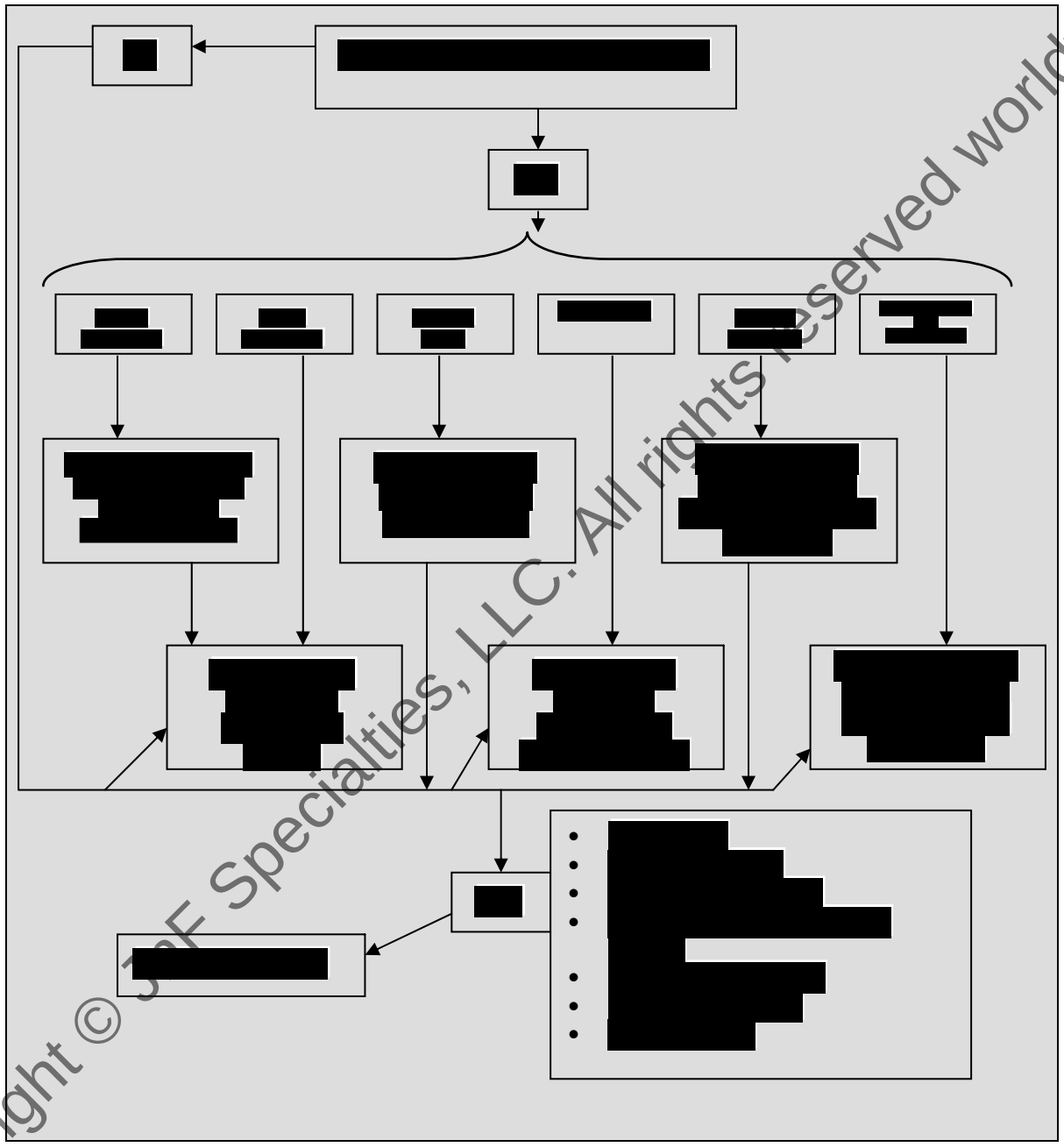


Your Logo

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
0-0			

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]

The Quality Manager also [redacted]

The Quality Manager also [redacted]

3.3 Facilities Manager

The Facilities Manager is responsible for [redacted]

3.4 Production Manager

The Production 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]

Product Managers are responsible for [redacted] which includes consideration for:

- [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] This position is responsible for [redacted] These duties include [redacted]

3.10 Quality Group Staff & Inspectors (including Receiving)

The Quality Group includes [redacted] are responsible for [redacted]

3.11 Production Operators

Production operators include [redacted]
Operators are responsible for [redacted] Operators are required to [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]

TRAINING PROGRAM

Origination Date: (mo/yr)

Manual No:	QMS-06 Training Program
Date:	Latest Revision Date
Assignment:	Customer, Unique ID, Part Number
Revision:	Draft, Redline, Released, Obsolete

Abstract:
This document describes requirements for the training program.

REVISION LOG

Issue	Date	Comment	Author
Orig	(your date)	Original Release	

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change
N/A		

TABLE OF CONTENTS

INTRODUCTION TO TRAINING PROGRAM

This training program document contains the policies and procedures the Company uses to determine its training requirements and to develop its training program. The training program ensures [redacted] The contents in this manual ensure [redacted] This manual [redacted] The Company controls this document according to the ***QMS-01 Control of Documented Information Procedure***. All training record forms are [redacted]

The Company uses a closed loop system to [redacted]

The Company's training program consists of the following basic components:

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

The Responsible Authority ensures [redacted]

1.0 BACKGROUND

Persons performing production processes are [redacted] All other Employees may be trained according to [redacted]

The Company has separate areas of study for the following staffing categories:

Technicians and other individuals performing fabrication, maintenance, preventive maintenance or alteration tasks such as:

- [redacted]
- [redacted]

- [redacted]
- [redacted]

The Company breaks down the training requirements for each staffing category based on [redacted] The Company has established minimum training standards for [redacted]

The procedures in this manual enable the Company to [redacted]

2.0 TRAINING NEEDS ASSESSMENT

The Company's needs assessment is [redacted]

2.1 Overall Needs Assessment.

To determine its overall training requirements, the Training Department and the managers of each technical area [redacted] This needs assessment results in [redacted] Appropriate training is [redacted] The areas of study, individual courses/lessons and instructors are [redacted] The Company continuously evaluates its overall training needs; however, the Company will revise the training program:

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

2.1.a Identification of the Training Needs Assessments.

The Company may identify additional training needs through:

- [redacted]

- [redacted]
- [redacted]

The Responsible Authority ensures [redacted] The Responsible Authority decides [redacted] The Responsible Authority is also responsible for [redacted]

2.1.b Changes to Work Scope.

Whenever the Company changes [redacted]

2.1.c Annual Training Program Review.

An annual review of the training program [redacted] As a part of this annual review, the Company [redacted] The Company makes changes that are required to [redacted]

2.2 Individual Needs Assessment.

Whenever the Company hires a new Employee or transfers an Employee to a task assignment, an assessment [redacted] The Company may [redacted] Courses of study are [redacted]

Initially, an assessment is [redacted] An initial assessment of new Employees is [redacted]

The Company measures [redacted] Each Employee is [redacted]

[redacted]

Employees being assigned to new tasks [redacted] The nature of the Company's work scope lends itself to [redacted]

3.0 COURSE DEFINITION

The Responsible Authority outlines training requirements for the individual based on [redacted]

An area of study is developed to [redacted] It includes [redacted]

The areas of study define [redacted]

While defining the course or lesson, the following information is documented, as appropriate:

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

The information required [redacted] This includes [redacted]

3.1 Indoctrination Training

Indoctrination training is provided to all new Employees within [redacted] but is not limited to the following courses:

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

3.2 Initial Technical Training

The Company hires personnel [redacted] All new Employees are [redacted]

3.3 Recurrent Training

Recurrent Training is [redacted] Recurrent training may include [redacted]

3.4 Remedial Training

[redacted] Remedial Training may consist of [redacted]

4.0 SELECTION OF TRAINING METHODS AND SOURCES

Using the information developed during the course definition phase, the Company [redacted]

The Company uses all training sources and methods available to [redacted] The Company uses various methods to train its Employees, which may include but are not limited to:

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

- [redacted]

The information required by [redacted]

Training Instructors or subject matter experts are [redacted] Subject matter expertise is established by [redacted]

5.0 TRAINING DOCUMENTATION

The Responsible Authority ensures training records are generated and maintained for all Employees that establish each individual is capable of performing assigned tasks.

The records include [redacted]

All documents showing proof of any of the aforementioned training are [redacted]

Any Employee may [redacted]

The Company retains and maintains a hard copy training record and an electronic file for each Employee. The hard copy training file contains, [redacted]

6.0 MEASUREMENT OF TRAINING EFFECTIVENESS

The training department [redacted]

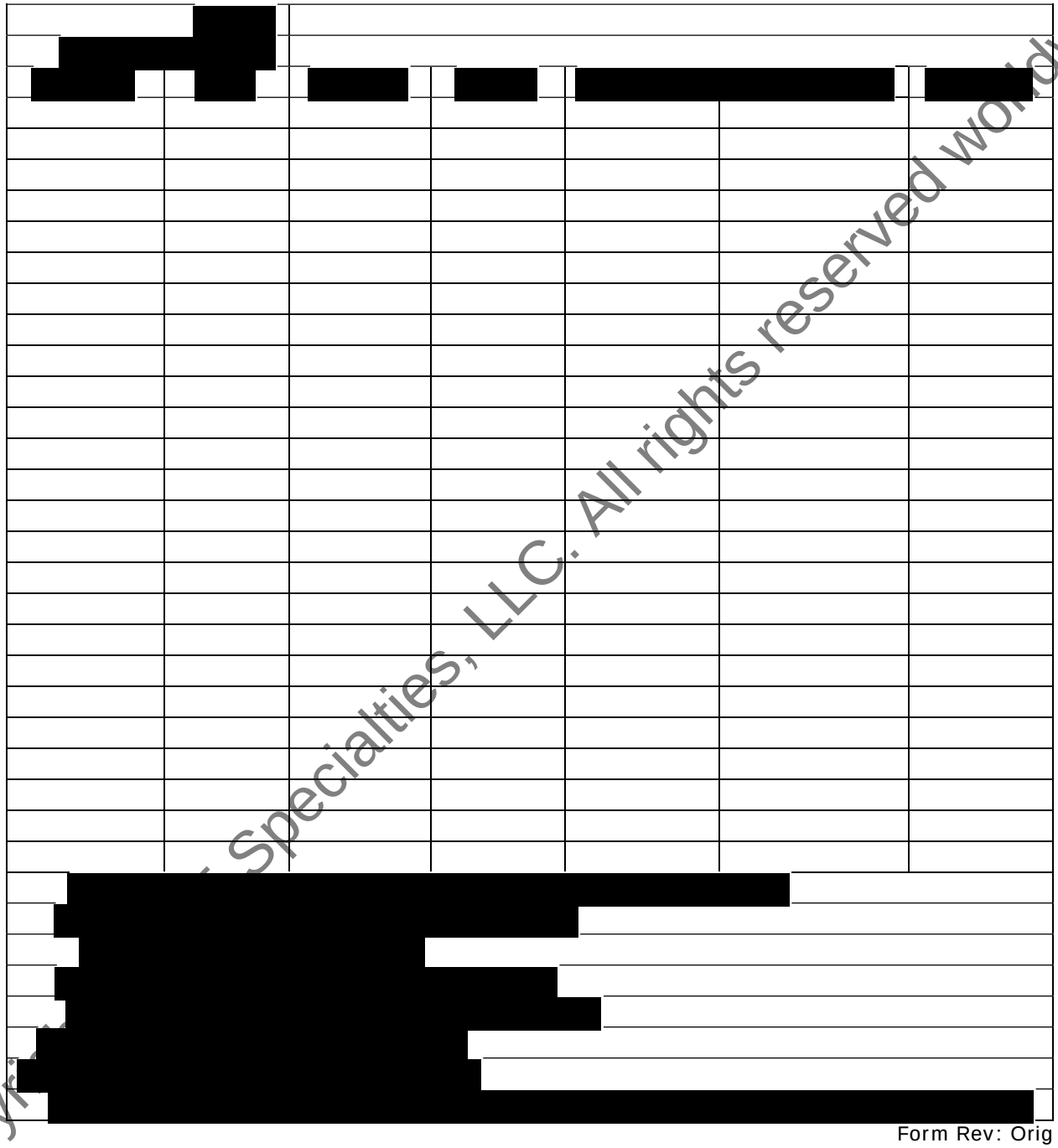
The Responsible Authority [redacted]

The Responsible Authority [redacted]

[redacted] The Responsible Authority [redacted]

Left blank intentionally

EMPLOYEE TRAINING SUMMARY FORM



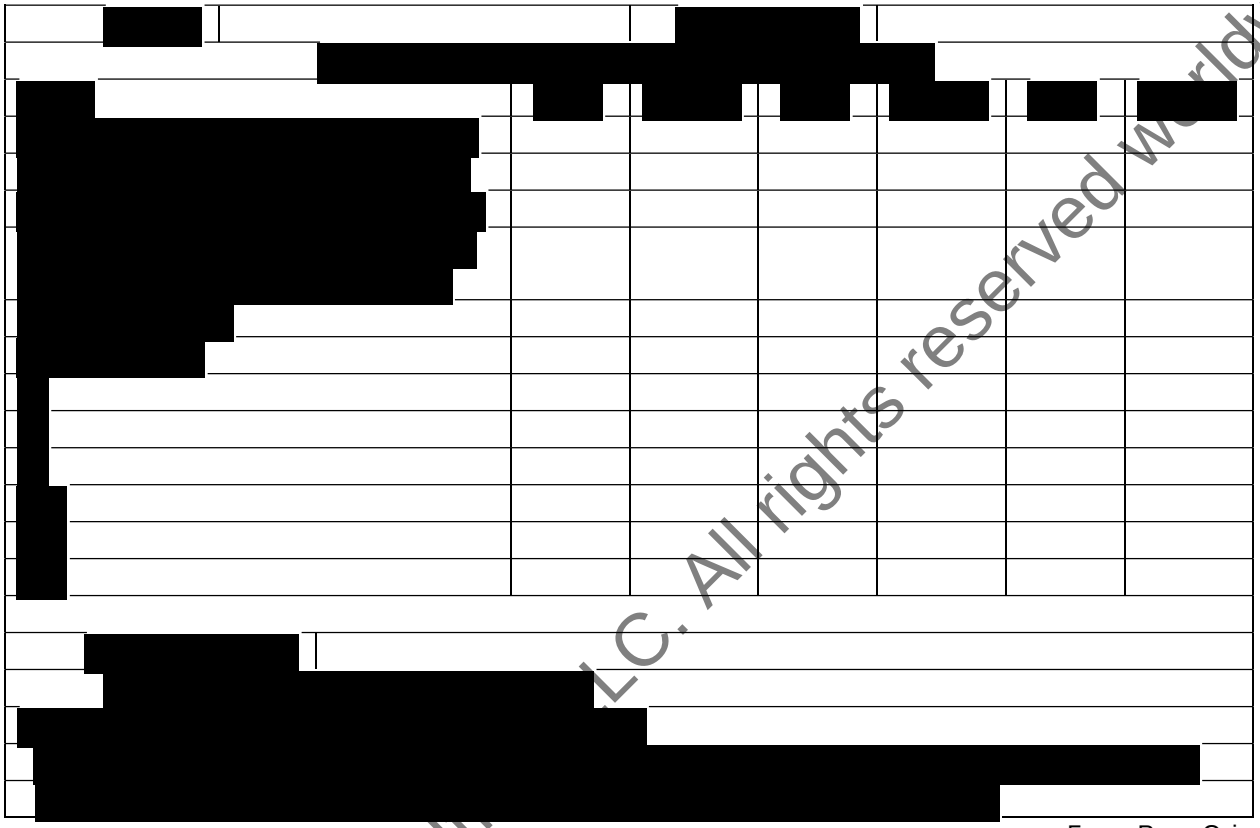
Form Rev: Orig

TRAINING RECORD

[redacted]

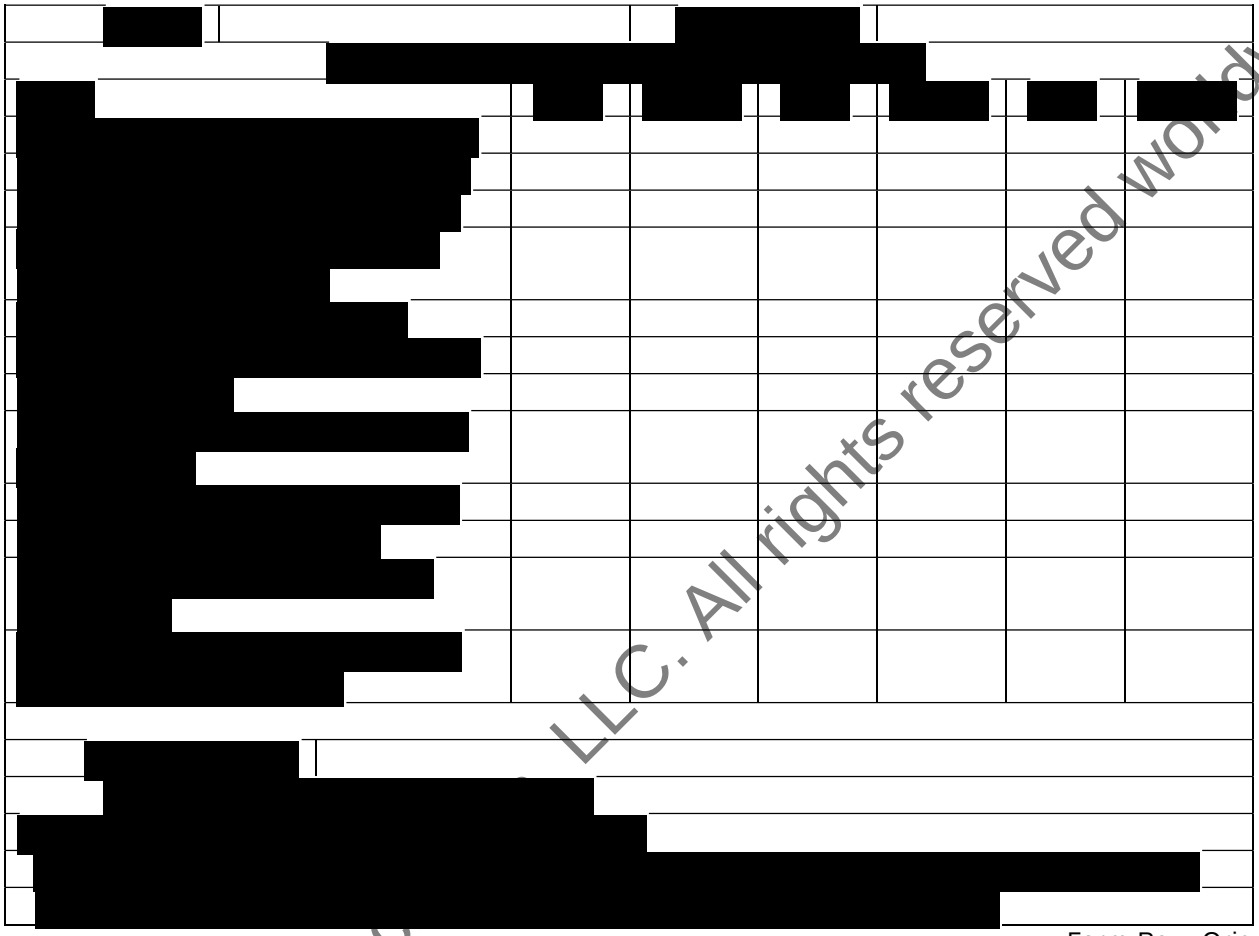
Form Rev: Orig

INDIVIDUAL TASK QUALIFICATION



Form Rev: Orig

INDIVIDUAL TASK QUALIFICATION



Form Rev: Orig

INDIVIDUAL TASK QUALIFICATION

Name:		Assignment:	

[redacted]

Form Rev: Orig

Your Logo

Your Company Name

TRAINING PROGRAM

Origination Date: XXXX

Document Identifier:	QMS-06 Training Program
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
0-0			

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 [redacted]

3.0 TRAINING PROCEDURE

Pay particular attention to [redacted]

3.1 Hiring

Employees are hired on their basis 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 the Company's general requirements, benefits, hours, workplace rules and safety rules. In addition, new employees undergo training according to [redacted] which describes the [redacted] and provides awareness of [redacted]

3.3 On the Job Training

Once an employee has completed initial indoctrination, they undergo on-the-job training relative to their position. This training is [redacted] The Company maintains a ***Training Matrix*** that [redacted] Records of such training are maintained according to the ***QMS-01 Control of Documented Information Procedure***.

3.4 Additional Training

At the discretion of management, additional training may be conducted at any time.

This may be necessitated by [redacted]

[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
0-0			

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 [redacted]

2.0 THEORY

The Company can only meet Customer requirements by [redacted] This process ensures [redacted]

3.0 PROCEDURE

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

Documentation is not required for [redacted]

The Company determines [redacted] by:

a) [redacted]

b)

c)

d)

e)

f.

g.

h.

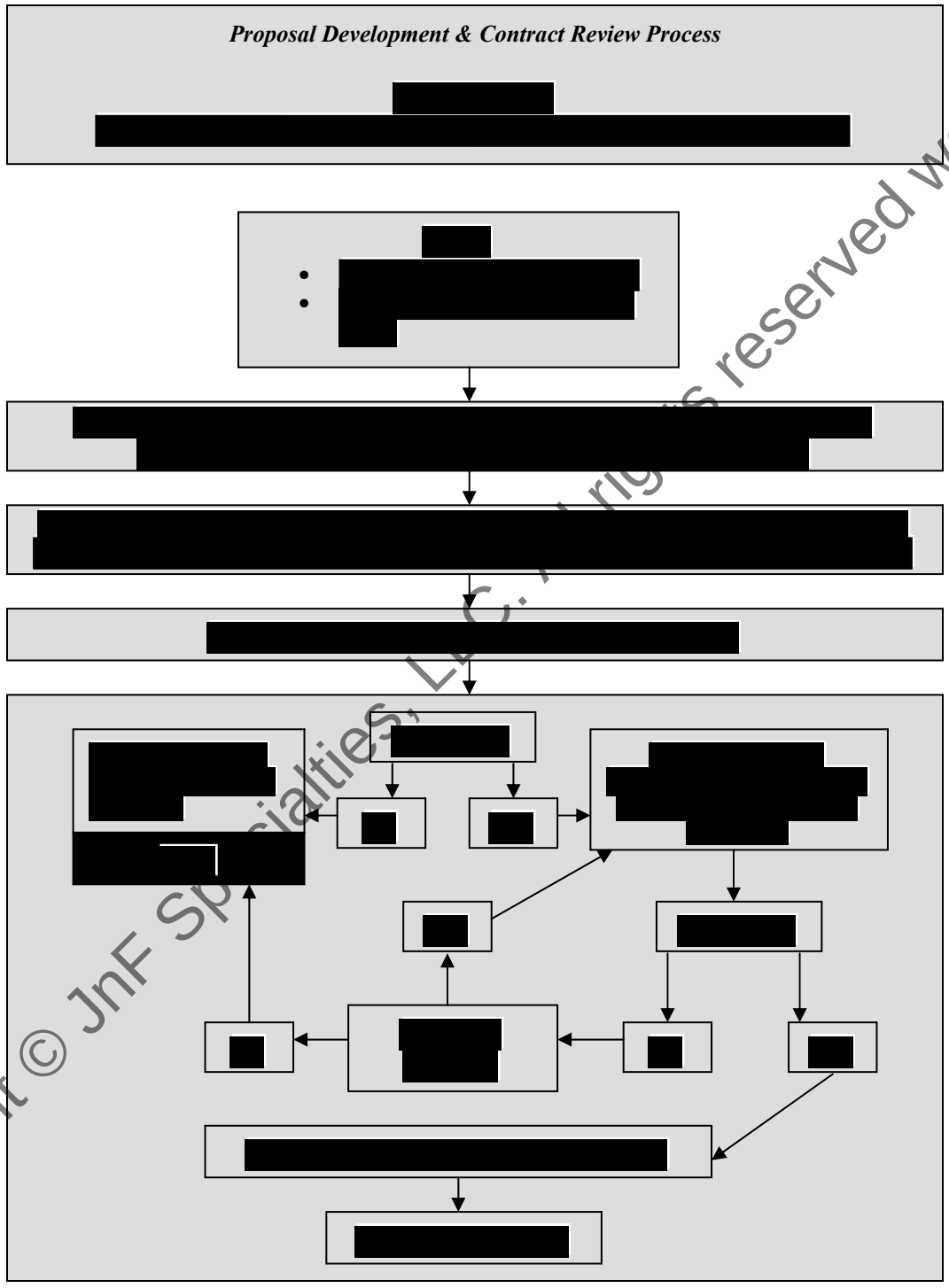
i.

j.

The Company identifies, reviews and controls This is accomplished by

See Process Map.

4.0 PROCESS MAP



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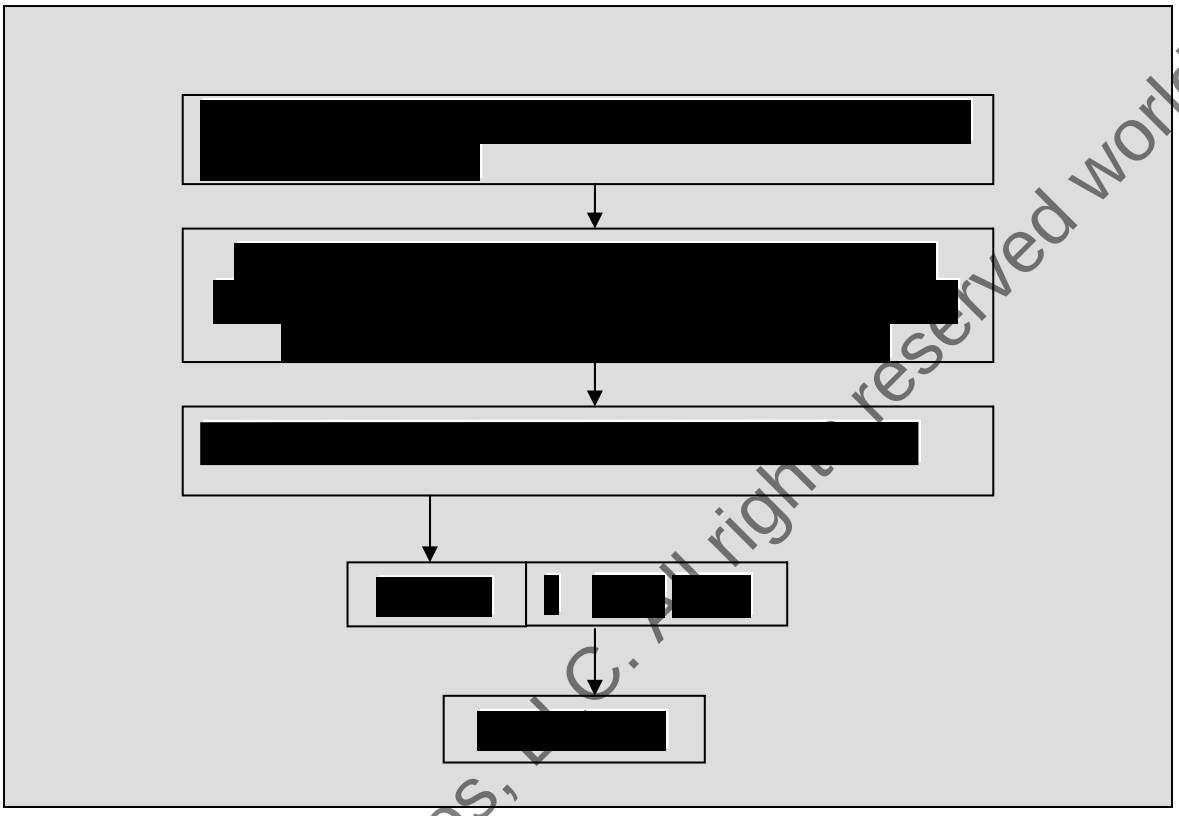


Your Logo

Your Company Name

PURCHASE ORDER REVIEW WORK INSTRUCTION

Origination Date: XXXX

Document Identifier:	QMS-08-1 Purchase Order Review Work Instruction
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
0-0			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

1	[redacted]	-- [redacted] -- --
2	[redacted]	-- [redacted] -- -- -- -- -- -- -- --
	IF	THEN
2.1	[redacted]	-- [redacted]
2.2	[redacted]	-- [redacted] --
2.3	[redacted]	-- -- [redacted]
2.4	[redacted]	[redacted]

		[redacted]
2.5	[redacted]	[redacted]
3	[redacted]	Add provisions for any one or combination of the following to the Requisition or P.O. when justified: -- [redacted]
4	[redacted]	[redacted]

		-- [redacted]
5	[redacted]	--
5.1	[redacted]	-- [redacted]
5.2	[redacted]	-- [redacted]
	IF	THEN
5.2.1	[redacted]	[redacted]
5.2.2	[redacted]	-- [redacted]
6	[redacted]	[redacted]

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
0-0			

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 [redacted]

2.0 THEORY

The purchase of materials [redacted] As a result, it is important [redacted]

3.0 PROCEDURE: SUPPLIER EVALUATION AND SELECTION

3.1 All suppliers of product related materials or services must be evaluated unless [redacted]

3.2 Supplier evaluation is conducted by following the format on the ***Supplier Evaluation Form***.

3.3 The ***Supplier Evaluation Form*** ensures [redacted]

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

3.5 The following ratings apply to suppliers:

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

3.6 Once entered into the ***Approved Supplier List***, suppliers are [redacted] subject to [redacted]

3.7 Using incoming (receiving) inspection results for product suppliers and Company employee feedback on service providers, the Responsible Authority (RA) [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 ***Supplier Performance Rating Spreadsheet***, which calculates the Supplier's current quality rating based on items received and items accepted. A new Supplier that rates 100% on their first delivery [redacted]

3.10 If a new Supplier rates [redacted], the Supplier remains at [redacted]

3.11 If any Supplier rates [redacted] the Supplier will [redacted]

3.12 If items are returned [redacted]

3.13 Any Supplier may [redacted]

3.14 Management may [redacted]

3.15 During management review, the entire ***Approved Supplier List*** is [redacted] See the ***QMS-04 Management Process Procedure***.

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 does not [redacted]

Verification activities include one or more of the following activities:

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

- [redacted]

When external provider test reports are utilized to verify externally provided products, the Company [redacted] according to the ***QMS-09 Receiving Inspection Procedure***.

3.17 Critical Products, Components or Activities

When the Company or Customer identifies products, components or activities as, [redacted] the Company [redacted] according to the ***QMS-09 Receiving Inspection Procedure***, and [redacted] that includes:

a) [redacted]

b) [redacted]

c) [redacted]

i. [redacted]

ii. [redacted]

iii. [redacted]

The on-site Supplier evaluation is recorded on the ***Supplier Survey Report***, which is retained and maintained according to the ***QMS-01 Control of Documented Information Procedure***.

3.18 Supplier Re-Evaluation

The Company determines supplier re-evaluation frequency [redacted] according to the ***QMS-04 Management Process Procedure***.

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] Particular attention is paid to [redacted] Purchasing documents [redacted] which may include [redacted]

4.3 Responsible Authorities ensure [redacted] which includes:

- [redacted]

4.4 When appropriate, the purchase order defines [redacted]

4.5 As applicable, purchase order information includes:

a) [redacted]

b) [redacted]

c) [redacted]

d) [redacted]

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

e) [redacted]

f) [redacted]

g) [redacted]

h) [redacted]

i) [redacted]

j) [redacted]

k) [redacted]

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

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

l) [redacted]

m) [redacted]

- [redacted]
- [redacted]

4.6 The requirements for delegation are defined [redacted]

4.7 When the Company or its Customer needs to perform verification activities at a Supplier facility, [redacted]

4.8 See the process map herein.

4.9 Emergency Purchasing Authority: The Company will [redacted] In such cases, [redacted]

5.0 OTHER PURCHASING RULES

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

5.2 Any employee of the Purchasing Department [redacted] The Operations Manager, will [redacted] Each employee [redacted]

5.3 The acceptance [redacted]

5.4 The acceptance [redacted]

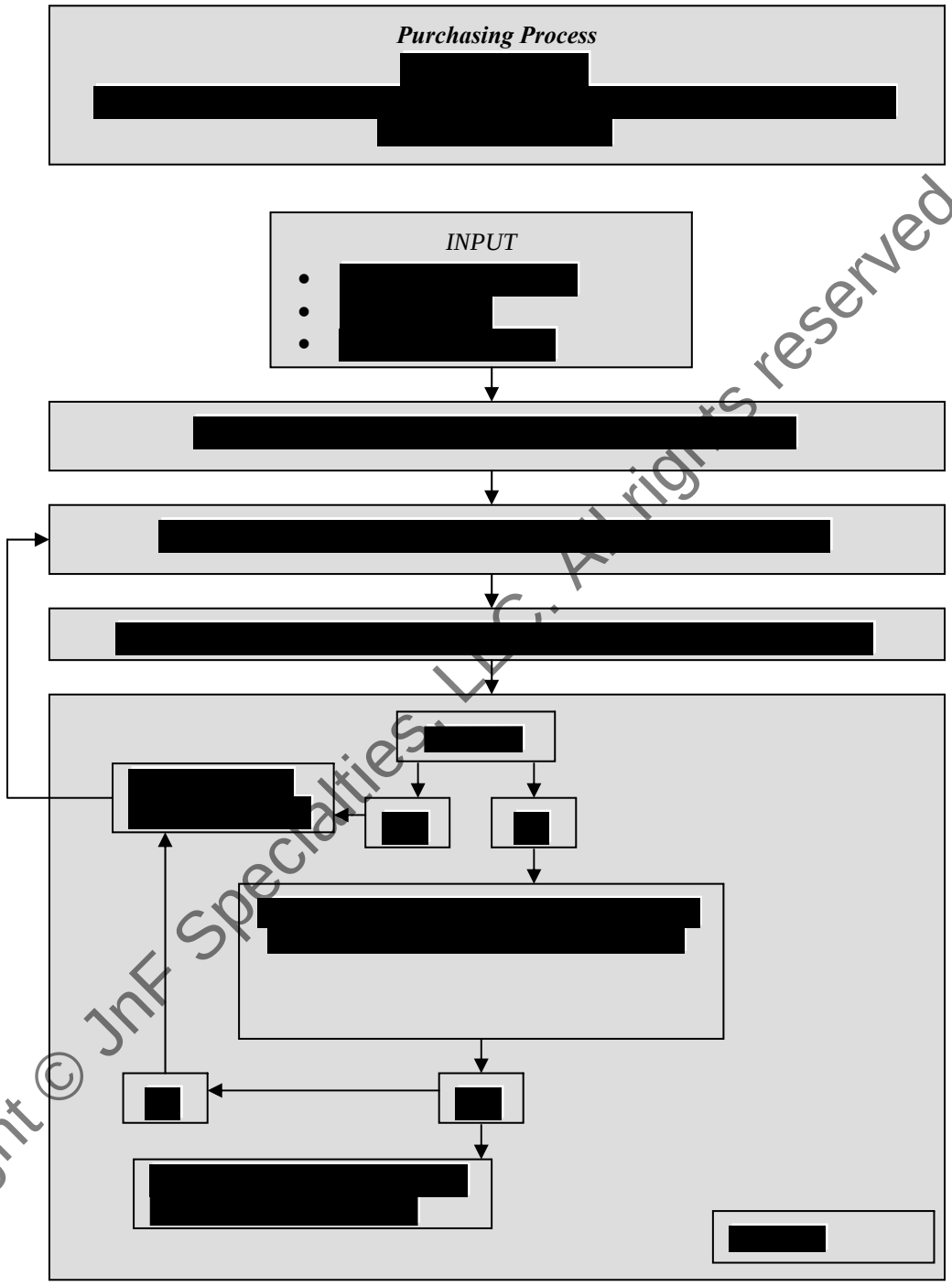
5.5 The Purchasing Department will [redacted]

5.6 The Purchasing Department will not, [redacted]

5.7 The Company will [redacted]

Left blank intentionally

6.0 PROCESS MAP



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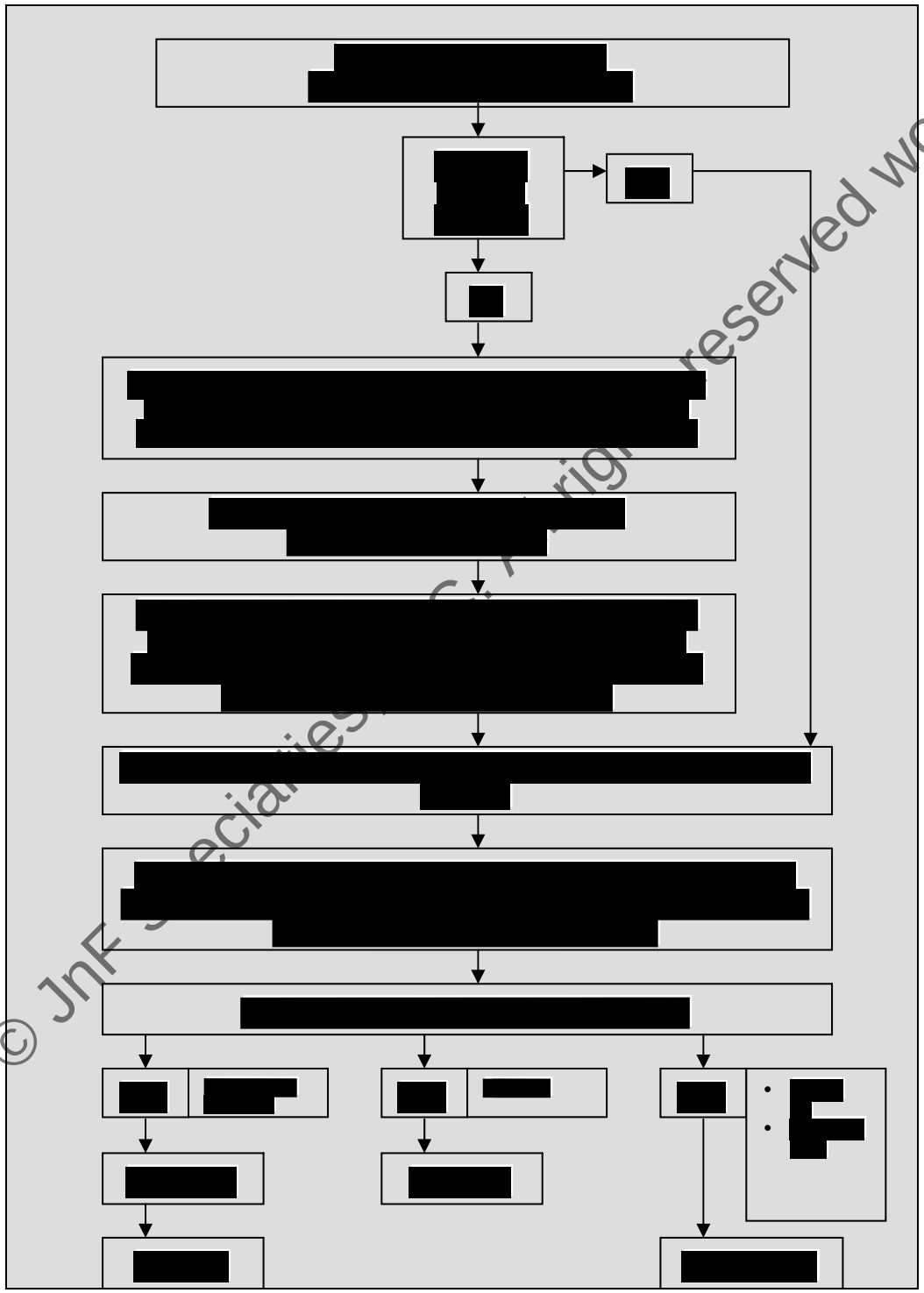

Your Logo

Your Company Name

RECEIVING INSPECTION PROCEDURE

Origination Date: XXXX

Document Identifier:	QMS-09 Receiving Inspection 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
0-0			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

1.0 PURPOSE

This document defines the Receiving process including [redacted]

2.0 THEORY

Receiving is the first line of defense to [redacted] however, [redacted] Receiving inspection cannot [redacted]

As a result of [redacted] the Company [redacted]

3.0 PROCEDURE: RECEIVING

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

4.0 PROCEDURE: RECEIVING INSPECTION

4.1 The inspector will receive the items and original paperwork from the RA and [redacted]

4.2 Inspections are performed according to *Appendix A* or as required by [redacted] The results are recorded on [redacted] the purchase order is processed according to *Appendix B*.

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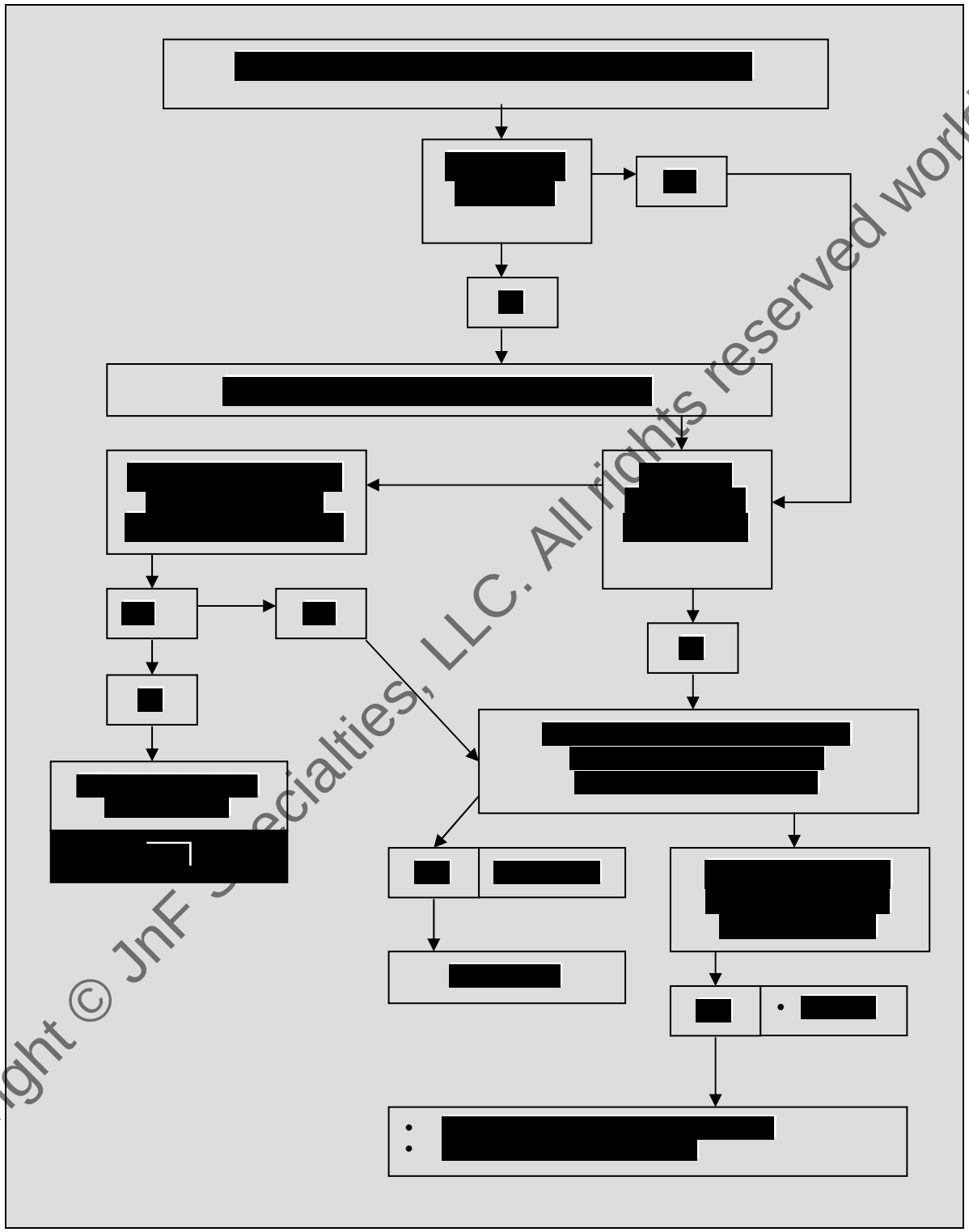
PROCESS MAP



APPENDIX A - RECEIVING INSPECTION WORK INSTRUCTIONS

Op 1: Acquire copy of ***Purchase Order***. Perform [redacted] verification [redacted] Examine the supply to [redacted] The Supplier's conformance certificate(s) should [redacted]

Op 2: Verify supply [redacted]

Op 3: [redacted] Items exempt [redacted]

Op 4: Verify the Supplier is [redacted]

If Supplier provides [redacted]

If Supplier provides [redacted]

Op 5: If the supply is [redacted]

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

Op 7: SAMPLING PLAN:

Sampling plan ***ANSI Z1.4*** AQL: 1.0 is required for [redacted] do not apply sampling plan for [redacted]

Randomly select items for [redacted], then…

Op 8: Verify [redacted] then…

Op 9: Verify [redacted] then…

Op 10: Verify [redacted] then...

Op 11: Review all documentation [redacted], then...

Op 12: Verify

Op 13: When raw material is

perform the following activities:

For

For

Op 14: When product is

Op 15: Verify

Op 16: If the Supplier is

Op 17: Affix a

Op 18: If supplies are

If the supply is

Op 19: Complete

Op 20: Complete

Op 21: Record

Process the ***Purchase Order*** according to *Appendix B.*

Op 22: If the Supplier's

Op 23: Inspect [redacted]

APPENDIX B - PURCHASE ORDER PROCESSING

Step	IF	THEN
1	[redacted]	[redacted]
2	[redacted]	[redacted]
2.1	[redacted]	[redacted] Closed PO's are subject to records control according to the ***QMS-01 Control of Documented Information Procedure***.

Your Logo

Your Company Name

PRODUCTION PROCEDURE

Origination Date: XXXX

Document Identifier:	QMS-10 Production 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 production process.

REVISION LOG

Issue	Date	Comment	Author
0-0			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

1.0 PURPOSE

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

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

2.0 THEORY

Production operations or tasks must be conducted under controlled conditions to ensure product and component quality.

By this we mean:

- [redacted]

3.0 PROBLEM RESOLUTION

All employees are instructed to immediately notify a Responsible Authority (RA) whenever [redacted]

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

No disciplinary action may be attached to an employee's attempt to resolve a problem (Corrective Action Procedure, 3.3).

- [redacted]

4.0 REQUIREMENTS

The Company implements product/component production and servicing provisions under controlled conditions, which includes:

- [redacted]

- [redacted]

5.0 PRODUCTION DOCUMENTATION

Documented information includes [redacted]

Documented information defines [redacted]

Process control documents include [redacted]

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

[redacted]

5.1 All revision controlled production documents are [redacted]

5.2 In addition to this process procedure, [redacted] Where required, these [redacted]

5.3 Such documentation includes [redacted]

5.4 The Company develops, retains and maintains documentation that includes [redacted], including criteria for [redacted]

5.5 Records that are created for [redacted]

6.0 PRODUCT AND COMPONENT IDENTIFICATION

The Company maintains the inspection/test and conformity/nonconformity status of deliverable goods throughout the product realization process. In addition, [redacted]

The Company controls [redacted]

6.1 Products and components are [redacted] by any of the following methods:

[redacted]

6.2 Lot traceability or individual serialization of parts and components is maintained [redacted] according to the ***Traceability Work Instruction***. Responsible Authorities [redacted] and instruct [redacted] Records for identification and traceability are retained and maintained according to the ***QMS-01 Control of Documented Information Procedure***.

Traceability requirements include:

- [redacted]
- [redacted]

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

6.3 Nonconforming products or components [redacted] according to the ***QMS-14 Control of Nonconformities Procedure***.

6.4 Any discovery of product or component that is [redacted]

6.5 IDENTIFICATION OF TRANSFER CONTAINERS

6.5.1 Whenever a portion of chemical is transferred from its original container to a [redacted]

6.5.2 Whenever a portion of chemical is transferred from its original container to a [redacted]

7.0 PRODUCT AND COMPONENT HANDLING

7.1 Work instructions [redacted] instruct Operators on the proper and safe handling of [redacted]

7.2 In all cases, Operators [redacted]

7.3 The Company provides suitable safety and personal protection equipment for handling hazardous or toxic materials. Operators are required to wear or use such equipment as directed by their supervisors or managers.

8.0 PRESERVATION

Preservation of deliverable goods is performed according to the ***Preservation Procedure*** for [redacted] or the ***QMS-11 Shipping Procedure*** for [redacted] Instructions are provided for:

- [redacted]

8.1 Operators will employ [redacted]

8.2 Operators will employ proper use of [redacted]

8.3 Operators will employ [redacted]

8.4 Operators will employ [redacted]

The Company reserves the right to [redacted]

8.5 FOD: [redacted]

8.6 [redacted] including [redacted]

8.7 [redacted]

9.0 CUSTOMER PROPERTY CONTROL

The Company controls, identifies, maintains, preserves, safeguards and verifies Customer property [redacted]

9.1 Customer Property (Property) means [redacted] Hardware property includes:

- [redacted]

9.2 All Customer furnished property [redacted]

9.3 Property [redacted] As practical, [redacted]

9.4 [redacted]

9.5 Property will only [redacted]

9.6 Customer provided equipment [redacted]

9.7 The Responsible Authority [redacted]

9.8 Requirements for the control of Property [redacted]

10.0 VALIDATION OF PROCESSES

Unless otherwise specified by engineering requirements, the ***Validation-Verification Form*** is used to record results of validation and verification activities.

10.1 Provisions for validation and verification includes:

- [redacted]

10.2 Validation and Control of Special Processes

When identified as critical to product performance by the Company or product specification, processes requiring validation include:

- [redacted]

Prior to their use, the Company establishes qualification and approval of special processes. In addition, [redacted]

Qualification and approval of special processes includes, as applicable:

- [redacted]

- [redacted]

11.0 PRODUCTION PROCESS VERIFICATION

The Company implements production process verification activities [redacted], which includes [redacted]

11.1 Control of Equipment, Tools, and Software Programs

Equipment, tools, and software programs used to [redacted] which includes [redacted]

12.0 INSPECTION AND TEST OF PRODUCT AND COMPONENT

The Company maintains suitable infrastructure for [redacted] The Company determines [redacted] Records of all inspection activities are retained and maintained according to the ***QMS-01 Control of Documented Information Procedure***.

12.1 Receiving Inspection

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 [redacted]

12.2.1 First article inspections are [redacted]

12.2.2 The Company will utilize the Customer provided First Article Inspection Report to record First Article inspection results when provided.

12.2.3 Where not provided, the Company [redacted]

12.2.4 Complete the first article inspection form [redacted] and [redacted]

12.2.5 Calibrated tools shall be used for first article inspection; however, [redacted]

1) [redacted]
2) [redacted]

12.2.6 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 [redacted] and as [redacted]

12.3.2 In-process inspections are [redacted]

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

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

When sampling is used as a means of product and component acceptance, the sampling plan is based upon ***ANSI Z1.4*** and the AQL is appropriate by [redacted]

12.3.3 Calibrated tools shall be used for in-process inspection; however, [redacted]

1) [redacted]
2) [redacted]

12.3.4 When applicable, complete the production inspection record [redacted]

12.3.5 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 [redacted] and [redacted]

12.4.2 100% sampling is required for final inspection unless [redacted]

12.4.3 Calibrated tools shall be used for final inspection; however, [redacted]

1) [redacted]
2) [redacted]

12.4.4 The Responsible Authority [redacted] according to [redacted]

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

Prior to product and component delivery, the Responsible Authority [redacted] The Company [redacted]

13.0 SHELF LIFE EXTENSION

Shelf life extension is subject to Customer Review and/or Approval

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

13.1.1 [redacted]

13.1.2 [redacted]

13.1.3 [redacted]

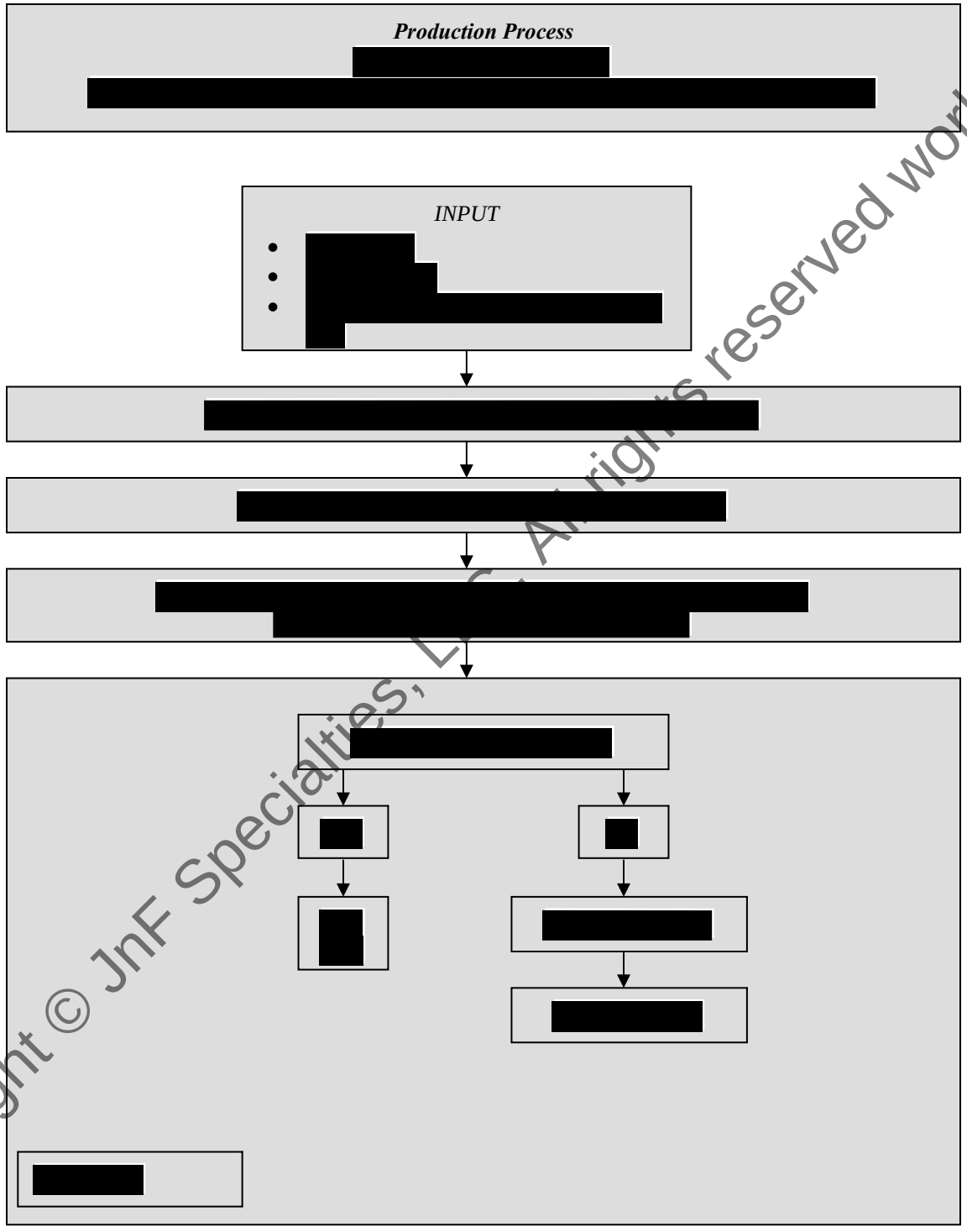
13.1.4 [redacted]

13.2 [redacted]

13.3 Raw material components whose shelf life [redacted]

Left blank intentionally

14.0 PROCESS MAP



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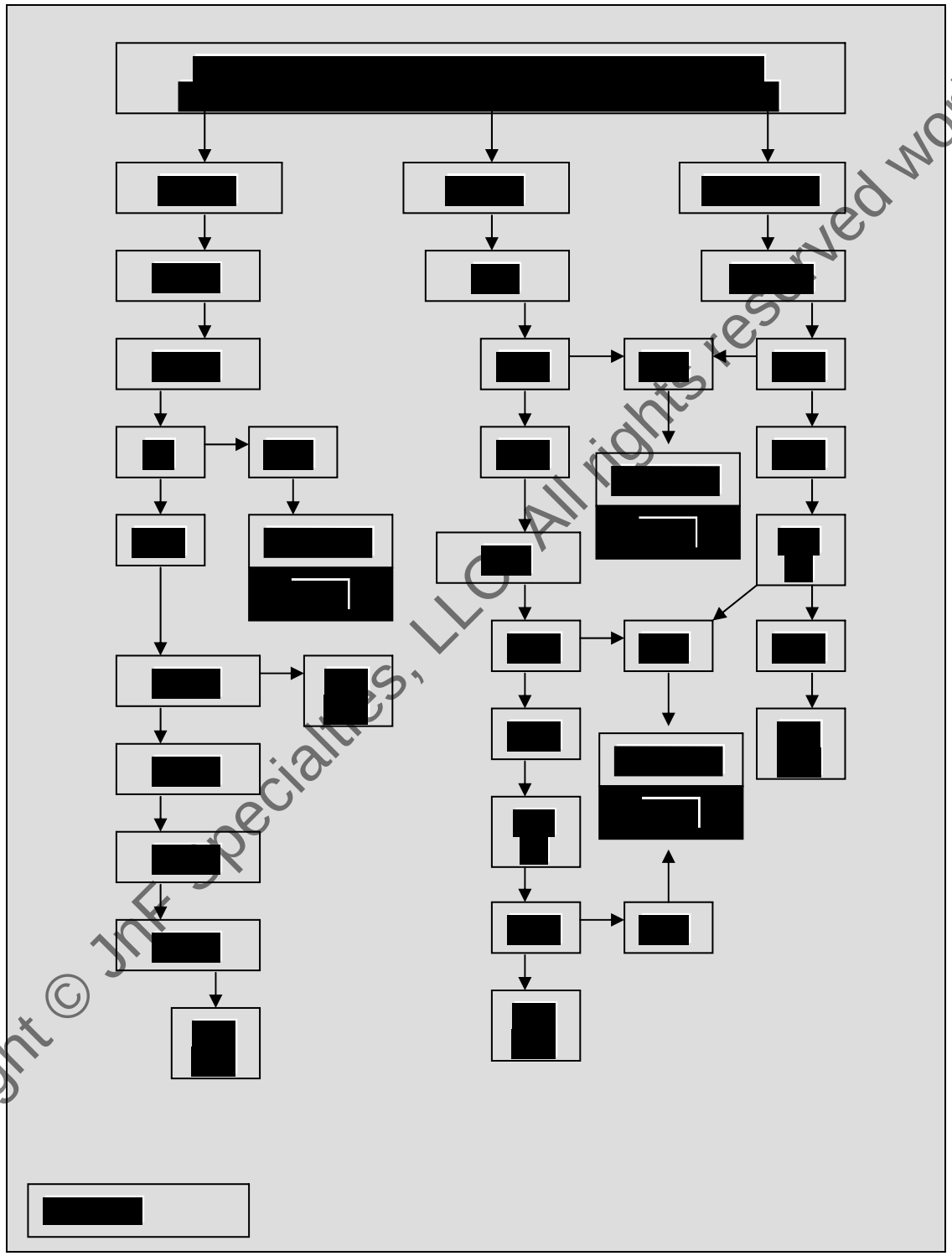

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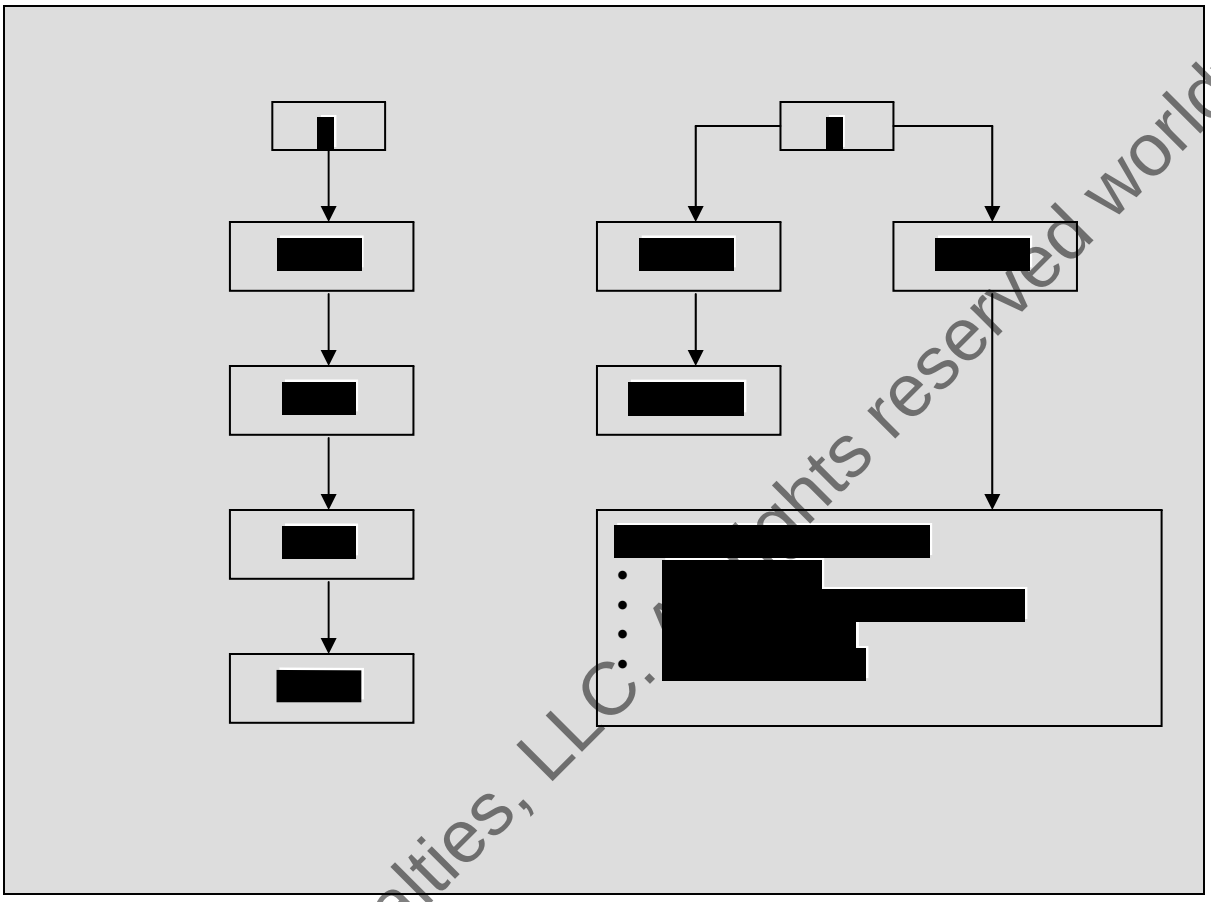


Your Logo

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
0-0			

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 [redacted] as a result, the Company [redacted]

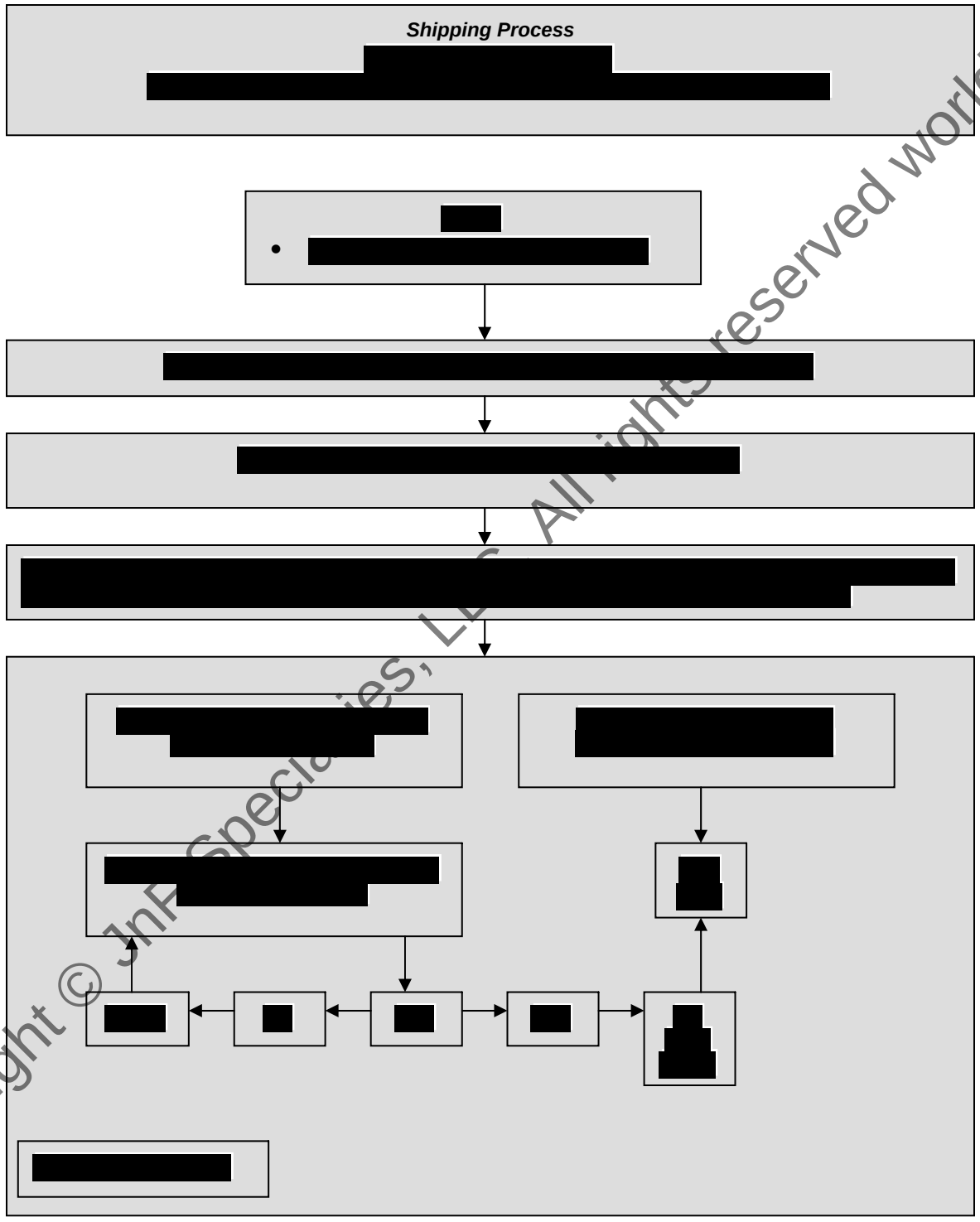
3.0 PROCEDURE: PACKAGING AND SHIPPING

Preservation activities shall provide instructions for:

- [redacted]

See Process Map.

4.0 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
0-0			

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.

2.0 THEORY

Internal auditing of a Company's quality system is [redacted]

3.0 INTERNAL AUDITING PROCEDURE

The Resonsible Authority takes into consideration [redacted]

3.1 Internal quality audits are [redacted] This is accomplished by [redacted]

3.2 Audit requirements include those of [redacted]

3.3 Auditors may not [redacted]

3.4 Minimum auditor training requirements are as follows:

- [redacted]
- [redacted]

3.5 The Responsible Authority plans audits according to [redacted] which includes:

- [redacted]

3.6 The Responsible Authority maintains the ***Internal Audit Schedule*** [redacted]

3.7 Using the ***Internal Audit Report***, the Lead Auditor [redacted] The audit team [redacted] to the ***Internal Audit Report***.

3.8 An audit team [redacted] All findings are recorded on the ***Internal Audit Report***.

3.9 The internal audit team submits requests for corrective action according to the ***QMS-13 Corrective Action Procedure*** as necessary to [redacted]

3.10 During the corrective action [redacted]

3.11 The completed ***Internal Audit Report*** is [redacted] and the ***Internal Audit Schedule*** [redacted]

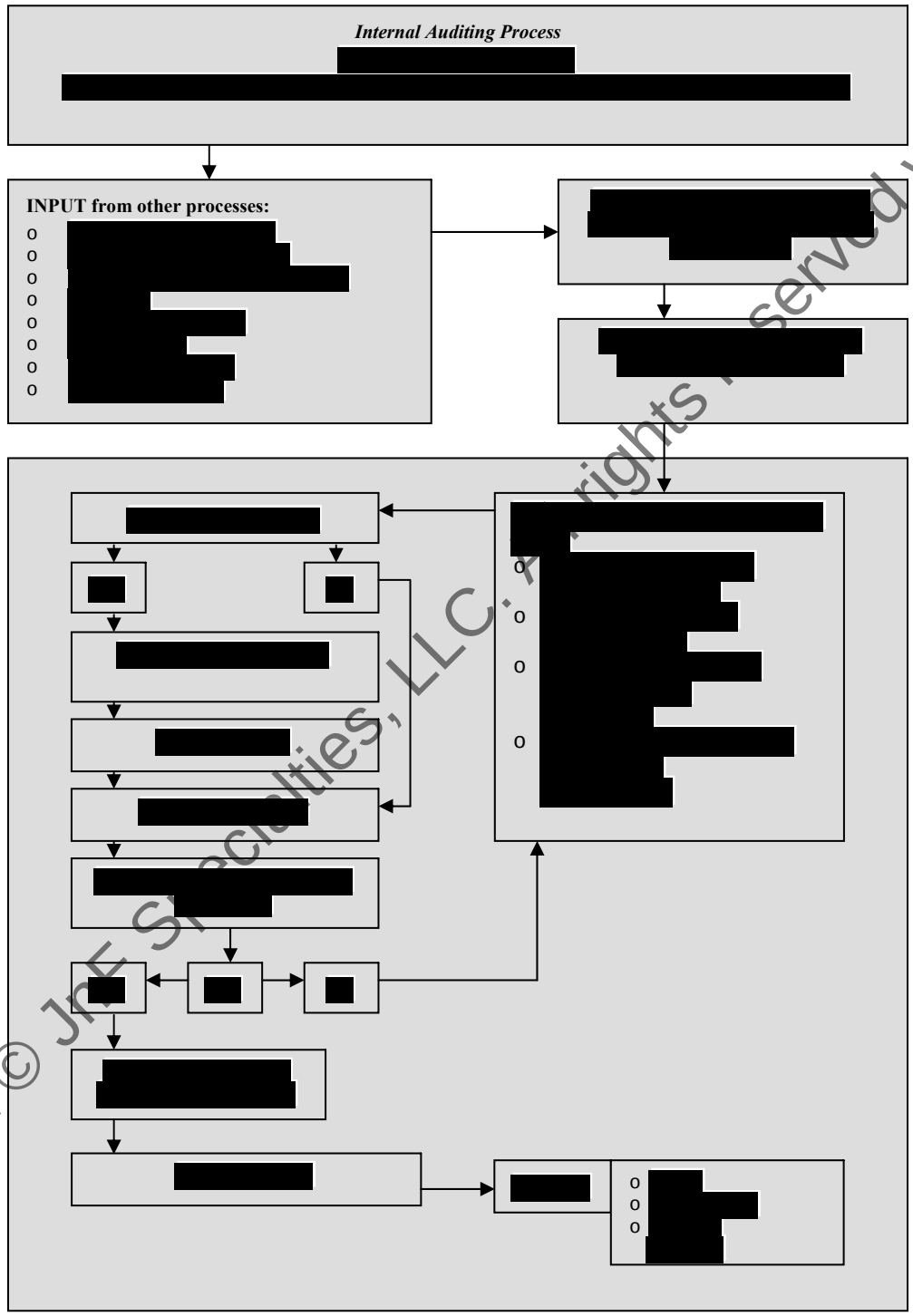
3.12 Copies of the completed audit report [redacted]

3.13 The results of internal audits [redacted] according to the ***QMS-04 Management Process Procedure*** and by [redacted]

3.14 In all cases, auditees are [redacted]

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
0-0			

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 and prevent nonconformities.

2.0 THEORY

Corrective action is taken to correct nonconformities, which could be [redacted]

[redacted]

Sources for preventive action opportunities include [redacted] Having a formal system to record and resolve existing and potential problems ensures that these problems do not occur or reoccur, thereby improving products, processes and the work environment.

3.0 PROCEDURE: INTERNAL REPORTS

3.1 The Company utilizes a ***Request for Support*** (RFS) form to record nonconformities related to its products, components and production process activities, [redacted] as well as [redacted] The form and system are also used for potential problems (preventive action). In all cases, [redacted] The Company determines if additional nonconformities exist based on their causes and takes further action when required.

3.2 ALL employees are [redacted]

3.3 No disciplinary action [redacted]

3.4 The [redacted] assigned the role of RFS Administrator.

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

3.6 If the Responsible Authority [redacted]

3.7 Actions taken are to the degree appropriate to the problem according to Responsible Authorities, which includes:

a) [redacted]
b)
c)
d)
e)
f)

g) [redacted]

3.8 The [redacted] monitors the ***RFS Log*** to determine [redacted]

3.9 In addition to corrective action efforts, [redacted] which are applied to preventive actions [redacted], and include:

a) [redacted]
b)
c)
d)
e)
f)

3.10 The management review process [redacted]

3.11 Where product, component or production process activity is suspected of a nonconformity, the Company applies corrective actions that include [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 [redacted]

4.2 ***ICAR***'s are processed through the same steps as the ***RFS*** but are [redacted]

4.3 Failure [redacted] to respond [redacted]

Left blank intentionally

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
0-0			

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 nonconforming items.

2.0 SCOPE

Items that have failed inspections or tests [redacted]

3.0 GENERAL PROCEDURE

3.1 "Nonconformance" is [redacted] that does not meet:

- [redacted]

3.2 Nonconforming items must be withheld pending disposition by a completed ***RFS*** [redacted] before shipment.

3.3 All employees are empowered to engage this procedure when they discover potential or nonconforming items. No employee may work on ***Yellow-Tagged*** nonconforming items.

3.4 Upon discovery of a nonconforming item, an employee may [redacted] For example, [redacted]

3.5 When an employee cannot [redacted]

3.7 The employee [redacted] The employee [redacted]

3.8 The employee [redacted] A ***Yellow-Tag*** may [redacted]

3.9 Upon receipt of the ***RFS***, the Responsible Authority [redacted]
The Responsible Authority [redacted]
Necessary actions are taken [redacted]

3.10 The Responsible Authority [redacted] which includes [redacted]

3.11 If the nonconforming item is ascertained or estimated to be the fault of a Supplier, the Responsible Authority may elect to [redacted] In such cases, [redacted]
Corrective actions are processed according to the ***QMS-13 Corrective Action Procedure***.

3.12 The Responsible Authority will also indicate on the ***RFS*** form if [redacted] is required [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]

Records of the nature of nonconformities, subsequent actions, concessions and MRB dispositions are retained and maintained according to the ***QMS-01 Control of Documented Information Procedure***.

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

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

3.14.1 MRB Qualification

A Material Review Board member must:

1) [redacted]
2) [redacted]

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

3.16 The Company shall take actions [redacted] Notifications shall include [redacted] A clear description of the nonconformity shall include [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

The MRB may determine that a ***Request for Support*** was prepared because of ambiguity or misinterpretation of a requirement. [redacted] may disposition the RFS as 'Clarification Only'. The condition must not be classified as [redacted] Further disposition action is at the discretion of the MRB. This MRB disposition is [redacted]

4.2.2 Conditional Acceptance

Nonconforming supplies or processes may be dispositioned 'conditional accept' if [redacted] A 'conditional accept' disposition is [redacted] Corrective action instructions, when required, are recorded on the ***Request for Support***. This MRB disposition is [redacted]

The evaluation and release under concession of nonconformities that do not satisfy Manufacturing Acceptance Criteria (MAC) is [redacted] provided that:

a) [redacted]

b) [redacted]

c) [redacted]

4.2.3 Non-Deliverable (Regrade for Alternative Applications)

Suspect supplies must be dispositioned 'Non-Deliverable' when [redacted] This MRB disposition is [redacted]

4.2.4 Notification

It is possible [redacted] This MRB disposition is [redacted]

4.2.5 Precautionary

The MRB may determine that a Request for Support was [redacted]

The condition must not be classified as [redacted] This MRB disposition is [redacted]

4.2.6 Repair (Non-Standard and Standard)

When an acceptable repair is possible, repair action may be authorized. The MRB [redacted] This MRB disposition is [redacted]

4.2.7 Request for Waiver/Deviation

When a supply is considered 'fit-for-use' by the MRB [redacted] This MRB disposition is [redacted]

4.2.8 Return to Supplier (Receiving Inspection)

When supplies deviate from requirements [redacted] This MRB

disposition is [redacted]

4.2.9 Rework (Non-Standard and Standard)

The MRB may disposition "Rework" according to [redacted] This MRB disposition is [redacted]

4.2.10 Scrap

Raw materials, parts and components [redacted] This MRB disposition is [redacted]

5.0 CUSTOMER DISPOSITION AUTHORITY

5.1 Major: [redacted]

5.2 RTV and Scrap dispositions are [redacted]

5.3 Minor: [redacted]

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

5.5 None: [redacted]

6.0 PROCESSING SCRAP

6.1 Nonconforming items dispositioned as scrap are [redacted]

6.2 [redacted] positively segregated until [redacted]

6.3 [redacted]

6.4 Scrap is [redacted]

Your Logo

Your Company Name

CALIBRATION PROCEDURE

Origination Date: Mo/Yr

Document Identifier:	QMS-15 Calibration Procedure
Date:	Your Date
Document Status:	Released

Abstract:
This document describes calibration procedures.

REVISION LOG

Issue	Date	Comment	Author
Orig	Mo/Yr	Original release	

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 [redacted]

3.0 DEFINITIONS

- [redacted]

4.0 GENERAL CALIBRATION PROCEDURE

4.1 Calibration is performed [redacted]

4.2 Measuring instruments are calibrated [redacted]

[redacted]

4.3 [redacted]

4.4 All M&TE are [redacted]

4.5 A ***Recall Log*** (and/or ***Recall Card***) is [redacted] The ***Recall Log*** (and/or ***Recall Card***) is retained and maintained according to the ***QMS-01 Control of Documented Information Procedure***.

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

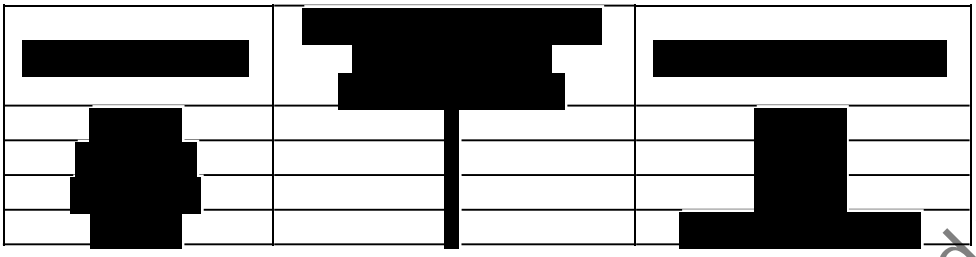
4.7 In addition to the ***Recall Log*** (and/or ***Recall Card***), a ***Calibration Report*** is [redacted] The ***Calibration Report*** is retained and maintained according to the ***QMS-01 Control of Documented Information Procedure***.

Calibration Instructions are [redacted] Instructions may [redacted]

4.8 Calibration intervals may [redacted]

4.9 Adjustable M&TE is [redacted] the schedule of *Table 1*. Nonadjustable M&TE is [redacted] The calibration interval [redacted]

TABLE 1, Calibration Intervals



4.10 Interval Adjustment: M&TE

4.11 M&TE calibration intervals may

4.12 Overdue items

4.13 A calibration sticker

A calibration tag

A tag or sticker

The tag or sticker

4.14 Calibration Standards/Special Equipment

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

."

Calibration of standards/special equipment

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 record and recall log is [redacted]

4.16 The calibration department places [redacted]

4.17 Traceability: [redacted]

4.18 Non-Calibrated M&TE: Upon request, non-calibrated M&TE may be submitted for calibration. Non-calibrated measurement devices may be used to accept or reject deliverable item quality characteristics 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 Software programs that are used for operation of production equipment are [redacted] however, [redacted]

4.19.2 [redacted]

4.19.3 [redacted]

4.19.4 [redacted]

4.19.5 [redacted]

4.19.6 Power supplies that are used in process control and test equipment are [redacted] however, [redacted]

4.20 Employee Owned Tools: Personal tooling or measuring equipment owned by employees are [redacted]

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

4.22 M&TE requiring transportation [redacted]

4.23 M&TE storage areas [redacted]

4.24 Archive / Long-Term Storage: [redacted] if it was [redacted]

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

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

5.0 OUT-OF-TOLERANCE EQUIPMENT AND TOOLING

5.1 Calibrated M&TE that is found to be significantly out of tolerance, [redacted]

5.2 M&TE found significantly out of tolerance [redacted]

5.3 An instrument whose calibration error is significantly out-of-tolerance [redacted]

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

6.0 LOST EQUIPMENT

6.1 Measurement and test equipment that cannot be located [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 an ***NIST*** traceable reference standard to calibrate a measurement device.

Requirement:

The measurement range of a device being checked for accuracy must be [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 - the reference standard must be set to a range that brackets the range on the voltmeter being checked for accuracy. For instance, [redacted]

OTHER MEASUREMENT DEVICES:

Any ***NIST*** traceable reference standard whose maximum measurement range is the same as the device being checked for accuracy [redacted]

For instance, [redacted]

APPENDIX 2

Nonadjustable M&TE is inherently stable and includes [redacted] ***NIST*** traceable gage block and weight "standards" are [redacted]

The Operator is [redacted]

For instance, [redacted]

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

[redacted]

Operators are required [redacted]

[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
0-0			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

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1.0 PURPOSE

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

2.0 ABBREVIATIONS

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
0-0			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

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1.0 PURPOSE

This document provides details on the Design and Development process.

2.0 THEORY

[redacted] Controlling the design and development activity ensures [redacted]

3.0 DESIGN & DEVELOPMENT PROCEDURE

3.1 General

The responsible engineering authority (REA) for design and development is [redacted] Design and development personnel from various business groups may include [redacted] Design and development planning outputs are recorded in the applicable ***Design Review*** according to the ***Design Review Work Instruction*** [redacted] and are controlled according to the ***QMS-02 Configuration Management Procedure***. Records of the design and development activities are retained and maintained according to the ***QMS-01 Control of Documented Information Procedure***.

3.2 Design and development planning

The Company considers the following conditions when determining the stages and controls for design and development:

- [redacted]

- [redacted]

3.3 Design and development inputs

The Company considers the following conditions when it determines requirements essential for the specific types of products and services to be designed and developed:

- [redacted]

The Company determines that design and development inputs are [redacted] The Company retains and maintains records for design and development inputs according to the ***QMS-01 Control of Documented Information Procedure***.

3.4 Design and development controls

The Company applies controls to the design and development process to ensure that:

- [redacted]

3.5 Design and development outputs

The Company ensures that design and development outputs:

- [redacted]

The Company approves the design [redacted]

The Company retains and maintains records for design and development output activities and controls according to the ***QMS-01 Control of Documented Information Procedure***.

3.6 Design and development changes

The Company identifies, reviews and controls changes [redacted] according to the ***QMS-02 Configuration Management Procedure***.

All changes are:

a) [redacted]
b)
c)
d)
e)

The Company retains records for:

- [redacted]

4.0 PROCESS MAP

Process Map continued…

Contingency Plan

Mo/Yr

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

Used On	Contract#:		**Your Company Name**					
Prepared By:		Date						
Your Dept:		Date						
Your Dept:		Date	**CONTINGENCY PLAN**					
Your Dept:		Date						
Your Dept:		Date	Size:	**A**	API#:		Form Rev: Orig	1 of 1

Your Company Logo

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1. Overview

The Company's Contingency Plan provides [redacted]

2. Scope

The objective of this plan is [redacted]

It is the intent of this Contingency Plan [redacted]

The scope of this plan [redacted]

All contingency plans [redacted]

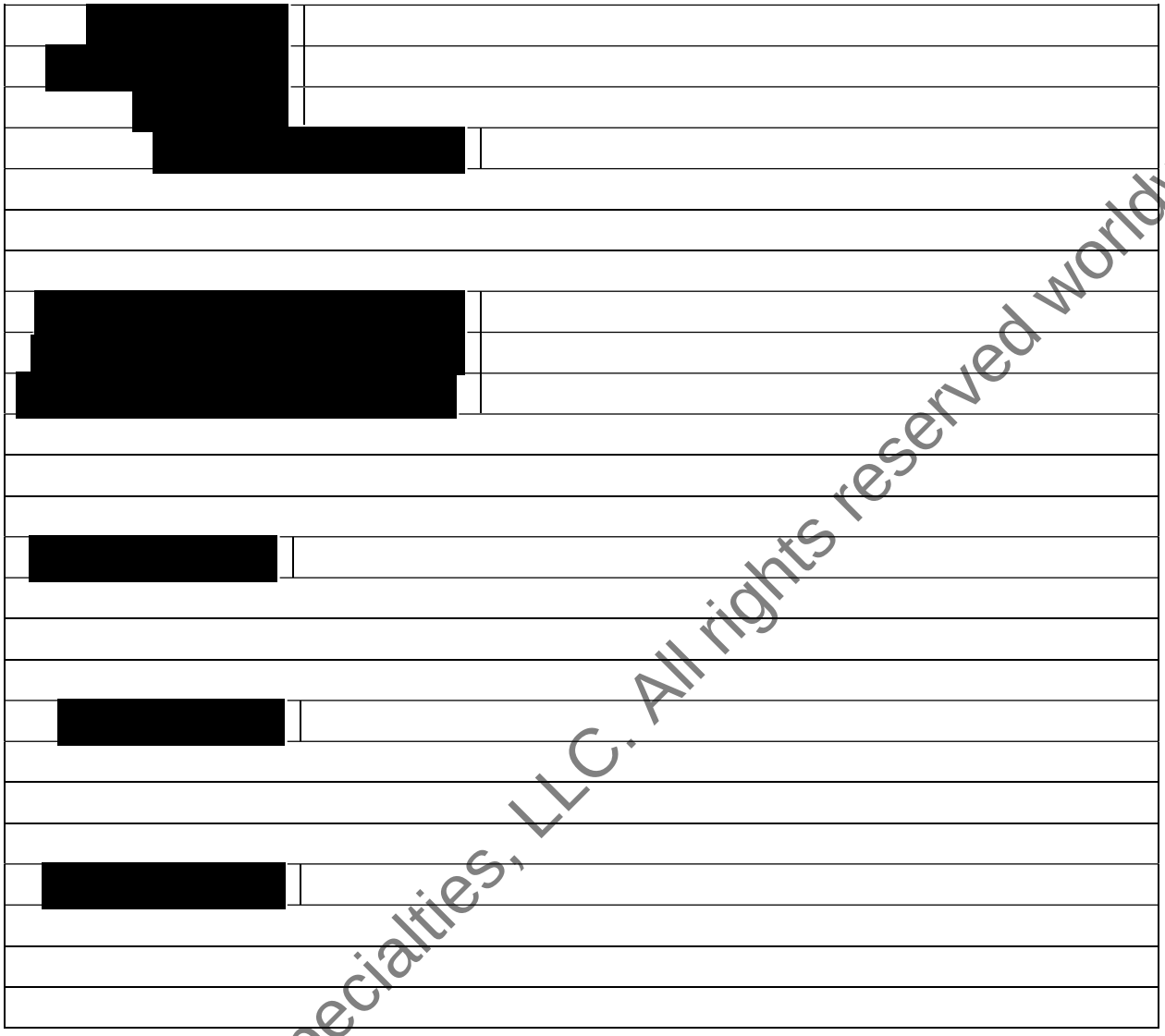
3. Plan Outline

The Contingency Plan [redacted]

Contingency plan items:

[redacted]

Sample Contingency Plan



Sample Contingency Plan

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 [redacted]

2.0 THEORY

Design review is used to [redacted]

To serve as a design reviewer indicates [redacted]

3.0 DESIGN REVIEW

All deliverable hardware and software [redacted] to assure [redacted]

3.1 Number and Type of Design Reviews

The number and type of design reviews [redacted] In principle, the design review [redacted] A system may [redacted]

3.2 Scheduling Reviews

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

3.3 Heritage Design Review

Designs that are qualified by another program [redacted]

3.4 Software and Service Reviews

Computer programs, contents of ROM, PROM and [redacted]

3.5 Subcontractor Reviews

Products and services from subcontractors [redacted] The responsible authority and appropriate support personnel [redacted]

3.6 Interfaces

Reviewers [redacted] For example [redacted]

3.7 Post Review Design Changes

Changes made to a design [redacted] Design changes, [redacted] Fully configured programs [redacted]

3.8 Design Review Items

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

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

3.9 Inappropriate Items for a Design Review

3.10 System Review Attendees

System review attendees should include

4.0 Types of Design Reviews

4.1 System Level Reviews

4.1.1 Baseline Design Review (BDR)

The BDR is held

The BDR is typically

The BDR must

The BDR should address the following:

1.

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 [redacted] - PDR is [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 [redacted]

4.1.3 Critical Design Review (CDR)

The system CDR is held immediately prior to [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 [redacted]

4.1.4 Environmental Review (ER)

The ER occurs prior to [redacted] Its purpose is to:

1. [redacted]
2. [redacted]

4.1.5 Buyoff Review

The buyoff review (also known as [redacted] is [redacted] it addresses:

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

For programs involving a qualification product, a buyoff review [redacted]

4.1.6 Operations Review

This review applies to programs [redacted] The review evaluates [redacted]

4.2 Subsystem Level Reviews

Subsystem level reviews are [redacted] These reviews are [redacted] This level of review [redacted]

4.2.1 Hardware Subsystem Reviews

Circuit design reviews are [redacted] Completion of this review permits [redacted] Electrical and mechanical subsystem reviews and review packages should contain (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 [redacted] The software CDR [redacted]

4.2.3 Fabrication Pre-release Review (FPR)

Prior to release of a drawing package to the shops for fabrication, an FPR (also known as Fabrication Feasibility Review – FFR) is held. This provides [redacted] The FPR consists of [redacted] The FPR 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 [redacted]

4.3 Other Reviews

Some programs require external reviews. These reviews [redacted] Interactions between external and internal providers [redacted]

5.0 Design Review Packages

All design reviews require [redacted]

Some Customers require [redacted]

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

System level review packages typically contain:

#	Document	Preparer
1	[redacted]	[redacted]
2	[redacted]	[redacted]
3	[redacted]	[redacted]
4	[redacted]	[redacted]
5	[redacted]	[redacted]
6	[redacted]	[redacted]
7	[redacted]	[redacted]
8	[redacted]	[redacted]
9	[redacted]	[redacted]

#	Document	Preparer
10	[redacted]	[redacted]
11	[redacted]	[redacted]
12	[redacted]	[redacted]
13	[redacted]	[redacted]

5.2 Circuit Design Review Data Package

Circuit design review packages typically contain:

#	Document	Preparer
1	[redacted]	[redacted]
2	[redacted]	[redacted]
3	[redacted]	[redacted]
4	[redacted]	[redacted]
5	[redacted]	[redacted]
6	[redacted]	[redacted]
7	[redacted]	[redacted]
8	[redacted]	[redacted]
9	[redacted]	[redacted]
10	[redacted]	[redacted]
11	[redacted]	[redacted]
12	[redacted]	[redacted]
13	[redacted]	[redacted]
14	[redacted]	[redacted]

5.3 Software Review Data Package

Software review packages typically contain:

#	Document	Preparer
1	[redacted]	[redacted]
2	[redacted]	[redacted]
3	[redacted]	[redacted]
4	[redacted]	[redacted]
5	[redacted]	[redacted]
6	[redacted]	[redacted]
7	[redacted]	[redacted]
8	[redacted]	[redacted]
9	[redacted]	[redacted]

6.0 Responsibilities

6.1 Program Manager

The program manager is responsible for [redacted]

[redacted] The program manager is responsible for [redacted] The manager prepares [redacted]

6.2 Chief Engineer

The chief engineer is responsible for [redacted]

[redacted] The chief engineer will [redacted] Issues concerning [redacted] referred to the chief engineer.

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] Reviewers have an obligation to [redacted] Reviewers should [redacted]

6.6 Chairperson

The Chairperson [redacted] The Chairperson must [redacted]

The Chairperson should [redacted]

The Chairperson is [redacted]

The Chairperson is responsible for [redacted]

[redacted]

6.7 Section, Group and Department Supervisors

Line supervisors are responsible for [redacted]

Supervisors should [redacted]

MAINTENANCE PROCEDURE

Origination Date: XXXX

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

Abstract:
This document describes the maintenance procedure for (your Co).

REVISION LOG

Issue	Date	Comment	Author

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

Left blank intentionally

1. Scope

This procedure is intended to establish recommended practices in the maintenance of production equipment owned and operated by (your Co name).

2.0 Preventive Maintenance

Preventive maintenance (PM) is the practice of [redacted] The intent of PM is to [redacted] The goal is to [redacted]

Some advantages of PM are:

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

PM does have some drawbacks:

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

Recommended electrical and mechanical maintenance practices for some equipment are [redacted]

3.0 General

Maintenance activities fall into three general categories:

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

3.1 Maintenance Schedules and Documentation

Complete, thorough and current documentation is [redacted]

Equipment maintenance [redacted] into a ***Maintenance Work Order***. When maintenance work orders [redacted]

The maintenance [redacted] This is important for [redacted]

The availability of [redacted] In addition, [redacted]

3.2 Safety during Maintenance

Performing maintenance on production equipment, [redacted]

4.0 Requirements

The Company promotes employee safety and equipment efficiency for its production equipment. To accomplish this, the following requirements apply:

1. [redacted]
2. [redacted]
   a. [redacted]
   b. [redacted]
   c. [redacted]
   d. [redacted]
   e. [redacted]
   f. [redacted]
   g. [redacted]
   h. [redacted]

   [redacted]
3. [redacted]

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

Appendix A: Production Equipment Assessment Form

PRODUCTION EQUIPMENT ASSESSMENT

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

PPP&M WORK INSTRUCTIONS

Program Name:		Contract #:		Date:	
P/N:		Prepared By:		Approval:	

(Delete demo content in template prior to application)

[redacted]

Vibration Sensor onto the handling

[redacted]

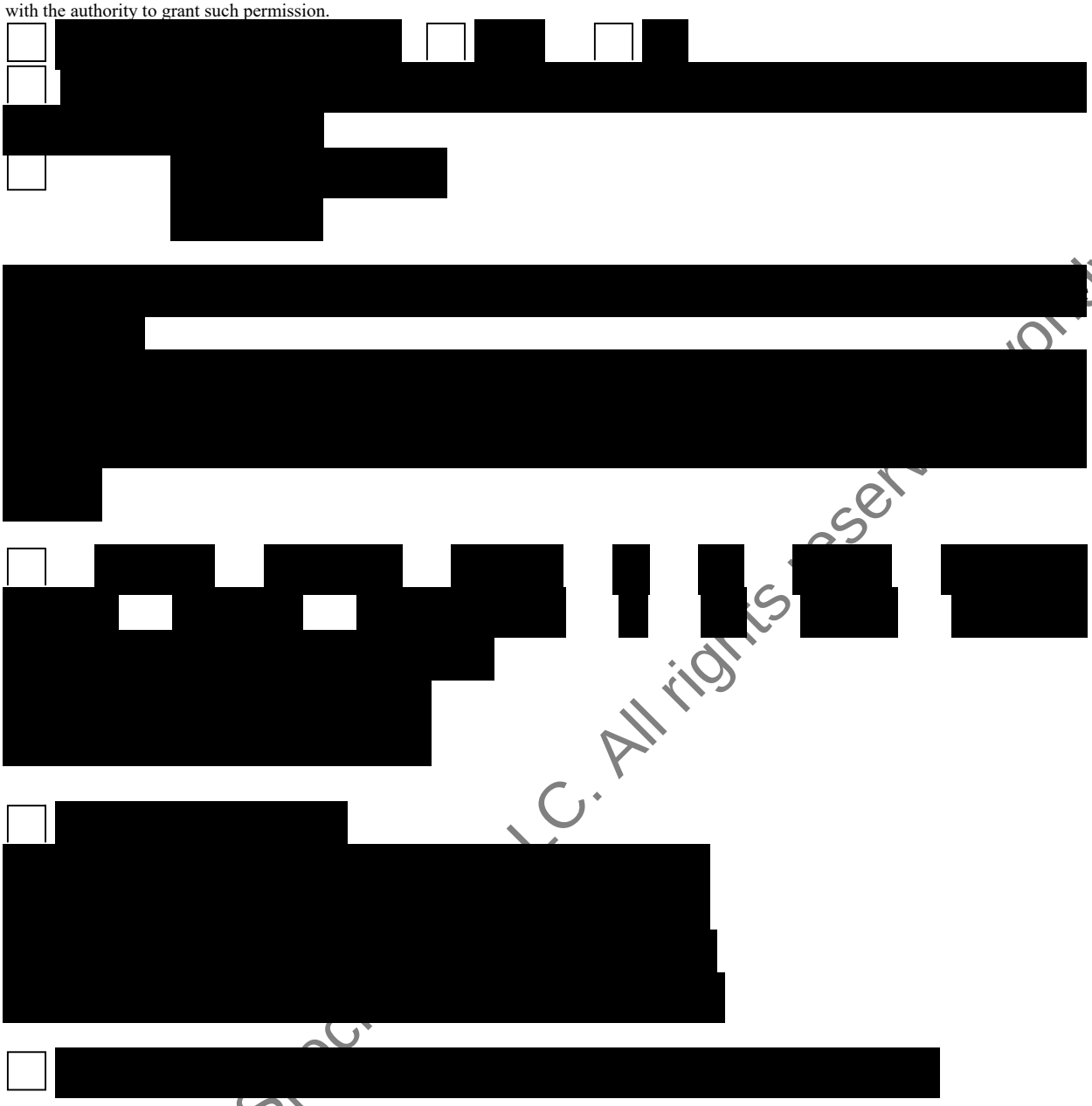
NOTE: All work on this order is [redacted]

[redacted]

NOTE: All work on this order is subject to inspection and test by the Customer at any time and place.
The Customer shall be notified 48 hours in advance of the time that articles or materials are ready for inspection or test.

[redacted]

NOTE: All work on this order is subject to inspection and test by the Customer at any time and place.
The Customer shall be notified 48 hours in advance of the time that articles or materials are ready for inspection or test.



NOTE: All work on this order is subject to inspection and test by the Customer at any time and place.
The Customer shall be notified 48 hours in advance of the time that articles or materials are ready for inspection or test.

Preservation Procedure

Mo/Yr

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

Used On	Contract#:		**Your Company Name**					
Prepared By:		Date						
Your Dept:		Date						
Your Dept:		Date	**PRESERVATION PROCEDURE**					
Your Dept:		Date						
Your Dept:		Date	Size:	**A**	API#:		Form Rev: Orig	1 of 4

Your Company Logo

1.0 Scope

The Responsible Authority specifies instructions for the proper handling, preservation, storage, packaging and shipping of supplies to protect quality and prevent damage, loss, deterioration, degradation or substitution of products. The instructions must [redacted] In the event that preservation criteria are not specified in the contract, [redacted]

The following routines apply:

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

PPP&M instructions must also include [redacted]

2.0 Shipping and Customer Receiving

Instructions are contained herein for the shipping carrier and the Customer for preventing damage to products.

3.0 REQUIREMENTS

3.1 Product Warnings

[redacted]

PRODUCT PERFORMANCE IS DEGRADED WHEN [redacted]

3.2 General

Every effort must be made to [redacted] Products must not be [redacted] Products must be [redacted] At no time [redacted]

3.3 Visual Examination

Each shipping container must be [redacted] Any observation must be [redacted]

3.4 Transportation

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

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

3.5 Handling

Products and shipping container instruments must not [redacted] Products must [redacted]
Products and shipping containers must [redacted]

3.6 Re-packaging for Re-Shipment

The shipping container is designed to [redacted]

3.7 Environmental Sensors

Shipping containers may [redacted]

3.8 Shipping Container Disposition

The shipping container and all internal components should [redacted]

3.9 Preservation, Packaging, Packing, and Marking Instructions

A copy of this procedure and a copy of the preservation, packaging, packing and marking (PPP&M) instruction must [redacted]

Re-shipment of the product should [redacted]

RISK ANALYSIS

Origination Date: (month year)

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

Abstract:
This document describes methods to [redacted] 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 [redacted]

2.0 Objective

The identification of risks is [redacted]

Risks associated with

A risk can be defined as

A risk priority number (RPN) is

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 [redacted] Once the management team has [redacted]

The team [redacted] using the worksheet in Figure 1 or Figure 2; for example, [redacted]

4.3 Ranking Potential Risks

The management team [redacted] The functional areas shown below are common to all business operations but any area can be substituted.

4.4 Calculating the Risk Priority Number

The risk priority number (RPN) [redacted] is recorded in Figure 1 or Figure 2.

The team should [redacted] within the established risk categories; such as, [redacted] see Figure 1 and Figure 2 examples.

Typical Risk Categories and Potential Risks:

Risk Categories

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

A guidance list of potential risks for functional areas is provided in the following tables. The management team should [redacted]

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

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

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

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

FUNCTIONAL AREA: [redacted]		
BUILDING & OPERATIONS RISKS	SECURITY RISKS	SPILL & RELEASE RISKS
[redacted]		[redacted]

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

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

FUNCTIONAL AREA: [redacted]		
[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 [redacted] according to the following criteria:

The management team

4.6 Example Functional Area:

4.6.1 – defined as the frequency of occurrence

Another point of view for this evaluation would be

1	
2	
3	
4	
5	

4.6.2 – defined as the

1	
2	
3	
4	
5	

4.6.3 – defined as the

1	
2	
3	

4	
5	

4.6.4 – defined as the This should be evaluated as The best approach is to

1	
2	
3	
4	
5	

4.6.5 – defined as

Examples include:

[redacted]	
1	[redacted]
2	[redacted]
3	[redacted]
4	[redacted]
5	[redacted]

4.6.6 [redacted] – defined as the [redacted] for instance, [redacted] Other considerations would be [redacted]

[redacted]	
1	[redacted]
2	[redacted]
3	[redacted]
4	[redacted]
5	[redacted]

4.6.7 [redacted] – defined as [redacted]

[redacted]	
1	[redacted]
2	[redacted]
3	[redacted]
4	[redacted]
5	[redacted]

Using the above sample functional area [redacted] the management team [redacted] using the worksheets in Figure 1 or Figure 2.

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

Typical Functional Areas to Consider for Potential Risks

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Your Logo

Your Company Name

Traceability Work Instruction

Origination Date: (your month/year)

Document Identifier:	Traceability Work Instruction
Date:	(Your month/year)
Project:	(Your Project Name)
Document Status:	Released

Abstract:
This document describes traceability requirements for (your product/component name).

REVISION LOG

Issue	Date	Comment	Author
Orig		Initial Release	

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

TABLE OF CONTENTS

1.0 PURPOSE

To ensure that correct materials are installed in deliverable goods, traceability must [redacted]

The material certification report must [redacted]

Traceable production process records must [redacted]

2.0 REFERENCES

Contract/Purchase Order
Material Specification **TBD**

3.0 EQUIPMENT

TBD

4.0 MATERIALS

TBD

5.0 REQUIREMENTS

5.1 Material Traceability

Material traceability [redacted]

Where batch traceability [redacted]

Traceability marking [redacted]

Traceability must [redacted]

5.1.1 Purchase orders for raw material must [redacted]

Records of identification and traceability shall be retained and maintained according to the ***QMS-01 Control of Documented Information Procedure***.

5.2 Receiving Inspection

5.2.1 Products and services produced by Suppliers for incorporation in deliverable goods are [redacted]

5.2.2 Receiving Inspection includes as a minimum:

- [redacted]

5.3 Discrepancy Reporting

Nonconforming products and components must be identified and processed according to the ***QMS-14 Control of Nonconformities Procedure***. Nonconforming items include [redacted]

The Company reports the receipt of any nonconforming items to [redacted]

5.4 Material Handling

All raw materials must be marked with a unique traceability number.

5.4.1 Stored raw materials of different alloys and material conditions requiring traceability must [redacted]

5.4.2 When traceability markings will be removed by a production process, the marking must [redacted]

[redacted] The traceability marking must [redacted]

5.4.3 Maintenance of traceability must [redacted]

5.5 Special Emphasis Material Certificate of Compliance

The Company prepares and submits a certificate of compliance certifying that [redacted]

The certificate of compliance shows traceability to the marking applied on each individual item and contains the following information:

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

6.0 WORKMANSHIP

A lot of raw material must be produced as [redacted]

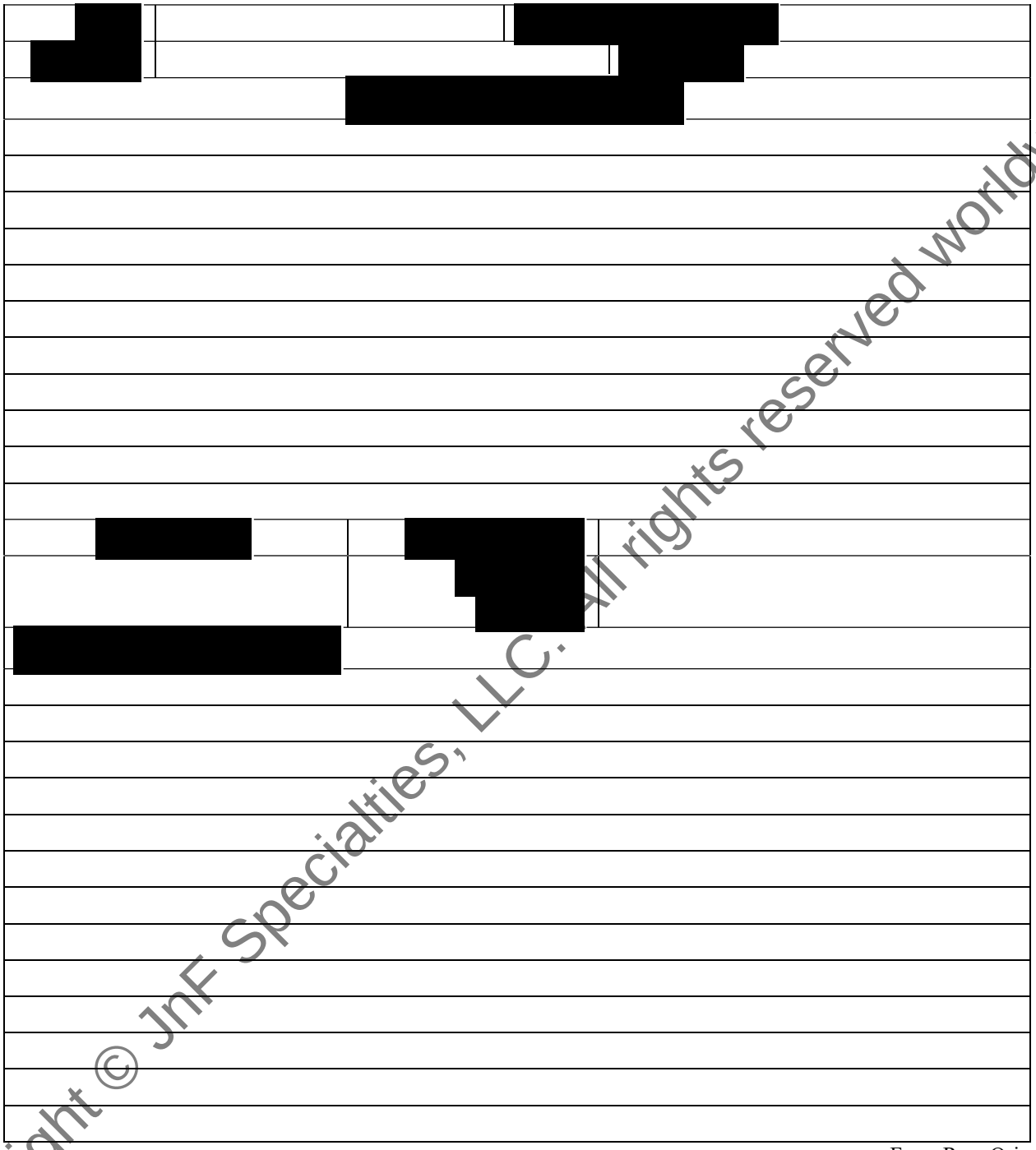
A traceability code or number providing traceability must [redacted]

Traceability must [redacted]

The process of establishing traceability must [redacted]

Traceability must [redacted]

ACTION ITEM



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**	API#:		Form Rev: Orig	1 of 3

(your logo)

Procedure:

Supplier evaluation:

[redacted]

A new Supplier is submitted to management for review. Management [redacted] according to the ***QMS-04 Management Process Procedure***.

Supplier capability/approval is determined by:

[redacted]

Complete the ***Supplier Evaluation Form***.

Acceptable Practice:

[redacted]

Suppliers that provide non-critical materials [redacted] or provide materials identified as [redacted] are required to be listed in this Approved Supplier List.

The Purchasing Group may [redacted]

Glossary:

*Non-deliverable materials: Supplies that **are not used** for delivery to a Customer (office supplies, building maintenance supplies, etc)

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]

BULLETIN

NUMBER: [redacted]

PAGE 2 TEXT BLOCK: Insert page 2 text here

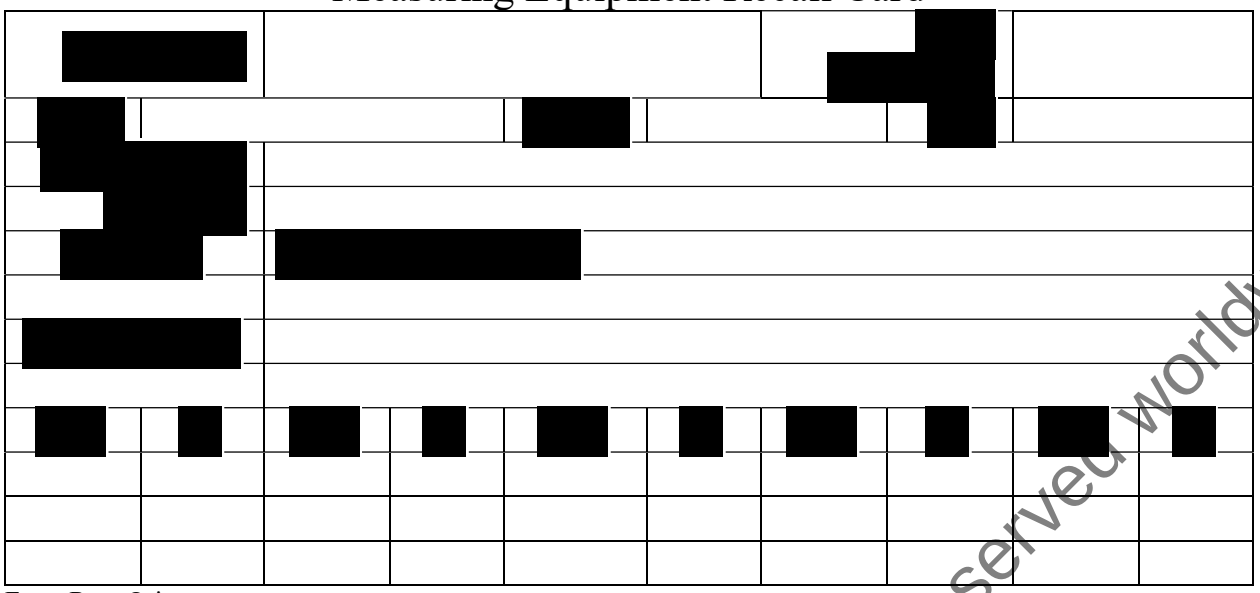
CALCULATED RISK RELEASE

[redacted]

Form Rev: Orig

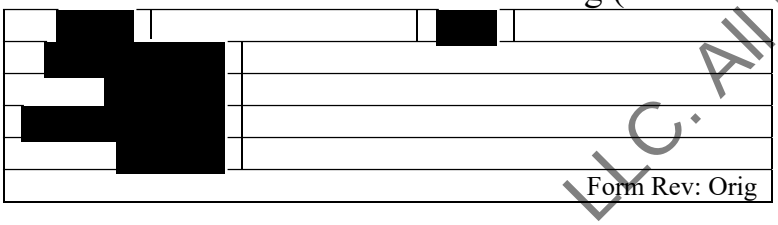
(your logo)

Measuring Equipment Recall Card



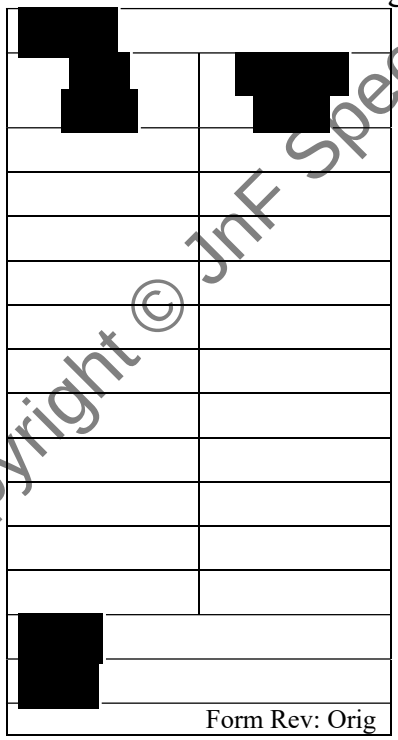
Form Rev: Orig

Instrument and Case Identification Tag (shrink to fit)



Form Rev: Orig

Instrument Deviation Tag (shrink to fit)



Form Rev: Orig

Measuring and Test Equipment Calibration Report

Remarks:

Form Rev: Orig

CALIBRATION IMPACT REPORT

[redacted]

[redacted]

[redacted]

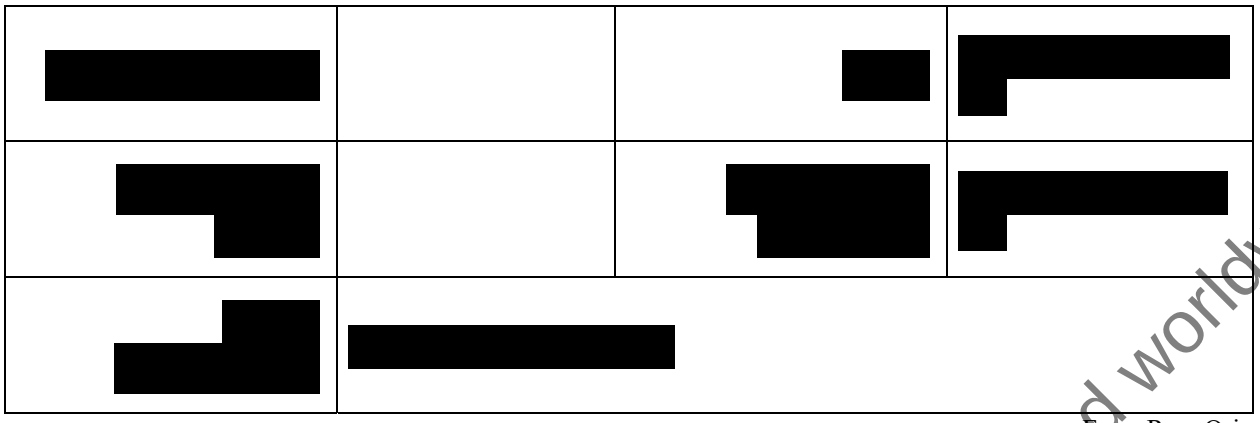
[redacted]

Form Rev: Orig

Instruction Rev: Orig	Calibration Instruction Sheet	Form Rev: Orig [redacted]
[redacted]		[redacted]
		[redacted]
[redacted]		[redacted]

[redacted]	[redacted]		[redacted]

Inherently Stable Measurement Equipment Log



Form Rev: Orig

MEASURING EQUIPMENT RECALL LOG

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

Form Rev: Orig

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 [redacted]		**(Your) Assembly**
1	QC	[redacted]
2	QC	
3	QC	
4	QC	
	IF	THEN
4.1	[redacted]	
4.1.1		
4.2		
Op#	STEP	ACTION
Steps may be performed before, during or after [redacted]		**(Your) Assembly**
5	QC	[redacted]
6	QC	
7	QC	
8	QC	
	IF	THEN
8.1	[redacted]	
8.2		

Configuration Definition

(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]

Form Rev: Orig

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

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

A/D = As Designed; A/B = As Built; or use A/T = As Tested

SUMMARY OF DATA LIST REVISIONS

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

Form Rev: Orig

CONFIGURATION DEFINITION DATA PACKAGE

(mo/yr)

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

Used On	Contract#:		**Your Co Name**					
Prepared By:								
RA:								
Quality:			**DATA PACKAGE**					
			Your Number					
			Size:	**A**	API#:		Form Rev: Orig	1 of 17

Your Co Logo

[redacted]	

CONFIGURATION DEFINITION DATA.

PURPOSE

This configuration definition data package is [redacted]

Customer PO No.:

ATTACHED

CONFIGURATION DEFINITION DATA.

The following items, as applicable, [redacted]

[redacted]

NOTE:
Data derived from measurements are not proprietary if [redacted]
Records are not proprietary if [redacted]
Records are proprietary if [redacted]

[redacted]

[redacted]	[redacted]	[redacted]

[redacted]

[redacted]	[redacted]	[redacted]

[redacted]

[redacted]	[redacted]	[redacted]

[redacted]

[redacted]	[redacted]

Expand these lists as required…

[redacted]

[redacted]

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

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

CONFIGURATION DEFINITION DATA.

[redacted]

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

CONFIGURATION DEFINITION DATA.

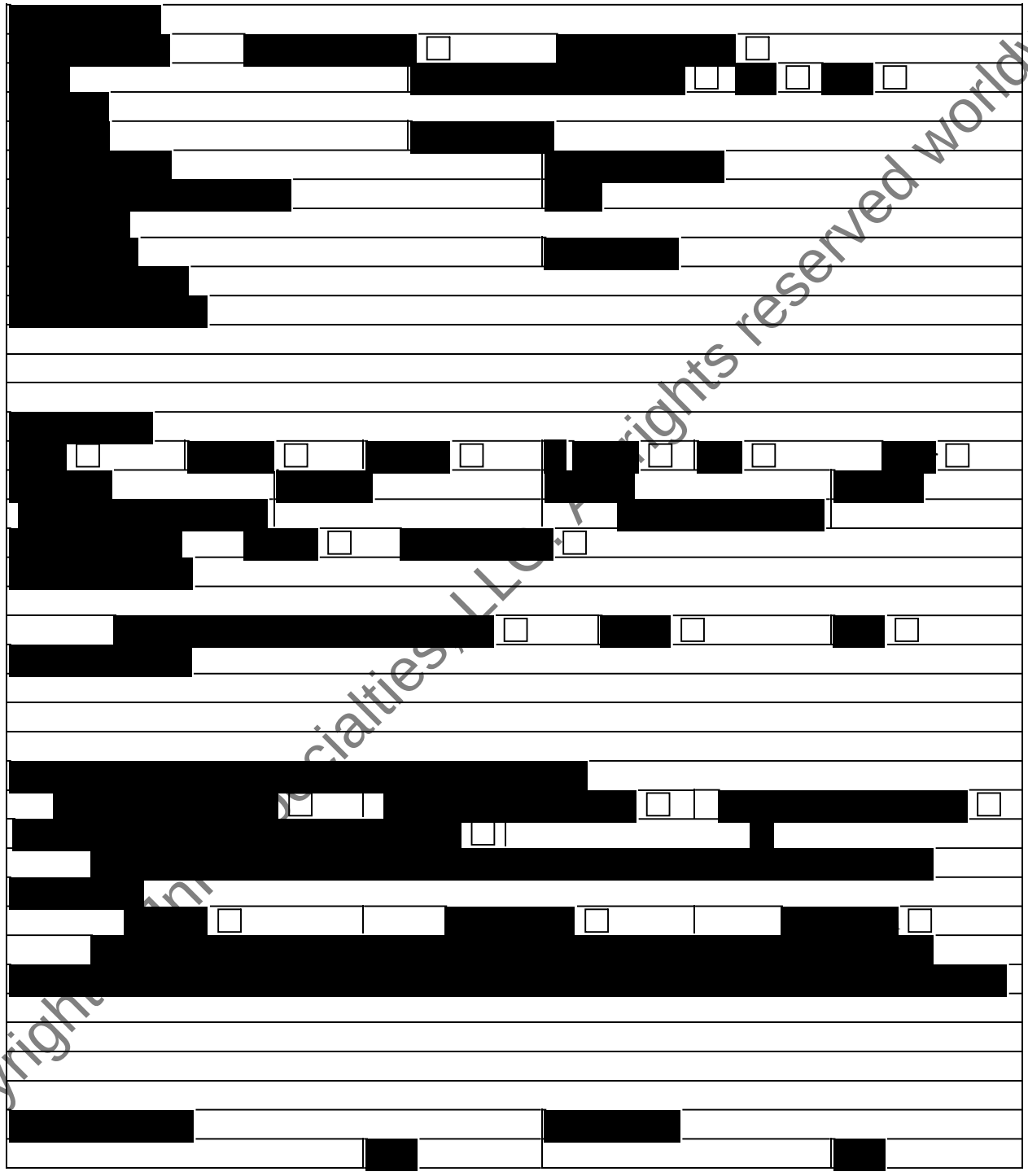
[redacted]

[redacted]

[redacted]

[redacted]

Contract Review



Form Rev: Orig

Compliance Matrix-1

(Program Name - Contract - Revision)

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

Form Rev: Orig

Compliance Matrix-2

(Program Name - Contract - Revision)

[redacted]	[redacted]	[redacted]

Form Rev: Orig

Work Breakdown Structure

Program Name – Contract - Revision		
[redacted]	[redacted]	[redacted]
[redacted]		
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☐		

Form Rev: Orig

Check-off each item that is completed

Your Logo	**INVESTIGATION AND CORRECTIVE ACTION REQUEST**

ICAR Responsible Supplier: _____

[redacted]

1. [redacted]
2. [redacted]
3. [redacted]
   a) [redacted]
   b) [redacted]
   c) [redacted]
4. [redacted]
5. [redacted]
6. [redacted]
7. [redacted]
8. [redacted]
9. [redacted]

(Your Logo)

CORRECTIVE ACTION REQUEST

API#:

Form Rev: Orig

This document expires 1 day after printing unless marked "Released". **Date Printed:**

Your Logo

Customer Perception Survey

Date

(Your Company Name) has made a commitment to our Customers to comply with [redacted]

Thank you for your support,

_____
(Your Signature)
(Your Name)

(Your Company Name)
CUSTOMER PERCEPTION SURVEY

1)	Score	
a)		
b)		
c)		
d)		
e)		
f)		
g)		
h)		
i)		
2)	Score	
a)		
b)		
c)		
d)		
e)		
f)		
g)		
h)		
i)		
3)	Score	
a)		
b)		
c)		
d)		
e)		
4)	Score	
a)		
b)		
c)		
Comments:		

Thanks again for your support.
Please Fax the completed survey to: (Your Phone)

Form Rev: Orig

CUSTOMER SATISFACTION SURVEY (Your Logo)

Date: (input date)

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

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

Greetings,

We are asking you to [redacted] Using a scale from 1 to 10 [redacted]

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

Thank you for participating in our survey.
Please fax your response to: (Your Phone)

Form Rev: Orig

DAILY RECEIVING RECORD

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

Form Rev: Orig

(Your Logo)

DESIGN REVIEW

Form Rev: Orig

Your Logo

Dimensional Analysis Record

Application		Revisions			
Next Assembly	Used On	Rev	Description	Date	Approved

The information contained in this drawing is proprietary and [redacted]

[redacted]

New Drawing EO Number:		
Approvals	Signature	Date
[redacted]		
[redacted]		
[redacted]		

[redacted]

[redacted]

Size	API Number	Sheet	Dwg Rev
A	Your#	1 of 2	TBD

This document expires [redacted] after printing unless marked "Released". **Date Printed:** [redacted]

Form Rev: Orig

Application		Revisions			
Next Assembly	Used On	Rev	Description	Date	Approved

The information contained in this drawing is proprietary and [redacted]				
NAME				
[redacted]	Size A	API Number	Sheet 2 of 2	Dwg Rev TBD
This document expires [redacted] after printing unless marked "Released". **Date Printed:** [redacted]				Form Rev: Orig

EO NUMBER:	DATE:	[redacted]

[redacted]

Form Rev: Orig

Your Logo

EO NUMBER: 101

[redacted]

REASON FOR CHANGE:

Create and release new quality management system based upon API Specification Q1, [redacted]

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 ISO 9001:2015:**

Calibration Procedure, QMS-15
Configuration Management Procedure, QMS-02
Control of Documented Information Procedure, QMS-01
Control of Nonconformities Procedure, QMS-14
Corrective Action Procedure, QMS-13
Definitions and Abbreviations Procedure, QMS-16
Design and Development Procedure, QMS-17
Internal Auditing Procedure, QMS-12
Maintenance Procedure
Management Process Procedure, QMS-04
Production Procedure, QMS-10
Proposal Development and Contract Review Procedure, QMS-07
Purchasing Procedure, QMS-08
Quality Policies Handbook, QMS-00
Receiving Procedure, QMS-09
Responsibilities & Authorities Procedure, QMS-05
Risk Mitigation and Planning Procedure QMS-03
Shipping Procedure, QMS-11
Training Procedure, QMS-06

Create and release the following list of QMS support documents:

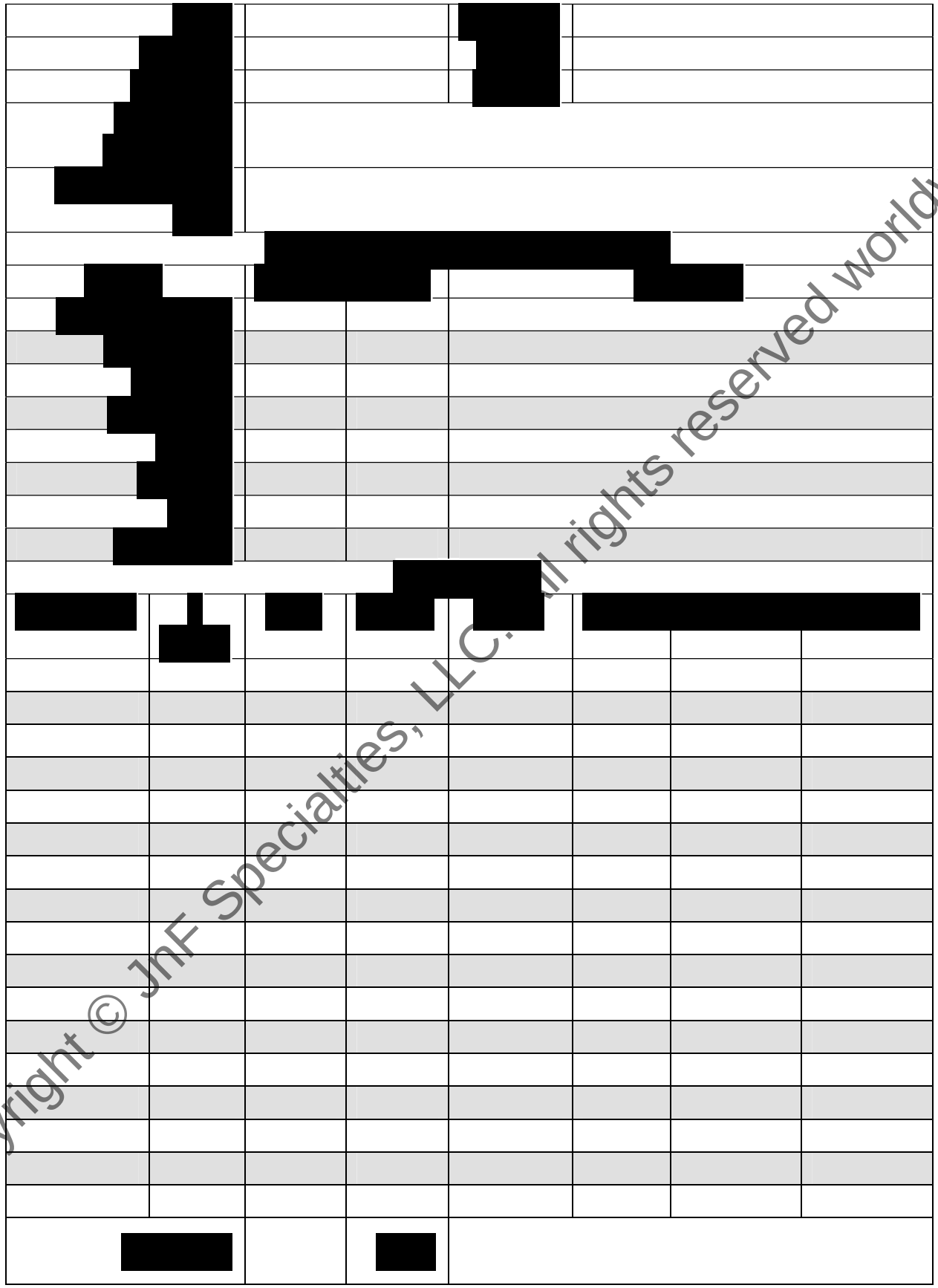
API Spec Q1 Assessment Checklist
Internal Auditor Training for ISO 9001
QMS Introduction for ISO 9001

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. Upload revised forms onto the applicable folder on a personal or Company PC.

Risk Assessment is [redacted]

[redacted]

First Piece Inspection Report



Form Rev: Orig

(Your Logo)

Your Address
Your Phone – Fax – Email

Your Company Name

Information Request

Form Rev: Orig

INSPECTION RECORD

[redacted]

Form Rev: Orig

(Your Logo)

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

INSPECTION REPORT

(Your Company Name)

Page of

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Remarks:

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(Your Logo)

INSPECTION SUMMARY

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INSPECTOR STAMP LOG

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Form Rev: Orig

(Your Logo)

PLAN - STEP ONE: Audit Preparation & Planning

Process to Audit (Audit Scope):	
Audit Date(s):	Lead Auditor:
Audit #:	Other Auditor(s) on Team:
Applicable Clauses of the API Spec Q1 Standard:	
Applicable Sections of the Quality Handbook:	
Revision of Quality Handbook:	

[redacted]	
[redacted]	[redacted]

DO - STEP TWO: Compare Documentation vs. Requirements

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[redacted]		
[redacted]		

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CHECK - STEP THREE: Compare Actual Practice vs. Requirements

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ACT - STEP FOUR: Verify the Effectiveness of the Process

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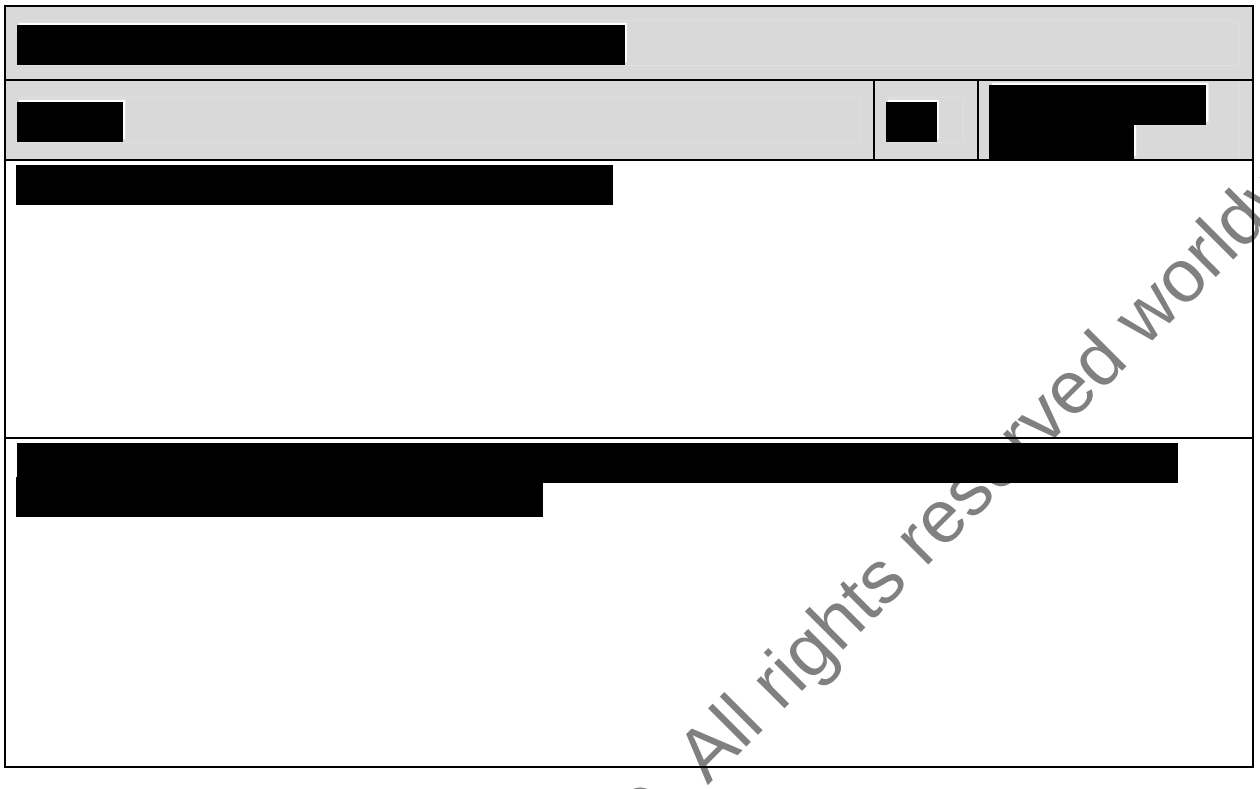
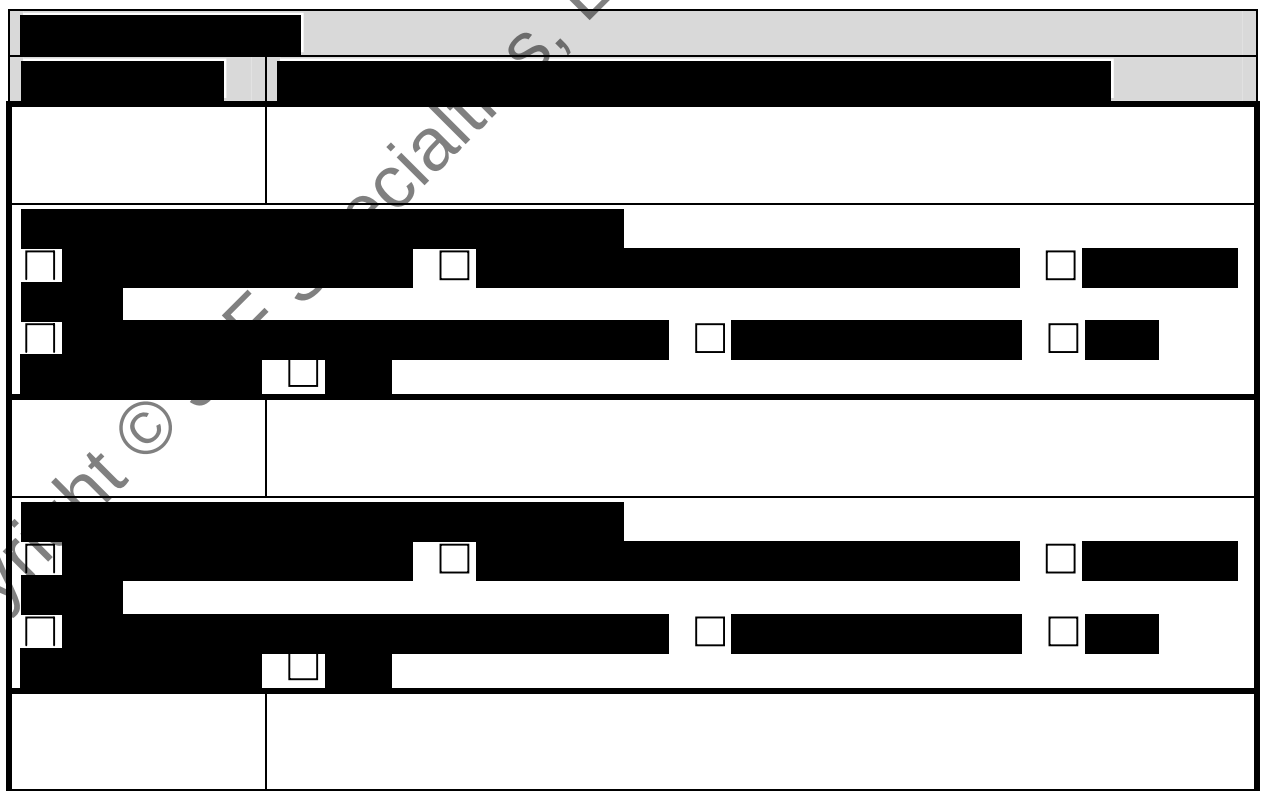
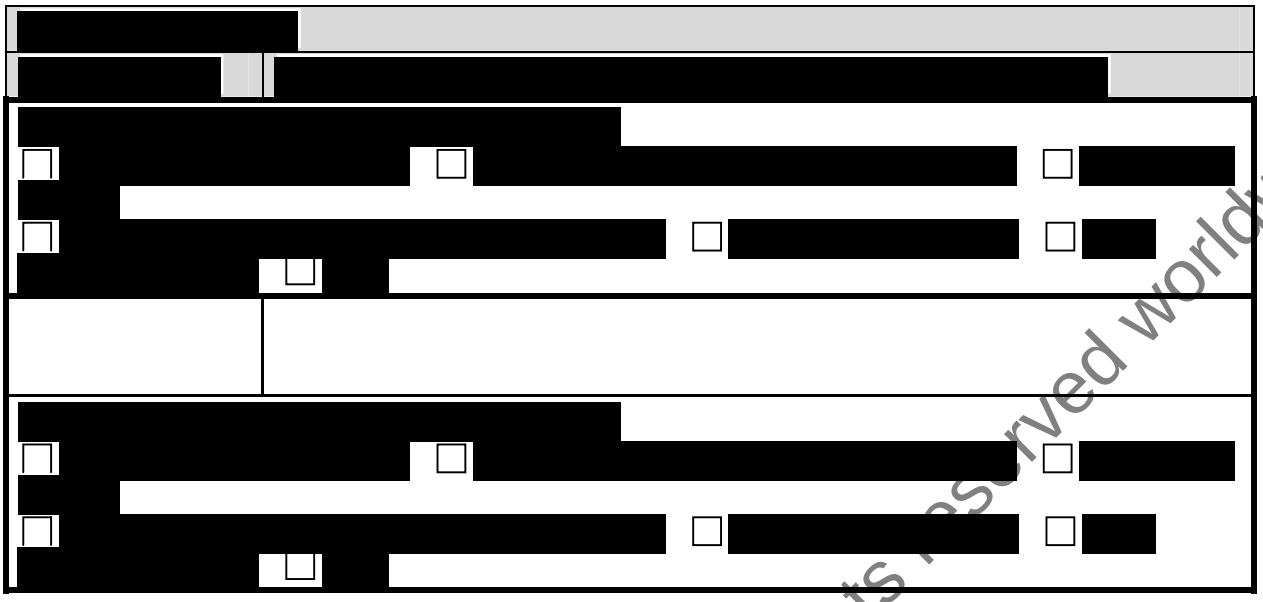


STEP FIVE: Summarize Your Findings for Nonconformity System





STEP SIX: Review Audit Report and Submit

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

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

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Your Company Name

INTERNAL AUDIT SCHEDULE

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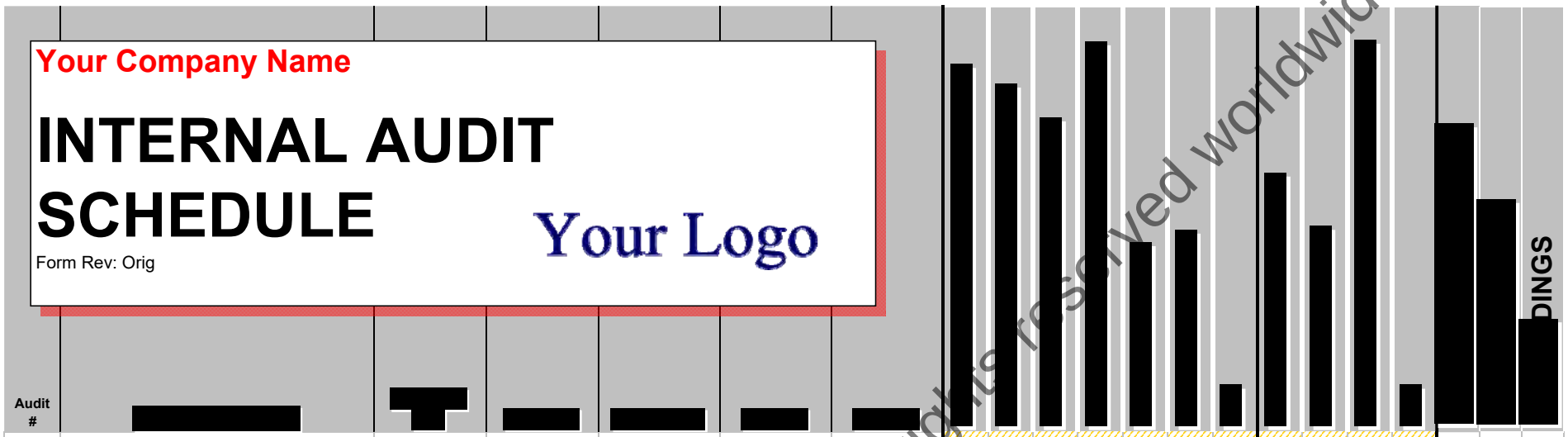

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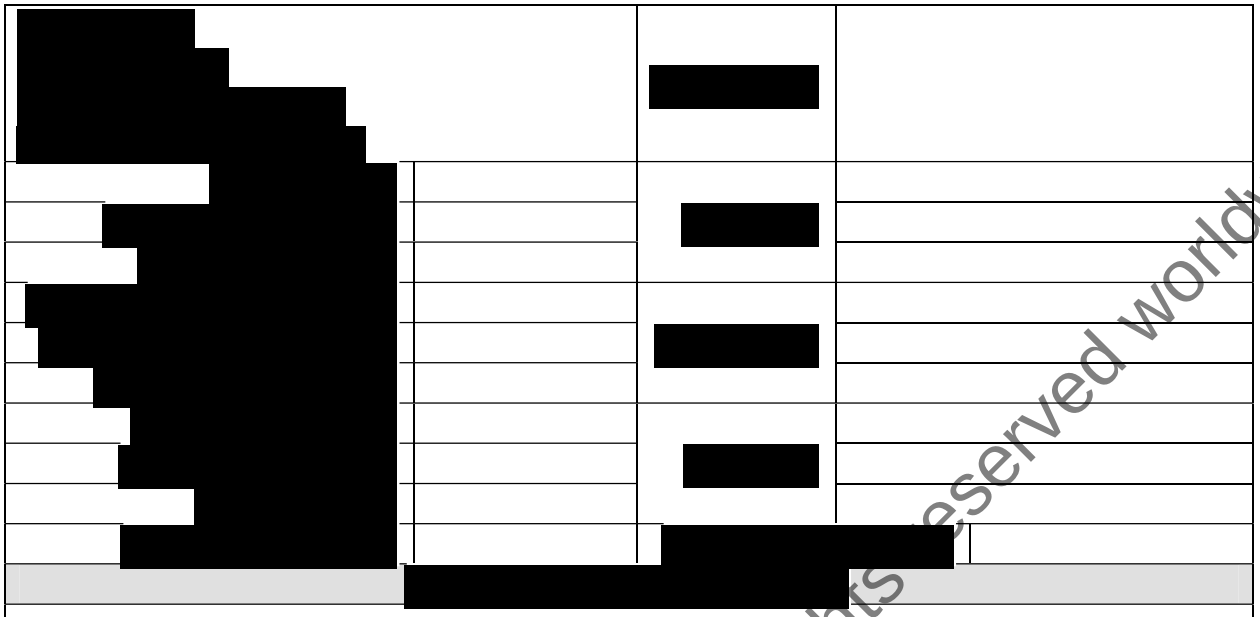
JOB SHEET

Job #: Rev:



Form Rev: Orig

Lab Request

[redacted]

Form Rev: Orig

MAINTENANCE WORK ORDER / LOG

Work Order / Log #: Rev:

Form Rev: Orig

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 used as [redacted] At all stages, management must [redacted]

Date of Review: **Recorded by:**

In Attendance:

NAME	TITLE

Absent:

NAME	TITLE

ITEM 1: [redacted]

☐ [redacted]

☐ [redacted]

ITEM 2: [redacted]

ITEM 3: [redacted]

ITEM 4: [redacted]

[redacted]

[redacted]

[redacted]

ITEM 5: [redacted]

ITEM 6: [redacted]

ITEM 7: [redacted]

Process	Quality Objective	Data Metric	Current Standing	Goal
[redacted]				

ITEM 8: [redacted]

ITEM 9: [redacted]

ITEM 10: [redacted]

ITEM 11. [redacted]

ITEM 12. [redacted]

ITEM 13. [redacted]

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ITEM 14. [redacted]

Action Item	Assigned to:	Required Response Date

ITEM 15. [redacted]

(Your Co Name) MASTER DOCUMENT LIST (MDL)	[redacted]		[redacted]	[redacted]
[redacted]		[redacted]		
[redacted]		[redacted]		
[redacted]		[redacted]		

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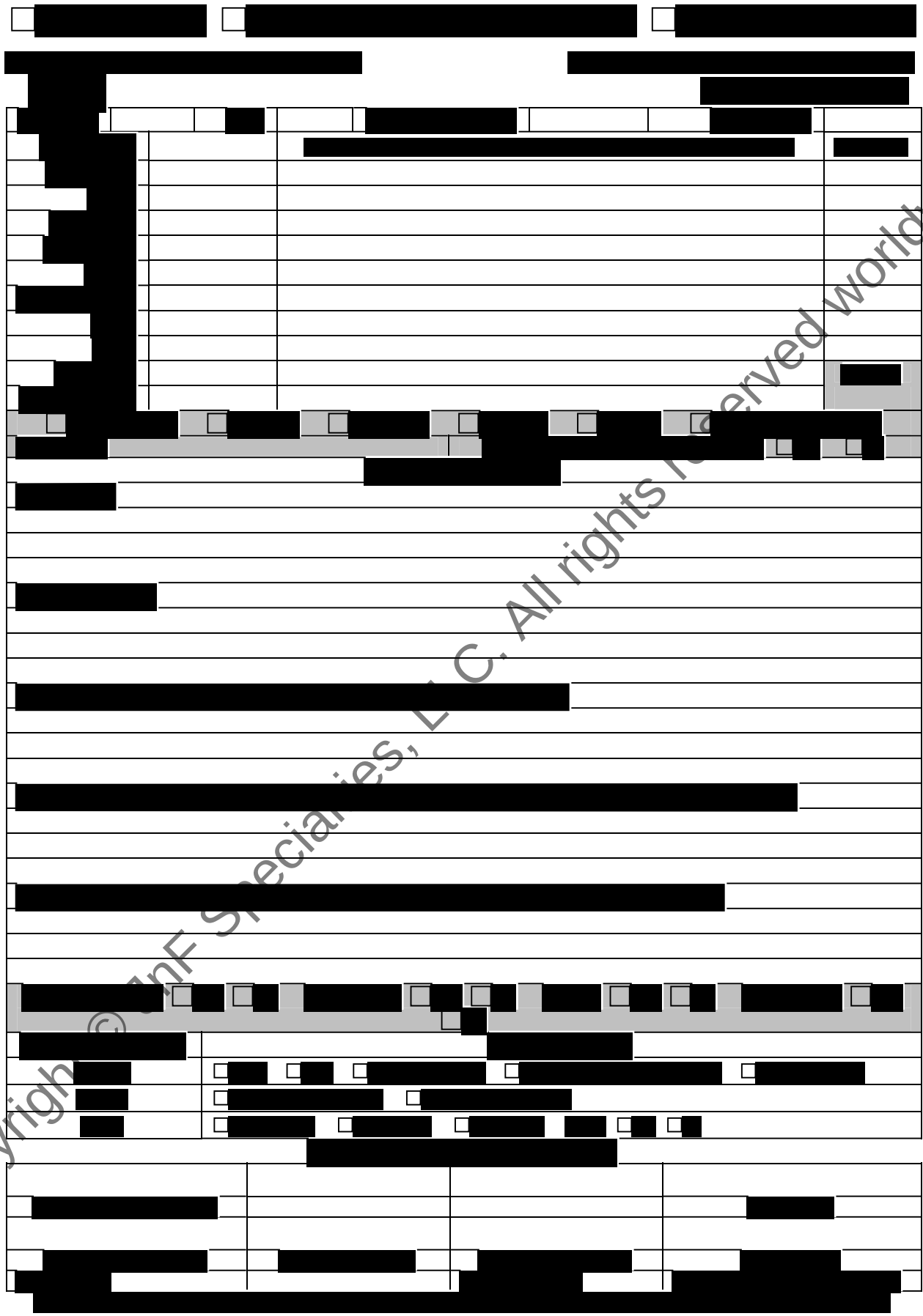
Form Rev: Orig

MATERIAL REPORT



(Your Logo) Use other side for additional information **Shaded Area for Administrative Use Only** Form Rev: Orig

PACKING SLIP

[redacted]

Production Control Document

(mo/yr)

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

Used On	Contract#:		**Your Company Name**					
Prepared By:								
Your Dept:								
Your Dept:			**PRODUCTION CONTROL DOCUMENT**					
Your Dept:			PCD-TBD					
Your Dept:			Size:	**A**	API#:		Form Rev: Orig	1 of 1

TABLE OF CONTENTS (content is simulated)

Instructions for producing PCD (remove these instructions when complete):

Electronic copy: [redacted]

Paper copy: [redacted]

PROPRIETARY STATEMENT

This Production Control Document is proprietary and may not be reproduced for any reason in whole or in part without the expressed written permission from an Officer of the Company with the authority to grant such permission.

CONTROLLED CHANGES

[redacted]

UNCONTROLLED CHANGES

[redacted] but not limited to:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]

QUALITY ASSURANCE

[redacted]

The Production Control Document includes:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]
e) [redacted]

Additional documents that support the work-product of the PCD are prepared as required, such as, but not limited to:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]
e) [redacted]
f) [redacted]

g) [redacted]
h)
i)
j)
k)
l)
m)

Documents that are referenced in the PCD [redacted]

WORKMANSHIP

[redacted]

Your Logo	Your Company Name	Production Equipment Assessment Form
API#:		Form Rev: Orig

PRODUCTION EQUIPMENT ASSESSMENT

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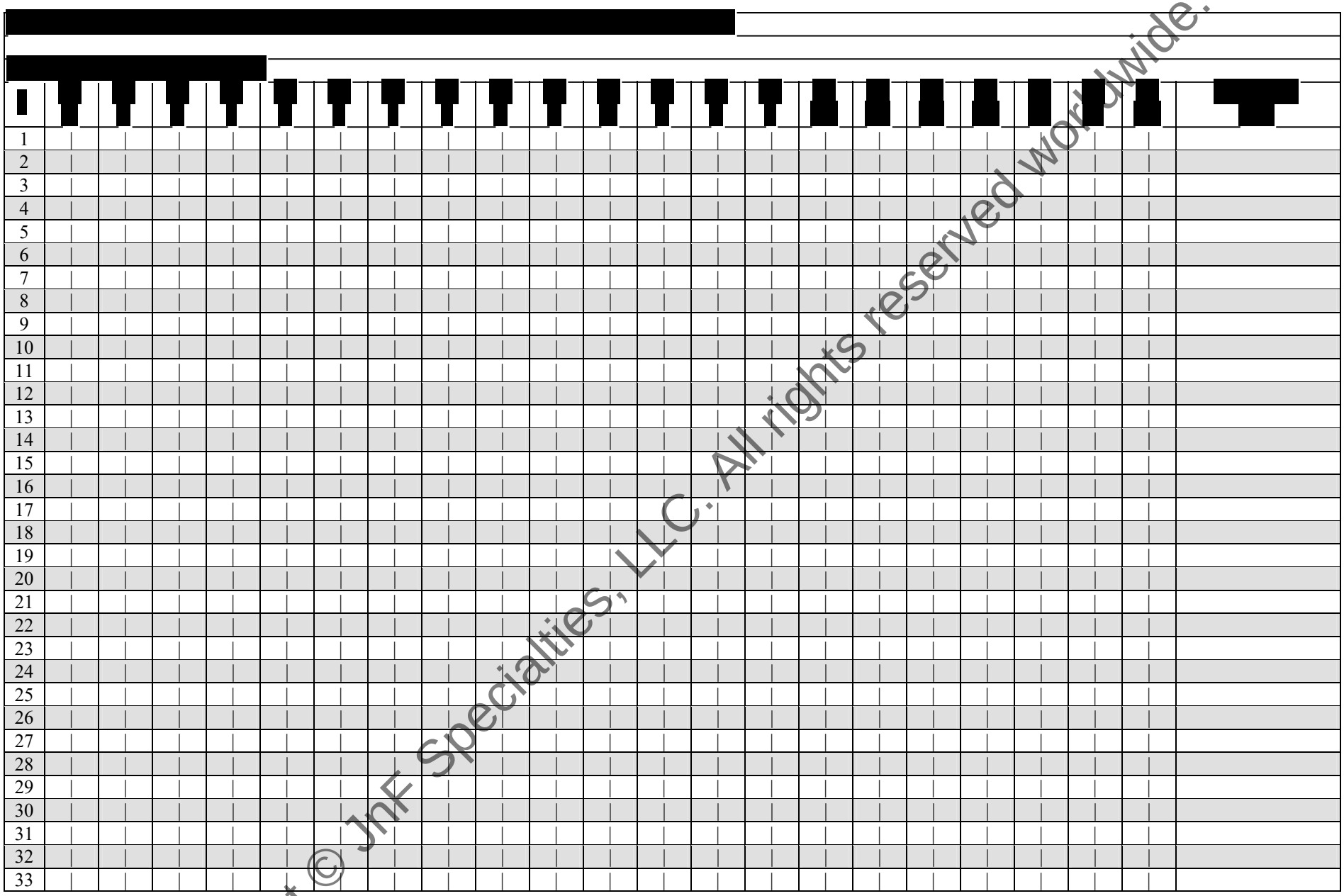

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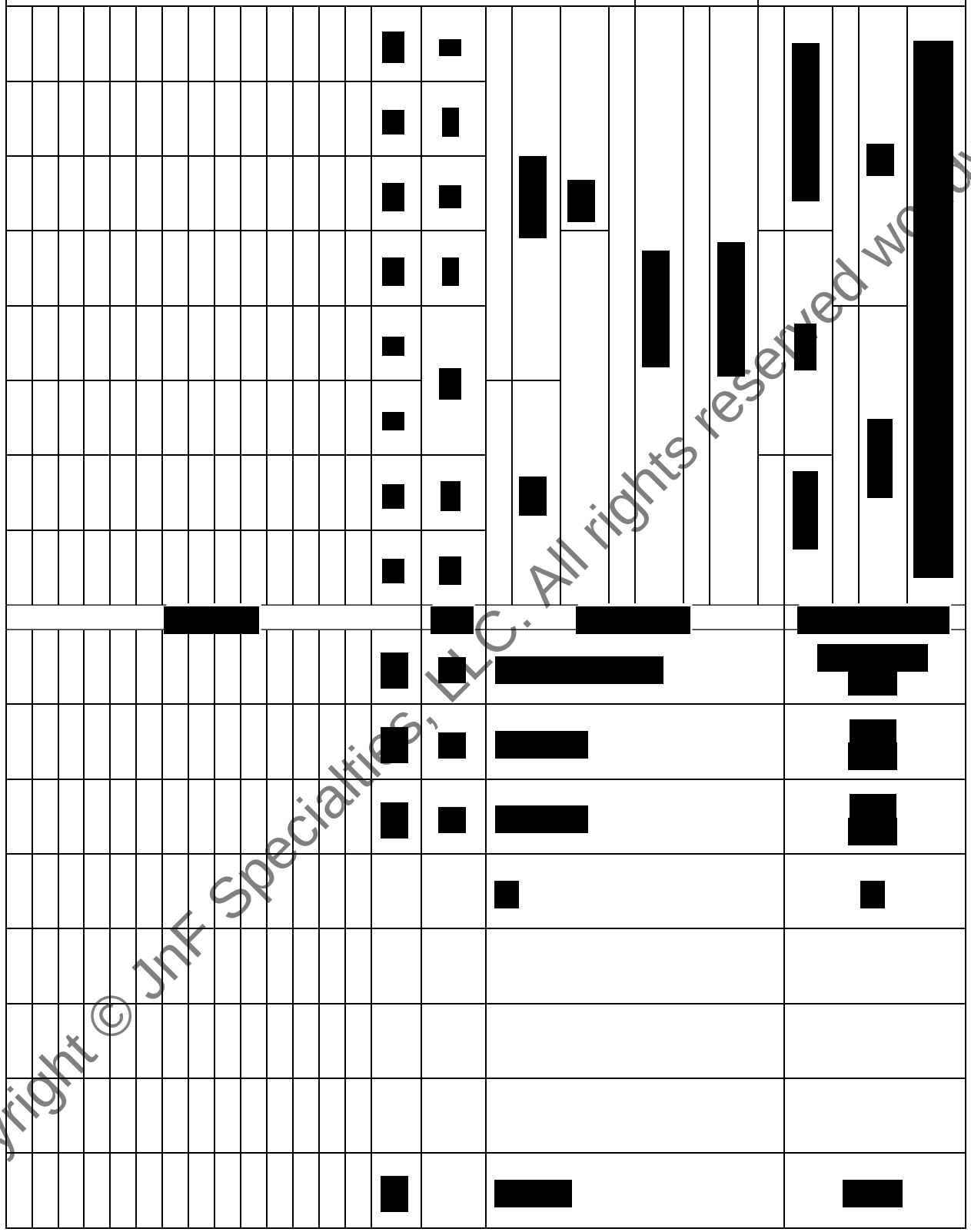

Form Rev: Orig

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Sheet ☐ of ☐

Product Release Record

PRR#

Your Logo

[redacted]

Form Rev: Orig

Property Certification from Supplier

(Your Logo)

Date:

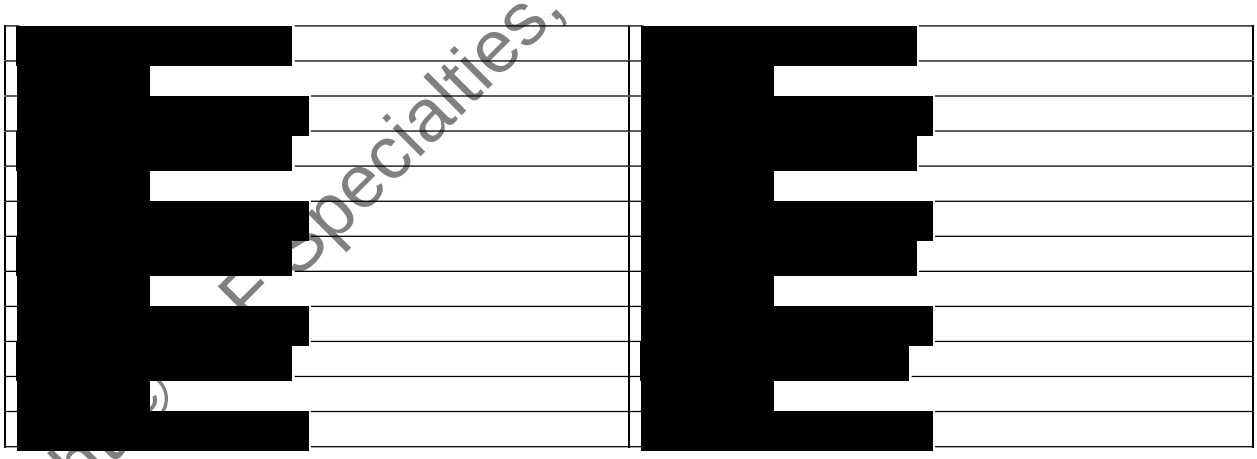
Attention:
Company:
Address:
City, State:
Zip Code:

Subject: Customer/Government Property located at your facility

Dear (insert your appropriate name)

Our records [redacted] If you have knowledge of other property [redacted] requests the return of the property by _____ to enable [redacted]

If we can assist you or if you have any questions, please do not hesitate to contact:
Name: _____ Phone Number:_____



Supplier/Subcontractor Certification:

[redacted]

Property Management Log

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Property Record

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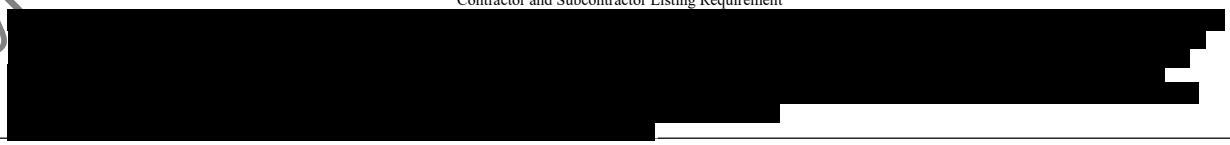
PURCHASE ORDER

(Your Company Name)

Terms and Conditions of Purchase

Contractor and Subcontractor Listing Requirement



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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 Company Name)
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Form Rev: Orig

GOOD TAG	(Your Company Name)
[redacted]	

Form Rev: Orig

WITHHOLD TAG		(Your Company Name)	
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[redacted]		[redacted]	
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Form Rev: Orig

BAD TAG		(Your Company Name)	
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Form Rev: Orig

(Your Logo)	Receiving Inspection Instructions	Form Rev: Orig Page 1 of 1

Oper	Qty	Description of Inspection Operation	Gage	Comment
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Drawing No:					**RECEIVING INSPECTION RECORD**					
Item Name:					(Your Company Name)					
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Receiving Log

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Form Rev: Orig

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REQUEST FOR CHANGE

Form Rev: Orig

(Your Logo)

REQUEST FOR SUPPORT

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

SUBCONTRACTOR: _____ DATE RECEIVED: _____

RFS#: SHEET _____ OF _____

Your Logo **Shaded Area for Administrative Use** Form Rev: Orig

Request for Support (RFS) Log

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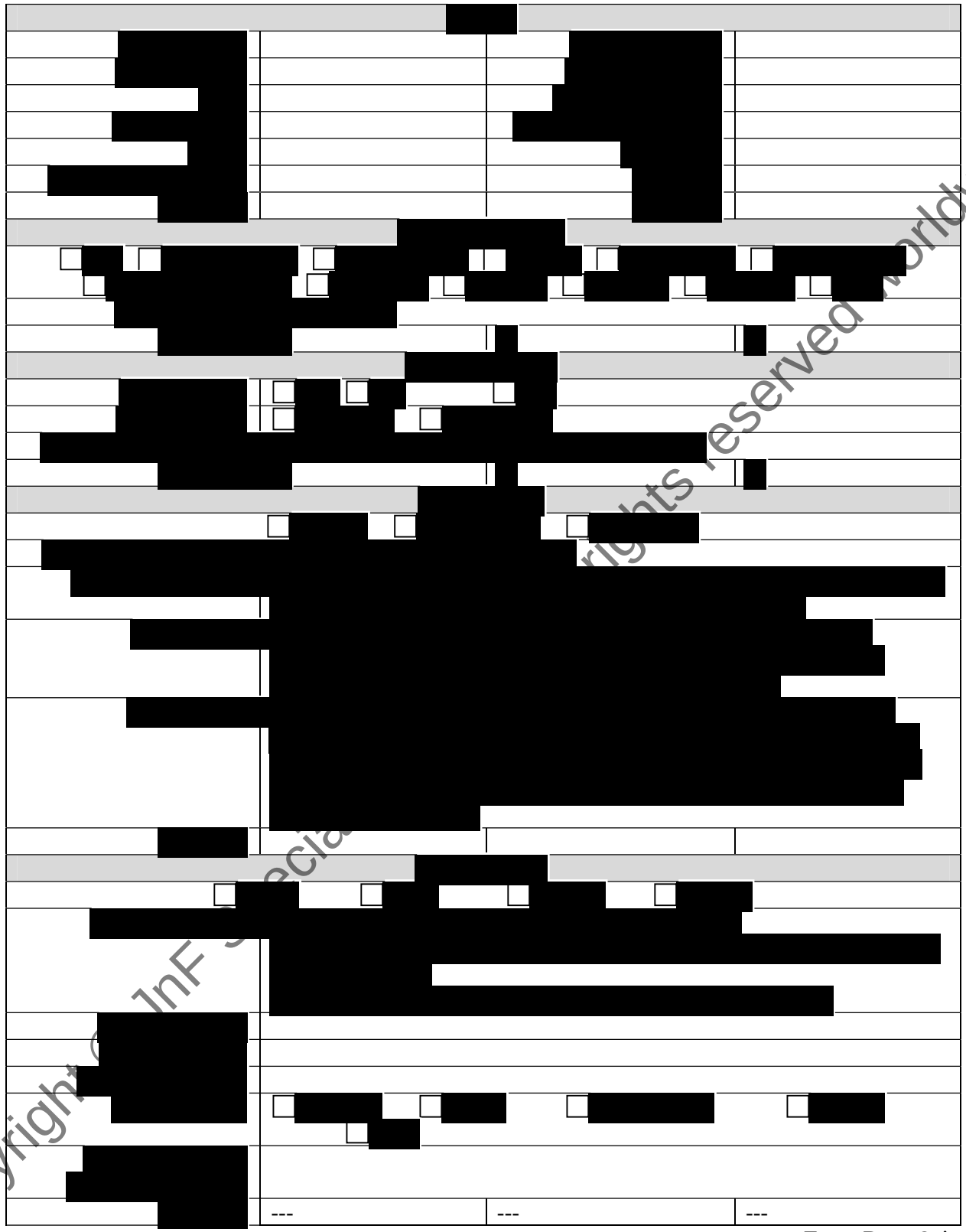
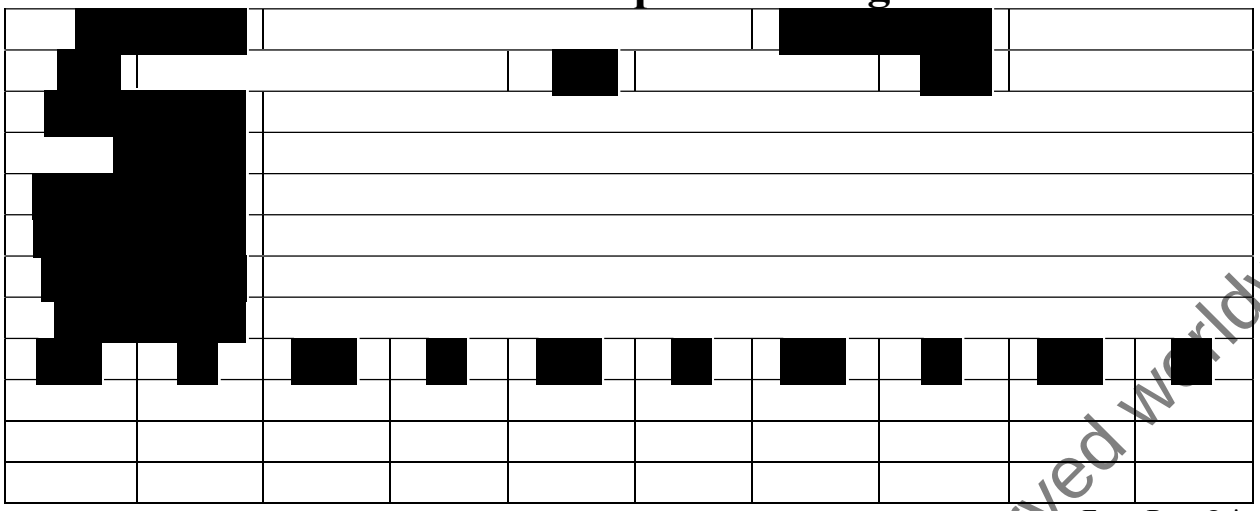
RISK ANALYSIS



Form Rev: Orig

Shelf Life Expiration Log



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Shipping Log

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Week #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	19	18	19	20	21	22
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End of Week:																							
Operator:																							
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Sample 3	719	738	719	732	709	716	724	729	715	723	747	731	712	726									
Sample 4	712	724	724	733	728	732	715	717	727	723	736	727	720	726									
Sample 5	716	725	740	716	727	718	736	728	712	716	734	728	728	720									
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Range - R	11	25	21	17	19	29	78	12	22	7	24	4	16	11									
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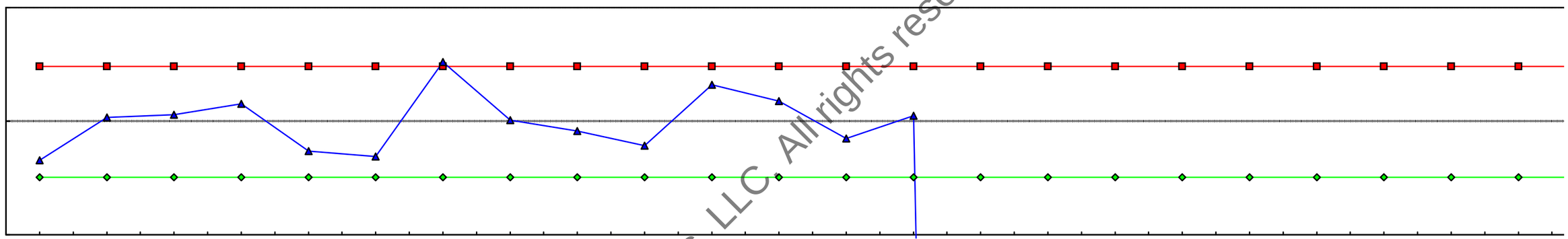
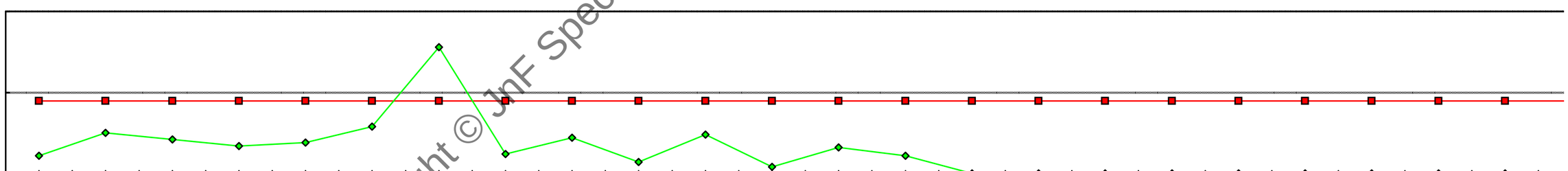


Range Control ?	O.K.	O.K.	O.K.	O.K.	O.K.	O.K.	?	O.K.	O.K.	O.K.	O.K.	O.K.	O.K.	O.K.									



X-Bar and R Form Rev: Orig

PLAN - STEP ONE: Audit Preparation & Planning

Process to Audit (Audit Scope): Storage and Assessment - see QMS-00 para 5.7.6.2	
Audit Date(s):	Lead Auditor:
Audit #:	Other Auditor(s) on Team:
Applicable Clauses of the API Spec Q1 Standard: Paragraph 5.7.6.2	
Applicable Sections of the Quality Handbook: Paragraph 5.7.6.2	
Revision of Quality Handbook:	

List any other applicable documents, if any:	
Document Title	Revision
QMS-10 Production Procedure paragraph 4.0	

DO - STEP TWO: Compare Documentation vs. Requirements

Read the applicable sections of the Company Quality Handbook.		
Question	Y/N	Evidence or Notes Sheet Ref. #
[redacted]		
[redacted]		
[redacted]		

Indicate any suggestions for improvement related to the documentation:

CHECK - STEP THREE: Compare Actual Practice vs. Requirements

Compare the requirements of the Quality Handbook and other documentation against what employees are actually doing in everyday practice.			
Requirement Reference	Question	Y/N	Evidence or Notes Sheet Ref. #
5.7.6.2	Are designated storage areas or stock rooms used to prevent damage or deterioration of product, pending use or delivery?		
[redacted]	[redacted]		

Compare the requirements of the Quality Handbook and other documentation against what employees are actually doing in everyday practice.

Requirement Reference	Question	Y/N	Evidence or Notes Sheet Ref. #
[redacted]	[redacted]		
[redacted]	[redacted]		
[redacted]	[redacted]		
[redacted]	[redacted]		

Review previous audits for this process. Review previous Nonconformance's issued against this process or as a result of previous audits for this process. Add additional checklist questions here, based on the previous audits, Nonconformance's or other documents or requirements, as you see fit.

Requirement Reference	Question	Y/N	Evidence or Notes Sheet Ref. #

ACT - STEP FOUR: Verify the Effectiveness of the Process

Review the applicable process map for this process.		
[redacted]	[redacted]	[redacted]
[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		
[redacted]		

STEP FIVE: Summarize Your Findings for Nonconformance System

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

OPPORTUNITIES FOR IMPROVEMENT	
[redacted]	

STEP SIX: Review Audit Report and Submit

[redacted]

STEP SEVEN: Submit Audit Report to Appropriate Managers

[redacted]

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

NOTES PAGE

[redacted]	[redacted]

(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]
☐
☐ _____

RESULTS OF INITIAL EVALUATION
(Ref. Purchasing Procedure)

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

[redacted] _____ [redacted] _____

RESULTS OF RECEIVING INSPECTION OR SERVICE FEEDBACK

[redacted]

☐ [redacted] ☐ [redacted]

[redacted]

NOTES

Supplier Evaluation

(Your Company Name)

QUALITY SYSTEM EVALUATION

Company Name:					
Street Address:					
City:		**State:**		**Zip:**	
Phone No:		**Fax No:**			

GENERAL INFORMATION

[redacted]

[redacted]

BUYER USE ONLY BELOW LINE

_____

[redacted]

_____
_____
_____
_____
_____
_____
_____

Form Rev: Orig

(Your Logo)

(Date)

Quality Manager«AddressBlock»

Re: Supplier Performance Rating Report
Performance Reporting Dates:
P.O. #

Dear QC Manager:

We have developed a Supplier Report Card that indicates your Quality Performance. Enclosed is a copy of your Quality Performance, which includes [redacted]

If you have any questions, please call or email us.

Sincerely,

Your Name
Your Company Name
Your Address
Your City, State, Zip
Phone
Fax
Email:

SUPPLIER QUALITY REQUIREMENTS

Origination Date: Mo/Yr

Document Identifier:	Supplier Quality Requirements
Date:	Your Date
Document Status:	Released

Abstract:
This document describes flowdown requirements for Suppliers.

REVISION LOG

Issue	Date	Comment	Author
Orig	Mo/Yr	Original Release	

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

☐PURPOSE and SCOPE

To establish the minimum requirements for supplier [redacted]

☐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 [redacted]

☐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

The Seller shall maintain [redacted]

The System shall provide [redacted]

Records shall be kept available for [redacted]

☐NEGOTIATIONS

It is not the intent of this specification to restrict the Seller in his mode of operation; therefore, it is possible that certain items herein may be subject to negotiation. Until such time as the subject of the negotiation is resolved, the Seller is obligated to [redacted]

☐PROPRIETARY INFORMATION

The Seller must identify in writing [redacted]

The written identification shall state [redacted]

The absence of such written identification is [redacted] If such written notification is given, Seller agrees [redacted]

☐PROCESS CONTROL

The Seller shall provide for [redacted]

Such instructions shall provide [redacted]

The Seller shall develop an Inspection/Test Plan specific in nature and related directly to the hardware produced.
The Plan shall identify [redacted] The Plan shall also identify [redacted]

Buyer contracts and resultant facility planning by Seller shall [redacted]

All Purchase Orders that apply to Buyer contracts generated by Seller shall [redacted]

When approval or certification of [redacted] the Seller shall [redacted] Special processes include, [redacted]

Seller MRB is not authorized. Seller shall notify Buyer [redacted]

Formal Failure Analysis and Corrective Action shall be required.

A Seller Failure Review Board is [redacted]

The Seller shall not change any [redacted]

When the Purchase Order requires Buyer acceptance of a 1st Article, [redacted]

The 1st Article item and the inspection record shall [redacted]

Notify Buyer 10 days prior to start of 1st Article production.

Neither surveillance, inspection and/or tests made by Buyer [redacted] shall relieve the Seller of [redacted]

Buyer may refuse to accept items delivered under the Purchase Order if [redacted]

Buyer reserves the right to [redacted]

☐SUBCONTRACTOR CONTROL

The Seller shall be responsible for [redacted]

Buyer inspection is required at your facility. Notify the Buyer Purchasing Manager at the start of production.

☐DRAWING and CHANGE CONTROL

The Seller shall [redacted]

The procedure shall [redacted]

☐RECEIVING INSPECTION

The Seller shall [redacted]

[redacted]

Acceptance requirements shall include [redacted]

All radiographic negatives, mechanical, physical, and chemical test results, and other inspections required to assure acceptance shall be made available to Buyer and Buyer Customer representatives upon request or as directed by the Buyer Purchase Order.

☐STOCK CONTROL

The Seller shall provide for [redacted]

Control shall cover [redacted]

Procedures for the handling of nonconforming material shall [redacted]

Buyer furnished material shall [redacted]

The Seller shall

The Seller shall

☐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

The Seller shall be responsible for [redacted]

A written procedure, compliant to ISO 10012, shall [redacted]

☐MATERIAL CONTROL

Nonconforming material shall [redacted]

Seller may not [redacted]

The Seller shall maintain traceability [redacted]

The Seller shall maintain controls to assure accomplishment of preservation, packaging and shipping requirements of the contract. The lack of a specific requirement in the Purchase Order does not relieve the Seller of the responsibility for packaging in a manner that will insure receipt of supplies at Buyer in an acceptable condition. Unless otherwise specified, [redacted]

Direct shipment of your supplies to Buyer's Customer is required. [redacted]

When product is returned by Buyer to the Seller because of failure to comply with Purchase Order requirements, the Seller shall [redacted] In all cases, when returning products to Buyer, the Seller will [redacted]

☐TECHNICAL REQUIREMENTS

Unless otherwise specified, Buyer is responsible for [redacted]

Ref: Page 1 / of /	(Your Company Name) SUPPLIER 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) SUPPLIER SURVEY REPORT Continuation…

[redacted]

Ref: Page 3 / of /	(Your Company Name) SUPPLIER SURVEY REPORT Continuation…

Tooling Sheet

[redacted]		[redacted]
[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]
Notes:		
Prepared By:		

Form Rev: Orig

(Your Logo)

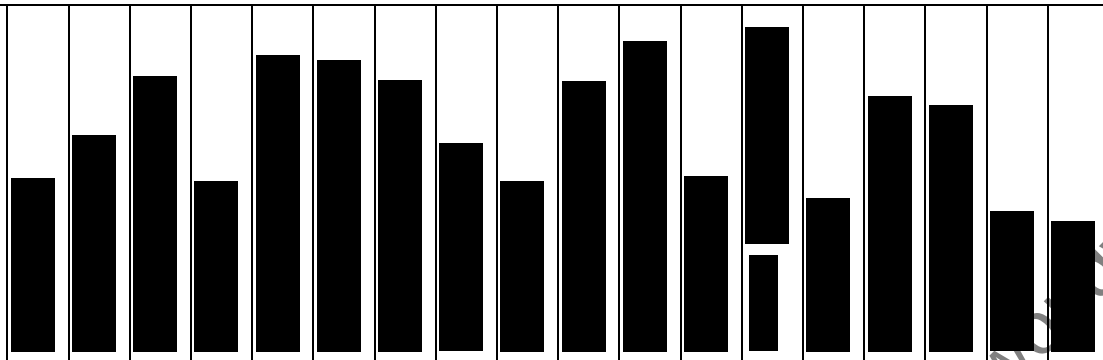
TRAINING LOG

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[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 X X X X X X
Br. eQMS	X X X X X X 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 X
E. eQMS	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 X X X
L. eQMS	X X X X X X
P. eQMS	X X X X X X X X
R. eQMS	X X X X X X
Ri. eQMS	X X X X X X X X X X X X X X
S. eQMS	X 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 X
Su. eQMS	X X 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 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 X X X X

[redacted]

ORIENTATION/TRAINING REQUEST

Form Rev: Orig

(Your Logo)

Your Company Name	TRAVELER Your Title	Your Form # Page 1 of 3

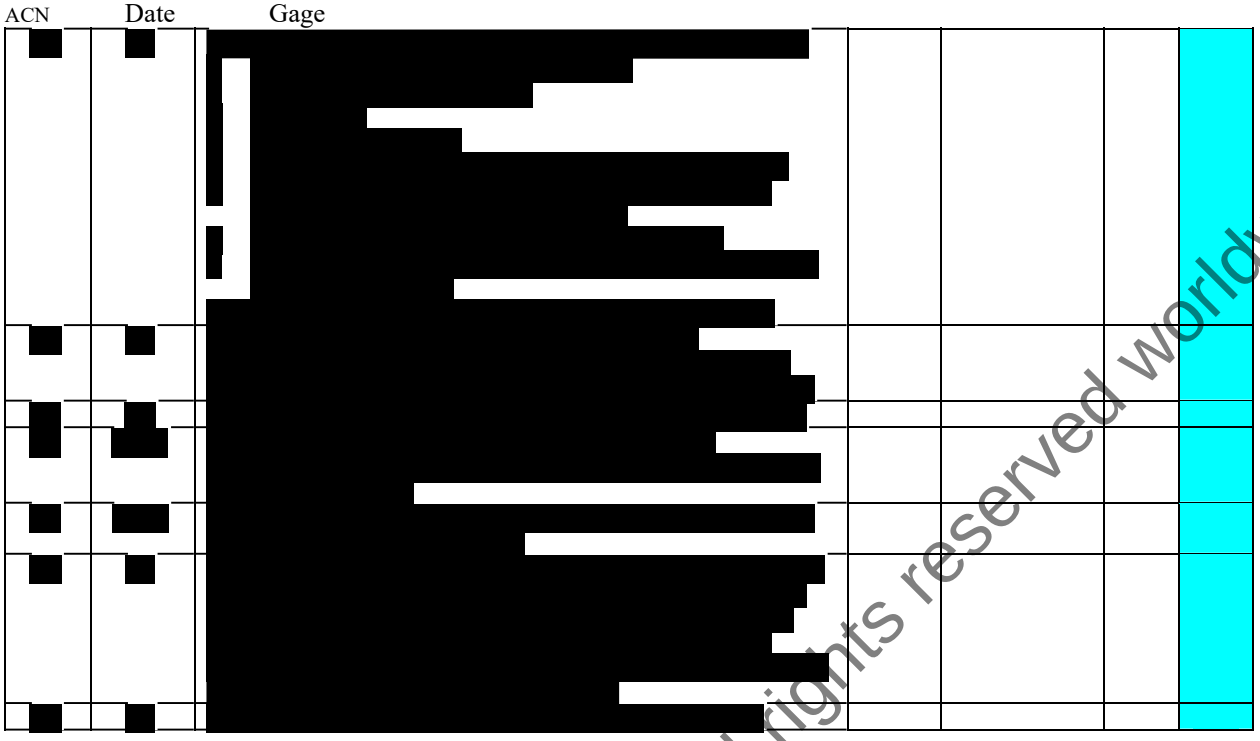
Your Company Name	TRAVELER Your #	Your Form # Page 2 of 3

OPER ACN	DEPT Date	Description of Task Gage		SIGN	RFS - ECP -

COMMENTS:

Your Company Name	TRAVELER Your #	Your Form # Page 3 of 3

OPER ACN	DEPT Date	Description of Task Gage		SIGN	RFS - ECP -



COMMENTS:

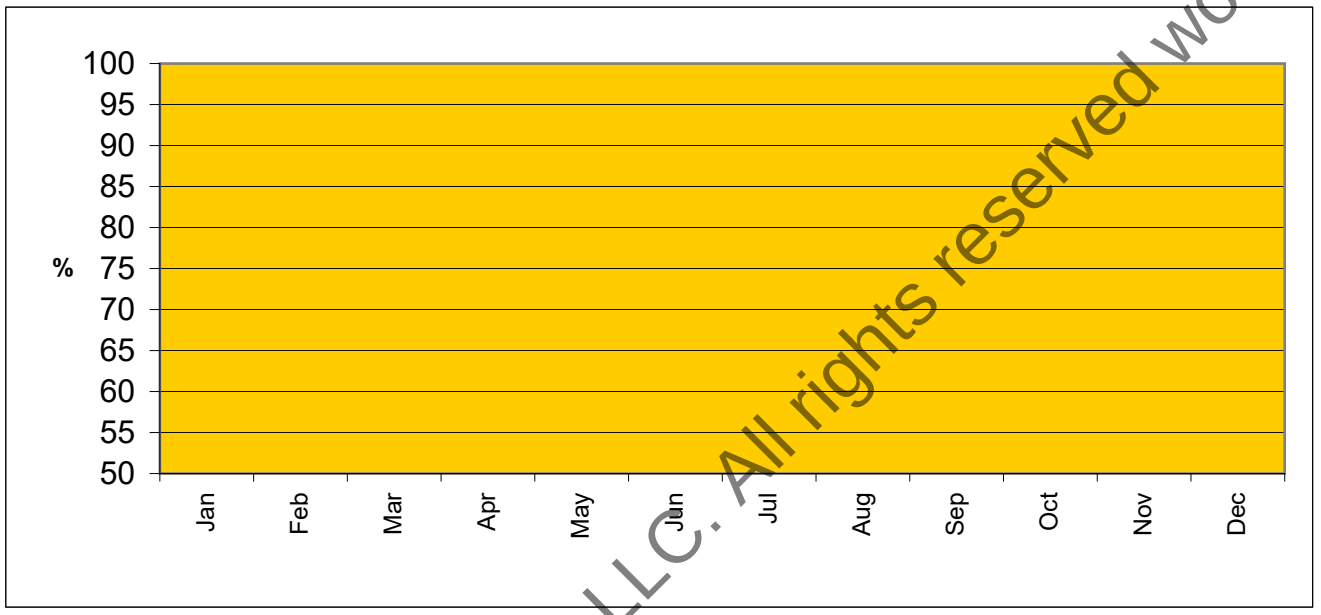
Pareto Analysis, (year)
Customer Satisfaction Rating

Date: _____

(Your Company Name)

Form Rev: Orig

Customer Satisfaction Rating



Customer Satisfaction

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	
Average Rating %	0	0	0	0	0	0	0	0	0	0	0	
Desired Rating	10	10	10	10	10	10	10	10	10	10	10	
Actual Rating												

Form R

Performance Rating Standards

Gold - 95% to 100%
Silver - 90% to 94%
Bronze - 80% to 89%
Yellow - <80%
Red - <50%

Customer Name:	(name)
Overall Rating %:	0

Your Compan
Cit

VALIDATION AND VERIFICATION

VALIDATION AND VERIFICATION

1.0 [redacted]

2.0 [redacted]

3.0 [redacted]

4.0 [redacted]

5.0 [redacted]

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

Application		Revisions			
Next Assembly	Used On	Rev	Description	Date	Approved

WORK INSTRUCTION NAME

[redacted]	[redacted]	[redacted]
1 ☐	[redacted]	
	IF	**THEN**
2 ☐	[redacted]	
	IF	**THEN**
3 ☐	[redacted]	
	IF	**THEN**
4 ☐	[redacted]	
5 ☐		
	IF	**THEN**
6 ☐	[redacted]	
7 ☐		
	IF	**THEN**
8 ☐	[redacted]	
9 ☐		
10 ☐		
	IF	**THEN**

Note 1: Sample

Step 1: ??	Step 2: ??	Step 3: ??

[redacted]			[redacted]	
			[redacted]	
[redacted]			WORK INSTRUCTION	
[redacted]	Size A	API# Number XXXX	Sheet [redacted]	Revision ???

Form Rev: Orig

Name				
[redacted]	Size A	API# Number XXXX	Sheet [redacted]	Dwg Rev ???

Form Rev: Orig

(Your Logo)

WORK ORDER

Job #: Rev:

t#:

Form Rev: Orig

Add to Cart