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QUALITY MANAGEMENT SYSTEM POLICIES AND PROCEDURES

Origination Date: XXXX

Document Identifier:	QMS-00 QMS Policies and Procedures
Date:	Latest Revision Date
Document Revision:	Orig

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

REVISION LOG

Issue	Date	Comment	Author
Orig			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

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

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Section 1: Scope

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

Section 2: Normative references

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

Section 3: Terms and Definitions

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

Section 4: Context of the Organization

4.1 Understanding the organization and its context

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

4.2 Understanding the needs and expectations of interested parties

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

4.3 Determining the scope of the quality management system

The Company's quality management system applies to all employees within all functional areas of the business operation.

The Company provides the following products and/or services:

Producer/Provider of [Your text]

NAICS code: [Your code(s)]

SIC code: [Your code(s)]

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

Non-Applicable Provisions of the QMS

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

4.4 Quality management system and its processes

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

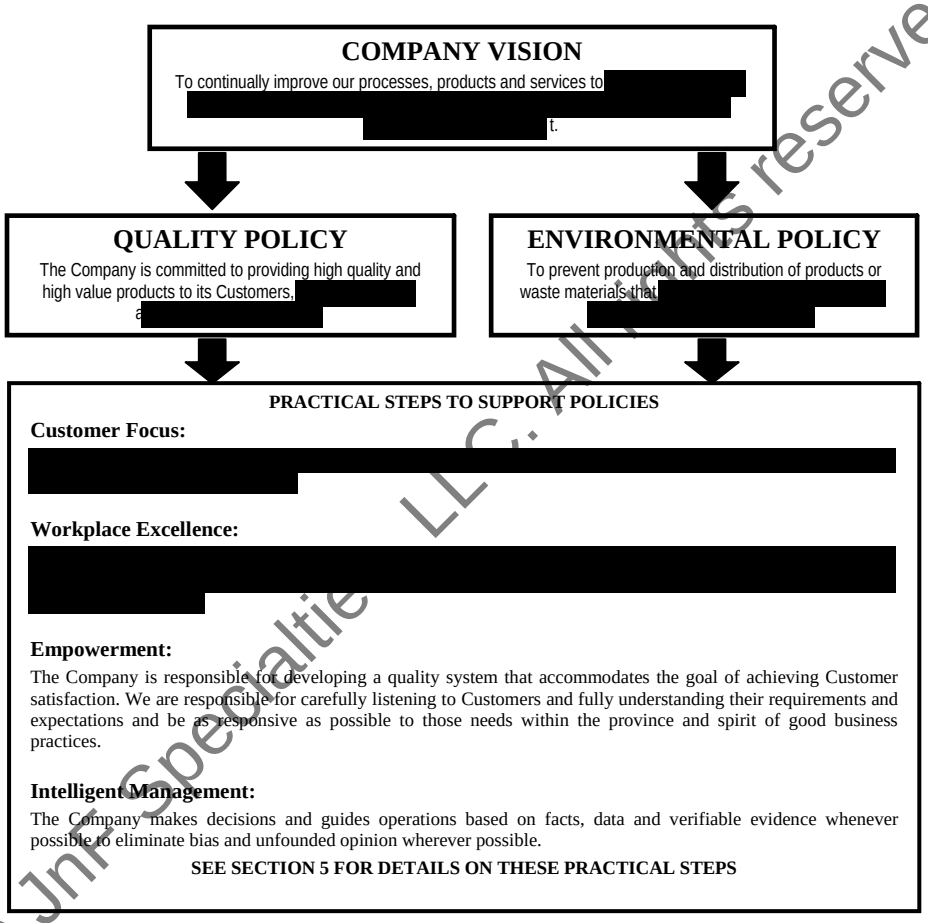
The Company uses a process-oriented method of management, which emphasizes the importance of:

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

- [redacted].

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

Every process has at least one QMS Procedure that defines it in greater detail that may include a process map. Process maps define the details of each process, which includes [redacted] The relationship between QMS procedures and their applicable ***ISO 9001*** clauses is shown in *Appendix A*. See *Appendix B* for applicable Company processes and documents. Outsourced processes and their controls are defined in *Appendix C*. See *Appendix E* for identification of key realization processes.



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Section 5: Leadership

5.1 Leadership and commitment

5.1.1 General

The Company uses the quality management system to guide and validate its decisions and to [redacted] Management participation in the QMS is described in the ***QMS-04 Management Process Procedure***.

5.1.2 Customer focus

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

5.2 Policy

5.2.1 Developing the quality policy

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

5.2.2 Communicating the quality policy

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

5.3 Organizational roles, responsibilities and authorities

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

IMPORTANT:

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

Section 6: Planning

6.1 Actions to address risks and opportunities

6.1.1 Planning for the QMS

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

opportunities to achieve [redacted]

6.1.2 Planning requirements

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

6.2 Quality objectives and planning to achieve them

6.2.1 Establishing quality objectives

The Company establishes and maintains documented information for quality objectives at relevant functions, levels and processes according to the ***QMS-04 Management Process Procedure***. Quality objectives are consistent with the quality policy and are [redacted] monitored, communicated and updated as required to enhance Customer satisfaction (see *Appendix D*).

6.2.2 Achieving quality objectives

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

6.3 Planning of changes

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

Section 7: Support

7.1 Resources

7.1.1 General

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

7.1.2 People

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

7.1.3 Infrastructure

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

7.1.4 Environment for the operation of processes

The Company determines, provides and maintains the environment necessary for the operation of its processes to achieve [redacted]

7.1.5 Monitoring and measuring resources

7.1.5.1 General

The Company determines and provides resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services according to the ***QMS-04 Management Process Procedure***, which ensures the provided resources are [redacted]

7.1.5.2 Measurement traceability

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

7.1.6 Organizational knowledge

The Company determines, maintains, uses and internally shares knowledge that is required to operate its processes. The Company considers the need for updating its organizational knowledge for each Customer according to the ***QMS-07 Proposal Development and Contract Review Procedure***.

7.2 Competence

The Company determines the necessary competence for Employees whose work affects the performance and effectiveness of the quality management system. The Company ensures Employee competence according to [redacted] the ***QMS-04 Management Process Procedure***, ***QMS-06 Training Procedure*** and ***QMS-01 Control of Documented Information Procedure***.

7.3 Awareness

The Company ensures Employees and Contractors are made aware of the Company's quality policy and applicable quality objectives. In addition, Employees and Contractors are made aware of their [redacted] according to the ***QMS-06 Training Procedure***.

7.4 Communication

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

7.5 Documented information

7.5.1 General

The Company's quality management system includes documented information required by ***ISO 9001*** and records necessary for the effectiveness of the quality management system.

7.5.2 Creating and updating

During creation and update of documented information, the Company reviews and approves documents prior to release for [redacted] according to the ***QMS-02 Configuration Management Procedure***. In addition, the Company determines an appropriate document format, which may include [redacted].

7.5.3 Control of documented information

7.5.3.1 Documents required by QMS and International Standard

The Company controls documented information to ensure it is available and suitable for use when and where it is needed and is protected from [redacted] according to the ***QMS-01 Control of Documented Information Procedure***.

7.5.3.2 Activities for control of documented information

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

Section 8: Operation

8.1 Organizational planning and control

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

8.2 Requirements for products and services

8.2.1 Customer communication

The Company communicates with its Customers by providing information relative to its products and services according to the ***QMS-07 Proposal Development and Contract Review Procedure*** and by obtaining [redacted]. Additional Customer communication channels include [redacted] according to the ***QMS-10 Production Procedure***.

8.2.2 Determining the requirements related to products and services

The Company ensures that it can meet the claims for products and services it offers and ensures requirements for products and services are defined, which includes [redacted] according to the ***QMS-07 Proposal Development and Contract Review Procedure***.

8.2.3 Review of requirements related to products and services

8.2.3.1 Ability to meet requirements

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

8.2.3.2 Retain documented information of review

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

8.2.4 Changes to requirements for products and services

When the requirements for products and services are changed, the Company applies ***QMS-07 Proposal Development and Contract Review Procedure*** to ensure Responsible Authorities are aware of changes. Applicable documents are revised according to the ***QMS-02 Configuration Management Procedure***.

8.3 Design and development of products and services

8.3.1 General through 8.3.6 Design and development changes

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

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

8.4 Control of externally provided processes, products and services

8.4.1 General

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

The Company determines and applies criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers that is based upon [redacted] according to requirements and ***QMS-08 Purchasing Procedure***. The Company retains documented information of these activities and any necessary actions arising from the evaluations.

8.4.2 Type and extent of control

The Company ensures that externally provided processes, products and services do not adversely affect the Company's ability [redacted] according to the ***QMS-08 Purchasing Procedure*** and ***QMS-09 Receiving Procedure***.

8.4.3 Information for external providers

The Company ensures that mandatory requirements are [redacted] according to the ***QMS-08 Purchasing Procedure***.

8.5 Production and service provision

8.5.1 Control of production and service provision

The Company implements production and services under controlled conditions according to the ***QMS-04 Management Process Procedure*** and ***QMS-10 Production Procedure***.

8.5.2 Identification and traceability

The Company uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services and identifies the status of outputs with respect to [redacted] the ***QMS-10 Production Procedure***. The Company controls the unique identification of outputs when [redacted]

8.5.3 Property belonging to Customers or external providers

Property used by the Company or under its control that is received from outside sources is controlled according to the ***QMS-10 Production Procedure***.

8.5.4 Preservation

The Company preserves production and service outputs to the extent necessary [redacted] according to the ***QMS-10 Production Procedure*** and ***QMS-11 Shipping Procedure***.

8.5.5 Post-delivery activities

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

8.5.6 Control of changes

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

8.6 Release of products and services

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

8.7 Control of nonconforming outputs

8.7.1 Identify and control nonconforming outputs

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

8.7.2 Retain documented information for nonconformities

Company records describe each nonconformance and include Customer approval when applicable, actions taken and identification of Responsible Authorities.

Section 9: Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

The Company's determines methods for monitoring, measurement, analysis and evaluation to ensure valid results by defining [redacted] according to the ***QMS-04 Management Process Procedure***, ***QMS-12 Internal Auditing Procedure*** and ***QMS-01 Control of Documented Information Procedure***.

9.1.2 Customer satisfaction

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

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

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

9.1.3 Analysis and evaluation

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

9.2 Internal audit

9.2.1 Conduct internal audits at planned intervals

The Company conducts internal audits at planned intervals to provide information [redacted] according to the ***QMS-12 Internal Auditing Procedure***.

9.2.2 Audit requirements

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

9.3 Management review

9.3.1 General

Top management reviews the Company's quality management system at planned intervals to ensure [redacted] according to the ***QMS-04 Management Process Procedure***.

9.3.2 Management review inputs

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

9.3.3 Management review outputs

Results from management reviews include [redacted] according to the ***QMS-04 Management Process Procedure***.

Section 10: Improvement

10.1 General

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

10.2 Nonconformity and corrective action

10.2.1 Required actions for nonconformities

When a nonconformance occurs, including complaints, the Company reacts to the nonconformance and, as applicable, takes action [redacted] according to the ***QMS-13 Corrective Action Procedure*** and ***QMS-14 Nonconformance Control Procedure***. The Company evaluates the need for action to eliminate the cause of each nonconformance to prevent recurrence or occurrence somewhere else by [redacted] The Company ensures corrective actions are appropriate to the effects of each nonconformance.

10.2.2 Required records for nonconformities

The Company retains and maintains records regarding [redacted] actions according to the ***QMS-01 Control of Documented Information Procedure***.

10.3 Continual improvement

The Company continually improves the suitability, adequacy and effectiveness of the quality management system according to the ***QMS-04 Management Process Procedure*** using [redacted].

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

Process	Applicable ISO 9001 Clauses
Configuration Management	See 8.3.1 for 8.3.6, 8.5.6 Design and Development Changes, Control of Changes (was [redacted])
Control of Documents	7.5.2, 7.5.3 Creating and Updating, Control of Documented Information (was [redacted])
Control of Records	7.5.2, 7.5.3 Creating and Updating, Control of Documented Information (was [redacted])
Control of Nonconformances	8.7 Control of Nonconforming Outputs (was [redacted])
Corrective Action	10.2 Nonconformity and Corrective Action (was 8.5.3 [redacted])
Internal Auditing	9.2 Internal Audit (was [redacted])
Management	4.4 Quality Management System and its Processes (was [redacted]) 7.5 Documented Information (was [redacted]) 5.1, 5.1.1 Leadership and Commitment, General (was [redacted]) 5.1.2 Customer Focus (was [redacted]) 5.2, 5.2.1, 5.2.2 Policy, Developing the Quality Policy, Communicating the Quality Policy (was [redacted]) 6.0 Planning (was [redacted] 5.3 Organizational Roles, Responsibilities and Authorities (was [redacted]) 5.3 Organizational Roles, Responsibilities and Authorities (was [redacted]) 7.4 Communication (was [redacted]) 9.3 Management Review (was [redacted]) 7.1.1, 7.1.2 General, People (was [redacted]) 7.2 Competence (was [redacted]) 7.1.3 Infrastructure (was [redacted]) 7.1.4 Environment for the Operation of Processes (was [redacted]) See 8.3.1 for 8.3.6, 8.5.6 Design and Development Changes, Control of Changes (was [redacted]) 8.2.1 Customer Communication (was [redacted]) 8.5.1, 8.5.5 Control of Production & Service Provision, Post Delivery Support (was [redacted]1) 7.1.5 Monitoring and Measuring Resources (was [redacted]) 9.1.1 Measurement, Analysis & Improvement: General (was [redacted]) 9.1.2 (was [redacted]) 9.1.1 General (was [redacted]) 9.1.3 Analysis and Evaluation (was [redacted]) 10.1 General, Continual Improvement (was [redacted])
Production	8.1 Operational Planning and Control (was [redacted]) 8.5.1, 8.5.5 Control of Production and Service Provision, Post Delivery Support (was [redacted]) 8.5.2 Identification & Traceability (was [redacted]) 8.5.3 Property Belonging to Customers or External Providers (was 7.5.4 [redacted]) 8.5.4 Preservation (was [redacted]) 8.6 Release of Products and Services (was [redacted]) 8.7 Control of Nonconforming Outputs (was [redacted])
Proposal Development & Contract Review	8.2.2 Determining the Requirements Related to Products and Services (was [redacted]) 8.2.3 Review of Requirements Related to Products and Services (was 7.2.2 [redacted])
Purchasing	8.4.1, 8.4.2 General, Type and Extent of Control (was [redacted]) 8.4.3 Information for External Providers (was [redacted])
Receiving	8.6 Release of Products and Services (was [redacted]oduct) 8.5.2 Identification & Traceability (was [redacted]) 8.5.3 Property Belonging to Customers or External Providers (was [redacted]) 8.5.4 Preservation (was [redacted]) 8.6 Release of Products and Services (was [redacted]) 8.7 Control of Nonconforming Outputs (was [redacted])
Shipping	8.2.2 Determining Requirements Related to Products and Services (was [redacted]) 8.5.1, 8.5.5 Control of Production and Service Provision, Post Delivery Support (was [redacted]) 8.5.2 Identification & Traceability (was [redacted]) 8.5.4 Preservation (was [redacted]) 8.7 Control of Nonconforming Outputs (was [redacted])

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Appendix B: Company Processes and Applicable Documents

Process	Applicable Company Procedures	Applicable Company Records
Corrective Action	QMS-13 Corrective Action	Corrective action records 10.2 (was [redacted])
Design & Development	QMS-17 Design & Development	Realization processes and resulting product meet requirements 8.1 (was [redacted]) Design and development planning 8.3.2 (was [redacted]) Design inputs records 8.3.3 (was [redacted]) Design review records 8.3.4 (was [redacted]) Design verification records 8.3.4 (was [redacted]) Design validation records 8.3.4 (was [redacted]) Design and development outputs 8.3.5 (was [redacted]) Design change records see 8.3.1 for 8.3.6 (was [redacted])
Internal Auditing	QMS-12 Internal Auditing	Internal audits 9.2 (was 8.2.2)
Management	QMS-00 Quality Handbook QMS-01 Control of Documented Info QMS-02 Configuration Management QMS-04 Management Process Procedure QMS-05 Responsibilities & Authorities QMS-06 Training QMS-15 Calibration QMS-16 Definitions and Abbreviation	Management review minutes 9.3.1 (was [redacted]) Training records 7.2, 7.3 (was [redacted]) Calibration records 7.1.5 (was [redacted])
Production	QMS-10 Production QMS-14 Control of Nonconformances	Traceability records (if required) 8.5.2 (was [redacted]) Records of loss, damage or nonconformances 8.5.3 (was [redacted]) Records of release authority of inspected product 8.6 (was [redacted]) Records of first article inspection 8.6 (was [redacted]) Control of nonconformances 8.7 (was [redacted])
Proposal Development & Contract Review	QMS-07 Proposal Development & Contract Review	Contract review records 8.2.3 (was [redacted])
Purchasing	QMS-08 Purchasing	Supplier evaluation records 8.4.1, 8.4.2 (was [redacted])
Receiving	QMS-09 Receiving QMS-14 Control of Nonconformances	Records of loss, damage or nonconformances 8.5.3 (was [redacted]) Control of nonconformances 8.7 (was [redacted])
Shipping	QMS-11 Shipping QMS-14 Control of Nonconformances	Records of loss, damage or nonconformances 8.5.3 (was [redacted]) Control of nonconformances 8.7 (was [redacted])

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Appendix C: Outsourced Processes

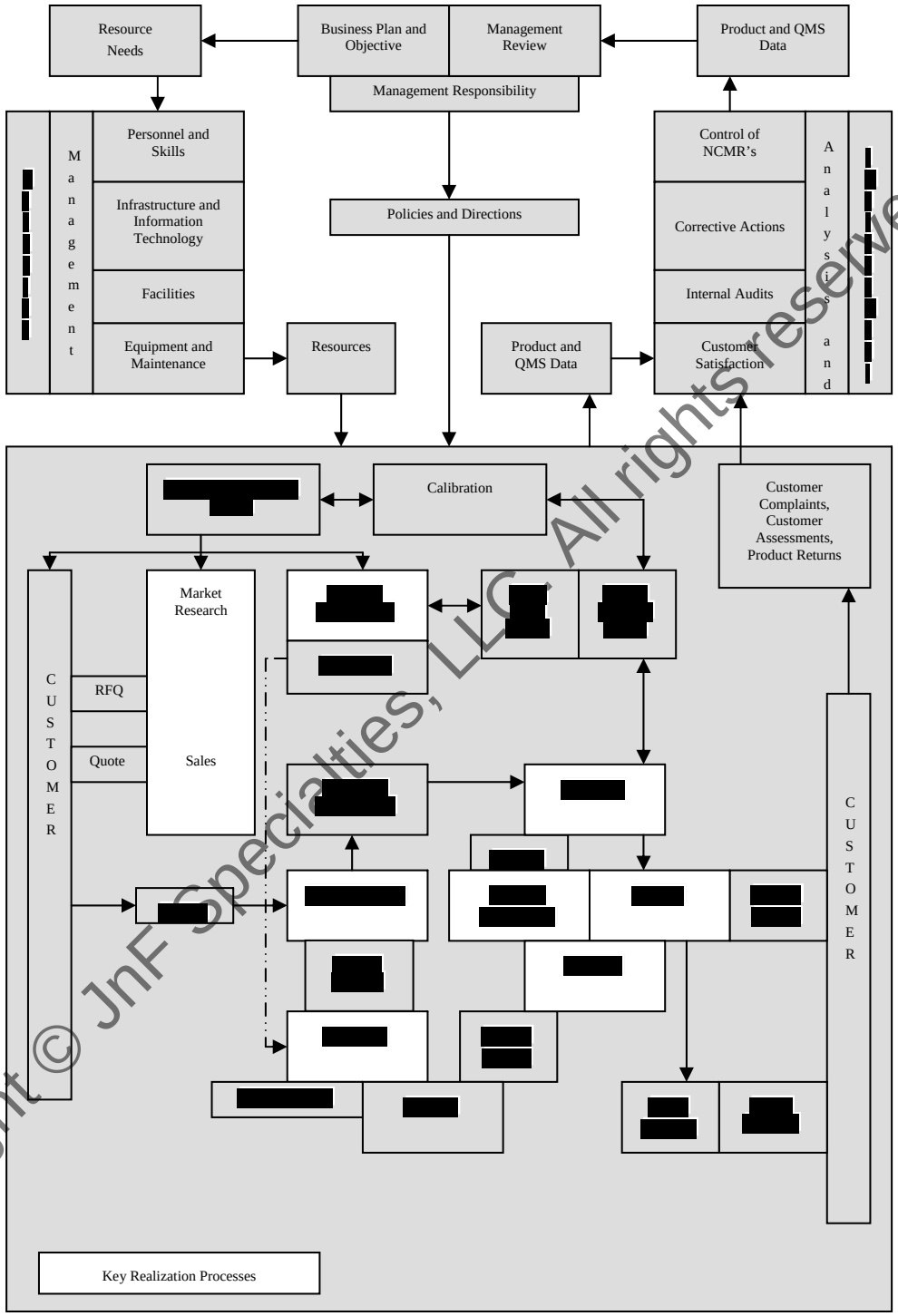
The following processes are outsourced and controlled as indicated:

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

Appendix D: Quality Objectives

Process	Quality Objective	Metric
Corrective Action	[redacted]	Nonconformance Trend Chart
Design & Development	[redacted]	Customer Satisfaction Rating
Internal Auditing	[redacted]	Internal Audit Reports
Management	[redacted]	Management Review Reports
Production	[redacted]	Product Yield Rating
Proposal Development & Contract Review	[redacted]	Customer Satisfaction Rating
Purchasing	[redacted]	Management Review Reports
Receiving	[redacted].	Subcontractor Performance Rating
Shipping	[redacted]	On-Time Delivery Rating

Appendix E: Identification of Key Realization Processes



8 Mandatory Procedures	22 Mandatory Forms
[redacted]	[redacted]
(delete this table prior to release of quality handbook)	(delete this table prior to release of quality handbook)

Your Logo

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MANAGEMENT PROCESS

Origination Date: XXXX

Document Identifier:	Management Process
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 review process.

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DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

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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 Management Policies and Procedures handbook; however, management itself must also be treated as a process. This means that management activities must have inputs, outputs, controls and reaction plans (when things do not work out as expected.) The Company must consider the results of analyses and evaluations and the outputs from management reviews to determine if there are needs or opportunities to be addressed as part of continual improvement.

The process map in the Appendix of this document 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]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [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]

[redacted]

4.2 This review shall include [redacted]

4.3 Minutes of the meetings are taken and maintained. The Management Review 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]
- [redacted]
- [redacted]
- [redacted]m
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

4.5 Management shall use action items or the corrective action system to take recorded actions as a result of review topics in an effort to [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]

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

- [redacted]s
- [redacted]ations

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 measurable in some fashion. The means of measurement are called "metrics" and the metrics are defined in the Management Review minutes.

5.3 Top management will assign goals to each process metric.

5.4 Throughout the year, assigned managers and staff will gather data according to the defined metrics.

5.5 During Management Review the data will be presented and recorded and an assessment made on whether each process succeeded in meeting its assigned goal.

5.6 When a process does not meet a goal, [redacted]

5.7 The current metrics, standings, previous goal and revised goals shall be [redacted] (See section 4.0 above.)

5.8 Over time, management shall assess performance of each process against the goals [redacted] 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 [redacted]

The following methods are used for internal communications:

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

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

6.2.1 Confidential Company Information

Company Employees must not reveal Confidential Company Information to External Parties except to the extent such disclosures are necessary [redacted]

[redacted]

6.2.1.1 Basic Company Information

Company Employees must not communicate Basic Company Information to External Parties except to the extent that such communication is part of their normal responsibilities. For example, [redacted]

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

- [redacted]

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

6.2.1.2 Written Company Information

All Written Company Information must conform to guidelines established from time to time.

All Written Company Information must be approved by the appropriate Responsible Authority before it is communicated to any External Party.

With respect to any Written Company Information regarding new business, clients, or other contract counterparties, or other Third Parties with a business relationship with the Company, care must be exercised to [redacted]

Written Company Information regarding [redacted] must also be approved by the appropriate Responsible Authority.

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]ation
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]vities
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

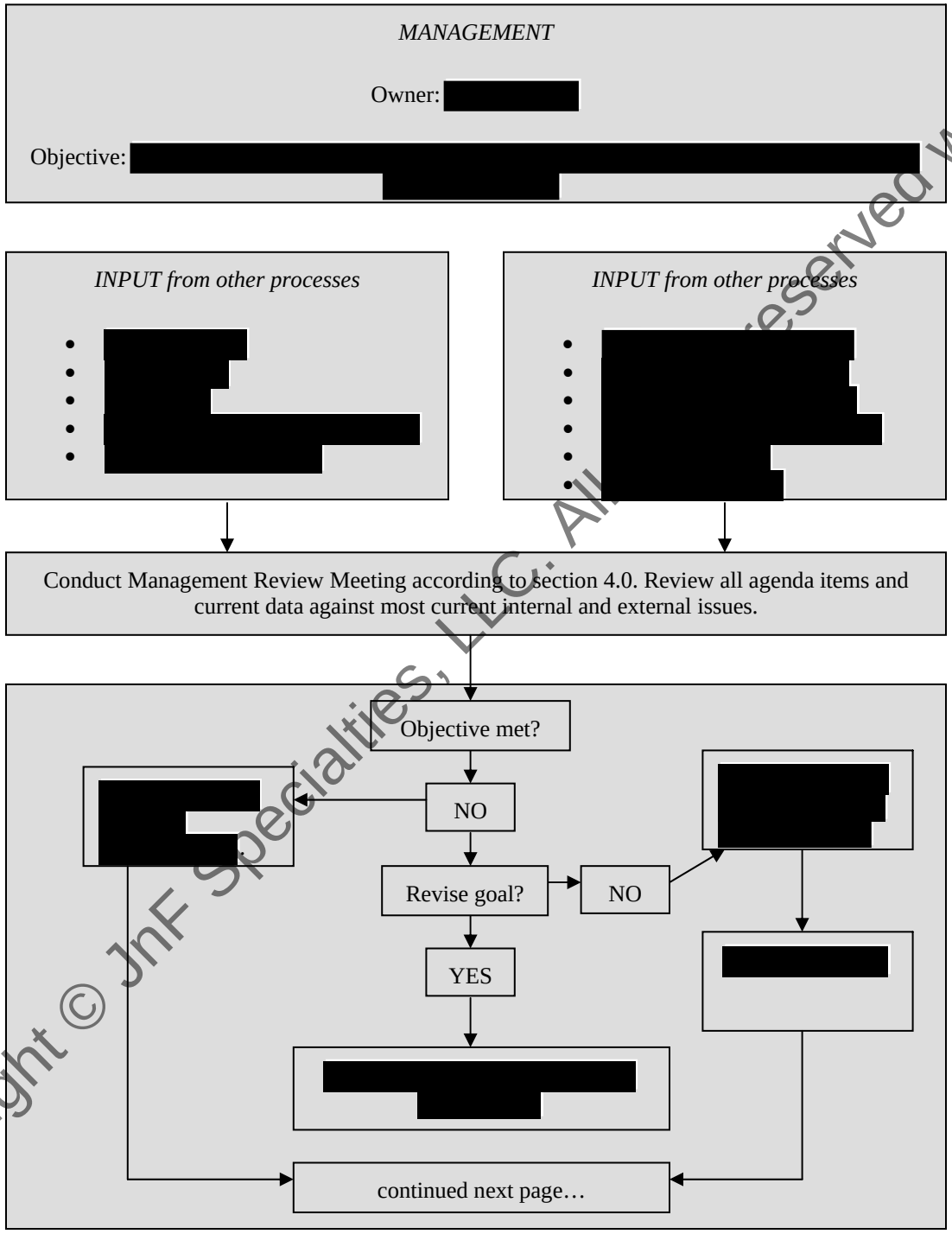
7.2 Like other management activities, resource management must [redacted].

7.3 To manage resources, top management must [redacted]

7.4 During Management Review, managers shall [redacted]

7.5 From that data, top management can [redacted]

Appendix A: Process Map



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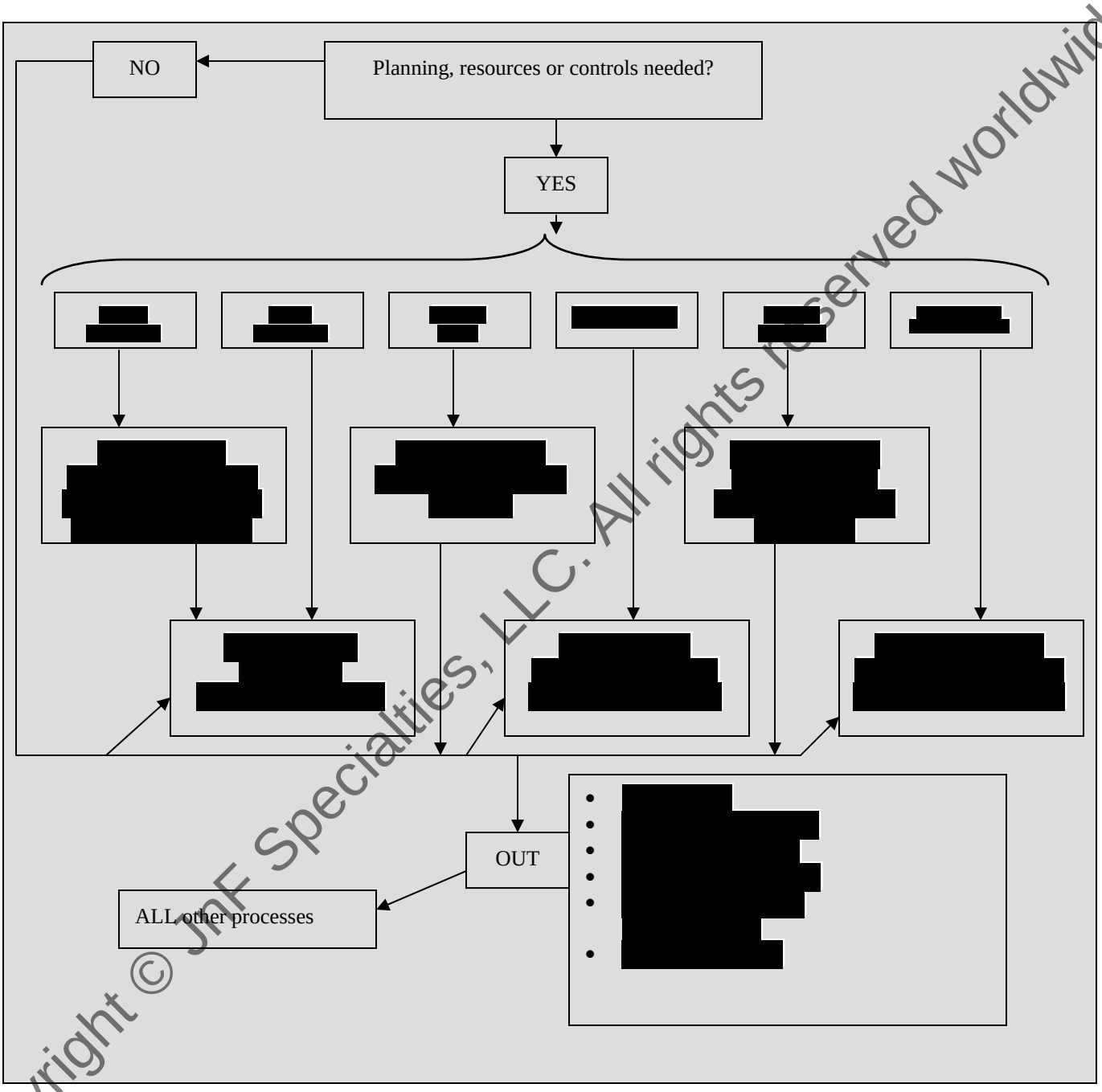

The main changes in ISO 9001:2015 are:

i. The adoption of a Higher Level Structure (HLS) as set out in Annex SL of ISO Directives Part 1.
    1. Scope
    2. Normative references
    3. Terms and definitions
    4. Context of the organization
    5. Leadership
    6. Planning
    7. Support
    8. Operation
    9. Performance evaluation
    10. Improvement

ii. An explicit requirement for risk-based thinking to support and improve the understanding and application of the process approach.
iii. Fewer prescribed requirements.
iv. Less emphasis on documents.
v. Improved applicability for services.
vi. A requirement to define the boundaries of the QMS.
vii. Increased emphasis on organizational context.
viii. Increased leadership requirements.
ix. Greater emphasis on achieving desired outcomes to improve customer satisfaction.

ISO 9001:2008 certifications will not be valid after three years from publication of ISO 9001:2015, which was September 15, 2015.

[redacted]

Organizations using ISO 9001:2008 are recommended to take the following actions:

i. Identify organizational gaps which need to be addressed to meet new requirements.
ii. Develop an implementation plan.
iii. Provide appropriate training and awareness for all parties that have an impact on the effectiveness of the organization.
iv. Update the existing quality management system (QMS) to meet the revised requirements and provide verification of effectiveness.
v. Where applicable, contact the organization's Certification Body for transition arrangements.

[redacted]

Here's how ISO 9001:2015 aligns with the format for "Plan - Do - Check - Act":

PLAN
Clause 4 - Context of the organization
Clause 5 - Leadership
Clause 6 - Planning for the QMS
Clause 7 - Support

DO
Clause 8 - Operations

CHECK
Clause 9 - Performance evaluation

ACT
Clause 10 - Improvement

[redacted]

Mandatory and recommended procedures and forms:

8 Mandatory Procedures

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

Recommended Procedures (when applicable)

- [redacted]

- [redacted]

22 Mandatory Forms

1. Confidence processes are carried out as planned (4.4.2.b)
2. Fitness for purpose of inspection persons (paragraph 7.1.5.1)
3. Measurement equipment calibration (paragraph 7.1.5.2)
4. Competence of persons (7.2.d)
5. Confidence in and conformity of products and services (8.1)
6. Results of the review of products and services requirements (8.2.3.2)
7. Design and development requirements have been met (8.3.2)
8. Design and development inputs (8.3.3)
9. Design and development controls (8.3.4)
10. Design and development outputs (8.3.5)
11. Design and development changes (8.3.6)
12. Controls applied to external providers (paragraph 8.4.1)
13. Characteristics of product to be produced and service to be provided, activities to be performed and results to be achieved (8.5.1)
14. Traceability of products and services (paragraph 8.5.2)
15. [redacted]
16. [redacted]
17. [redacted]
18. [redacted]
19. [redacted]
20. [redacted]
21. [redacted]
22. [redacted]

Now that the ISO 9001 standard is a little more complex, are you wondering how to begin a quality control plan? We'll help you facilitate the changes in ISO 9001 as quickly and efficiently as possible with our "as-a-matter-of-fact" approach and with our **no charge/no-expiration support by phone and email**.

[redacted]

Purchase the updated ISO 9001:2015 standard at:

ANSI.org Webstore

[redacted]

MANAGEMENT REVIEW REPORT

Origination Date: XXXX

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

Abstract:
This document provides the management review report.

CREATION LOG

Issue	Date	Comment	Author
0-0			

REVISION RECORD

Issue	Item	Reason for Change

[redacted]

Please complete each section - this form may used as the final report or used as a template to type and publish more formal Management Review Meeting records. At all stages, management must consider proper, proactive measures to take to improve the Company and determine where it is necessary to apply corrective action. [redacted]

Date of Review: **Recorded by:**

In Attendance:

NAME	TITLE

Absent:

NAME	TITLE

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

The Company is committed to [redacted]

☐ Quality Policy reviewed and [redacted]

☐ Quality Policy needs revision. Following changes recommended:

ITEM 2: Internal audit results. [redacted].

ITEM 3: Status of MR System corrective actions. [redacted]

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

EQUIPMENT RESOURCES REQUIREMENTS

[redacted]

[redacted]

[redacted]

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

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

[redacted]

ITEM 7: Review of quality objectives, data and goals. *Review the current Quality Objectives as outlined in the Quality Manual and modify goals accordingly.*

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

ITEM 8: Discuss Customer feedback and complaints not already discussed as part of the NCR system review. [redacted].

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

[redacted]

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

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

ITEM 12. Set date for next Management Review:

ITEM 13. NCR's FILED AT THIS MEETING:

Line Item	Corrective?	Nature of Issue
1		
2		
3		
4		
5		
6		

ITEM 14. [redacted]

[redacted]	[redacted]	[redacted]

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

[redacted]

ACTION ITEM

Date:	[redacted]
[redacted]	

Assigned To	Requested By:
	Telephone Number:

[redacted]

Form Rev: Orig

Signature: _____

Date: _____

[redacted]

Your Logo

ACTION PLAN

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

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

Form Rev: Orig

[redacted]

Your Logo

Quality System Impact Analysis			
Auditor(s):	Procedure Name and # under Audit:		
Date:	Supervisor Affected:	Areas Audited:	
Brief Description of Practice: [redacted]	Audit Record: (Describe [redacted]		
Procedure Required? Yes ____ No ____		Signed by Auditor (Date):	CA Number
If yes, [redacted] ? Yes ____ No ____		Signed by Procedure Owner (Date):	
Audit Follow up: [redacted]			
Comments:			

Form Rev: Orig

[redacted]

Your Logo

Your Company Name

PROCESS ORIENTATION CHECKLIST

Origination Date: XXXX

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

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

[redacted]

REVISION LOG

Issue	Date	Comment	Author
0-0			

DOCUMENT CHANGE RECORD

Issue	Item	Reason for Change

[redacted]

Defined properly, a quality management system is viewed as a system of processes. After identifying organizational support and process realization processes or departments that affect quality, a documented procedure or process map is helpful to understand their operation and interaction. In describing the organization's planned arrangements for processing, many answers in this checklist should be included in procedures describing each process or department affecting quality. This checklist can be used as [redacted]

Process Name:	
Question	**Answer** (N/A if not applicable)
Process Characteristics	
Who owns the process?	
Who is responsible for performing and overseeing the process?	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
Support Process Question **With Who - training, knowledge, skills**	
What criteria have been established for Operator competency?	
Support Process Questions **With What - equipment, installations**	
What machines, materials, safety equipment, test equipment, computer systems and software are used in the process?	
[redacted]	

Process Name:	
Question	**Answer** (N/A if not applicable)
Support Process Questions With What Key Criteria - measurements, assessments	
What in-process/final verification criteria are associated with the output?	
[redacted]	
Input - what should be received	
Upon what inputs does the process operate, e.g., document(s), materials, tooling, schedule, etc?	
[redacted]	
Output - what should be delivered	
What output does the process produce?	
[redacted]	
[redacted]	
Support Process Questions Performance indicators	
How is the process identified throughout the process?	
How is inspection status identified throughout the process?	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	

Process Name:	
Question	**Answer** (N/A if not applicable)
Support Process Question **How - instructions, procedures, methods**	
What instructions are available to Operators?	
Are documents/work instructions approved?	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
Workmanship	
Process Map Step 1: (name)	
Is this a key characteristic in the process?	
If so, [redacted]	
[redacted]	
[redacted]	
Process Map Step 2: (name)	
Is this a key characteristic in the process?	
If so, [redacted]	
[redacted]	
[redacted]	
Process Map Step 3: (name)	
Is this a key characteristic in the process?	

Your Logo	Your Company Name	Document Name or ID
CAGE: xxxxx		Rev: xx

Process Name:	
Question	**Answer** (N/A if not applicable)
If so, [redacted]	
[redacted]	
[redacted]	
Process Map Step 4: (name)	
Is this a key characteristic in the process?	
If so, [redacted]	
[redacted]	
[redacted]	
[redacted]	

Continuous Improvement Resources	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	

PROPRIETARY INFORMATION	This document expires 30 days after printing unless marked "Released". **Date Printed:** [redacted]	Form Rev: Orig