Your Logo

Your Company Name

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.

TABLE OF CONTENTS

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 general/specific 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 15161, 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 15161 or ISO 9001*** standard. (list your exclusions to 15161/9001)

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.

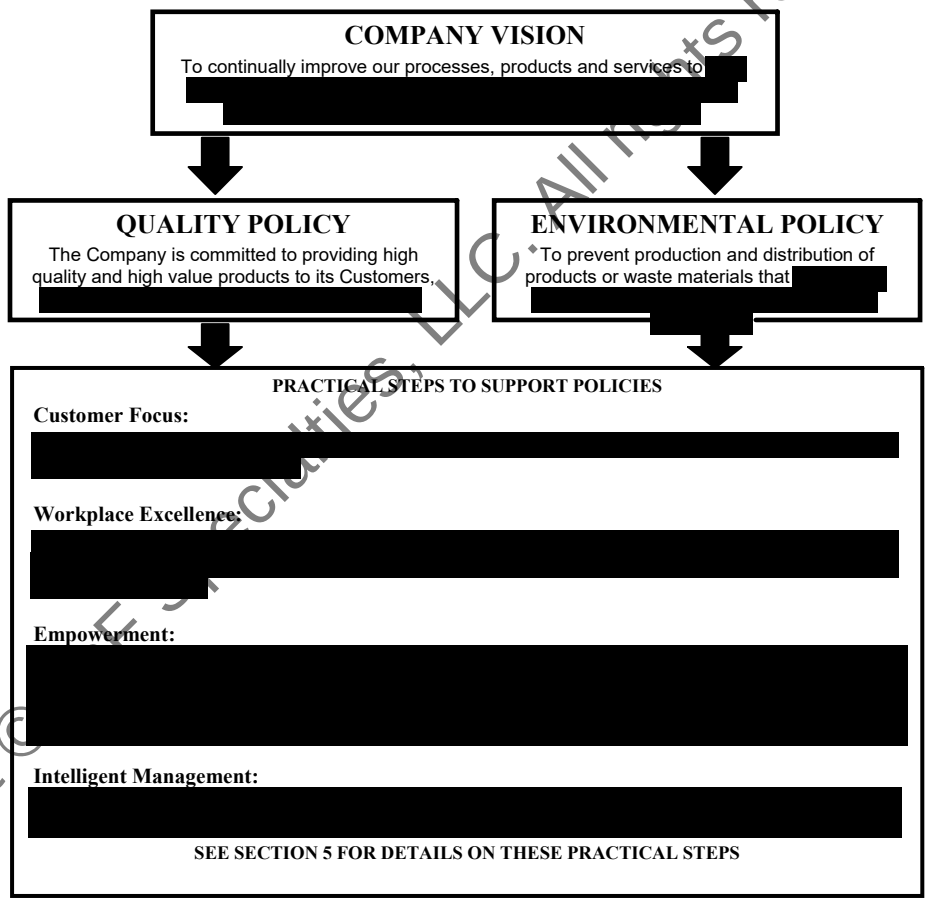
The Company uses a process-oriented method of management, which emphasizes the importance of:

- [redacted]
- [redacted]

- [redacted]
- [redacted]
- [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 15161 and ISO 9001*** clauses is shown in *Appendix A*. See *Appendix B* for applicable Company processes and documents. Outsourced processes and their controls are defined in *Appendix C*. See *Appendix E* for identification of key realization processes.



Left blank intentionally

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***. Top management nominates members of the HACCP team and supports their activities.

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 Establishing 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*). Objectives are aligned throughout the organization and indicate the nature of the hazards that the Company considers critical for the safety of foodstuffs.

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 design, construction and layout of food processing areas, hygiene of equipment, food safety, and 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 [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 [redacted]

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***.

Left blank intentionally

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 [redacted]

7.5.2 Creating and updating

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

Quality planning primarily uses HACCP with respect to food safety. The results of the HACCP study and CCPs is entered into process planning; this identifies critical areas and shows their correct direction. The Company focuses on processes

from raw material delivery, through [redacted] Records are maintained that link back to HACCP plans in which CCPs were identified and the methods of controlling them. Planning takes into consideration:.

a) [redacted]

b) [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***.

When designing the process for managing a product recall, a specific individual is nominated to manage the process and is the sole point of contact with the Customer and the Consumer.

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 [redacted]

8.3 Design and development of products and services

8.3.1 General through 8.3.6 Design and development changes

The Company's design and development process 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 (OSHA, CSPC, etc)

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***.

There are some processes where verification of results can be uneconomical or impossible without a destructive test. Examples include [redacted] (CIP) processes. The Company ensures complete control of the process by verifying the process before product is made (during process design), ensuring all personnel are adequately trained, ensuring [redacted] and "in-process"

records are complete and record the processing parameters. Reliance on post-process inspection and testing is minimal. The process is designed, executed and controlled to ensure that all possible hazardous inputs are [redacted]

8.5.2 Identification and traceability

The Company uses suitable means to identify outputs when [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] Two categories of [redacted] monitoring and measurement [redacted] that requires special attention are [redacted] the following:

a) Tests based on senses

Tests that are based on sight, odor, taste and texture (i.e. any organoleptic tests) combine the following elements:

1) [redacted]
2) [redacted]
3) [redacted]

b) Special tests

[redacted]

Samples of manufactured product are retained for the period of the stated shelf-life or as specified by Customer requirements. The storage and control of these samples ensures [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 [redacted] according to the ***QMS-14 Control of Nonconformities Procedure***. The Company takes appropriate actions based on [redacted]

8.7.2 Retain documented information for nonconformities

Company records describe each nonconformance and include [redacted]

Section 9: Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

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

Monitoring and measurement is extremely important in the application of an HACCP system, which is referenced in HACCP Principle 4 (establish a system to monitor control of the CCP) and Principle 6 (establish procedures for verification to confirm that the HACCP system is working effectively). The Company uses HACCP to ensure [redacted] Where possible, rapid or on-line quality control methods are used. Monitoring and measurement records form the backbone of the HACCP system since the records generated provide [redacted]

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]

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

The Company strives to develop with the Customer key performance indicators (KPIs) and measures, which include:

- [redacted]

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 [redacted]

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]

Left blank intentionally

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 [redacted] according to the ***QMS-13 Corrective Action Procedure*** and ***QMS-14 Control of Nonconformities 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] according to the ***QMS-01 Control of Documented Information Procedure***.

10.3 Continual improvement

The Company continually improves [redacted] according to the ***QMS-04 Management Process Procedure*** using [redacted]

Left blank intentionally

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 Documented Information	7.5.2, 7.5.3 Creating and Updating, Control of Documented Information (was [redacted])
Control of Nonconformities	8.7 Control of Nonconforming Outputs (was [redacted])
Corrective Action	10.2 Nonconformity and Corrective Action (was [redacted])
Internal Auditing	9.2 Internal Audit (was [redacted])
Management	4.1 Understanding the organization and its context 4.2 Understanding the needs and expectations of interested parties 4.3 Determining the scope of the QMS (was [redacted]) 4.4 Quality Management System and its Processes (was 4.1 [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, Establishing the Quality Policy, Communicating the Quality Policy (was [redacted]) 5.3 Organizational Roles, Responsibilities and Authorities (was [redacted]) 5.3 Organizational Roles, Responsibilities and Authorities (was [redacted]) 6.1.1 Planning for QMS (was [redacted]) 6.1.2 Planning Requirements (was 5.4.2 [redacted]) 7.1.1, 7.1.2 General, People (was [redacted]) 7.1.3 Infrastructure (was [redacted]) 7.1.4 Environment for the Operation of Processes (was [redacted]) 7.1.5.1 Monitoring and Measuring Resources: General (was [redacted]) 7.2 Competence (was [redacted]) 7.4 Communication (was [redacted]) 7.5 Documented Information (was [redacted]) 8.2.1 Customer Communication (was [redacted]) 8.5.1, 8.5.5 Control of Production & Service Provision, Post Delivery Activities (was [redacted]) 9.1.1 General (was [redacted]) 9.1.2 Customer Satisfaction (was [redacted]) 9.1.3 Analysis and Evaluation (was [redacted]) 9.3 Management Review (was [redacted]) 10.1 Improvement: General (was [redacted])
Production	8.1 Organizational Planning and Control (was [redacted]) 8.5.1, 8.5.5 Control of Production and Service Provision, Post Delivery Activities (was [redacted]) 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])
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 [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]) 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 Activities (was [redacted]) 8.5.2 Identification & Traceability (was [redacted]) 8.5.4 Preservation (was [redacted]) 8.7 Control of Nonconforming Outputs (was [redacted])

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]5) 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 [redacted])
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 Nonconformities	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 Nonconformities	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 Nonconformities	Records of loss, damage or nonconformances 8.5.3 (was [redacted]) Control of nonconformances 8.7 (was [redacted])

Left blank intentionally

Appendix C: Outsourced Processes

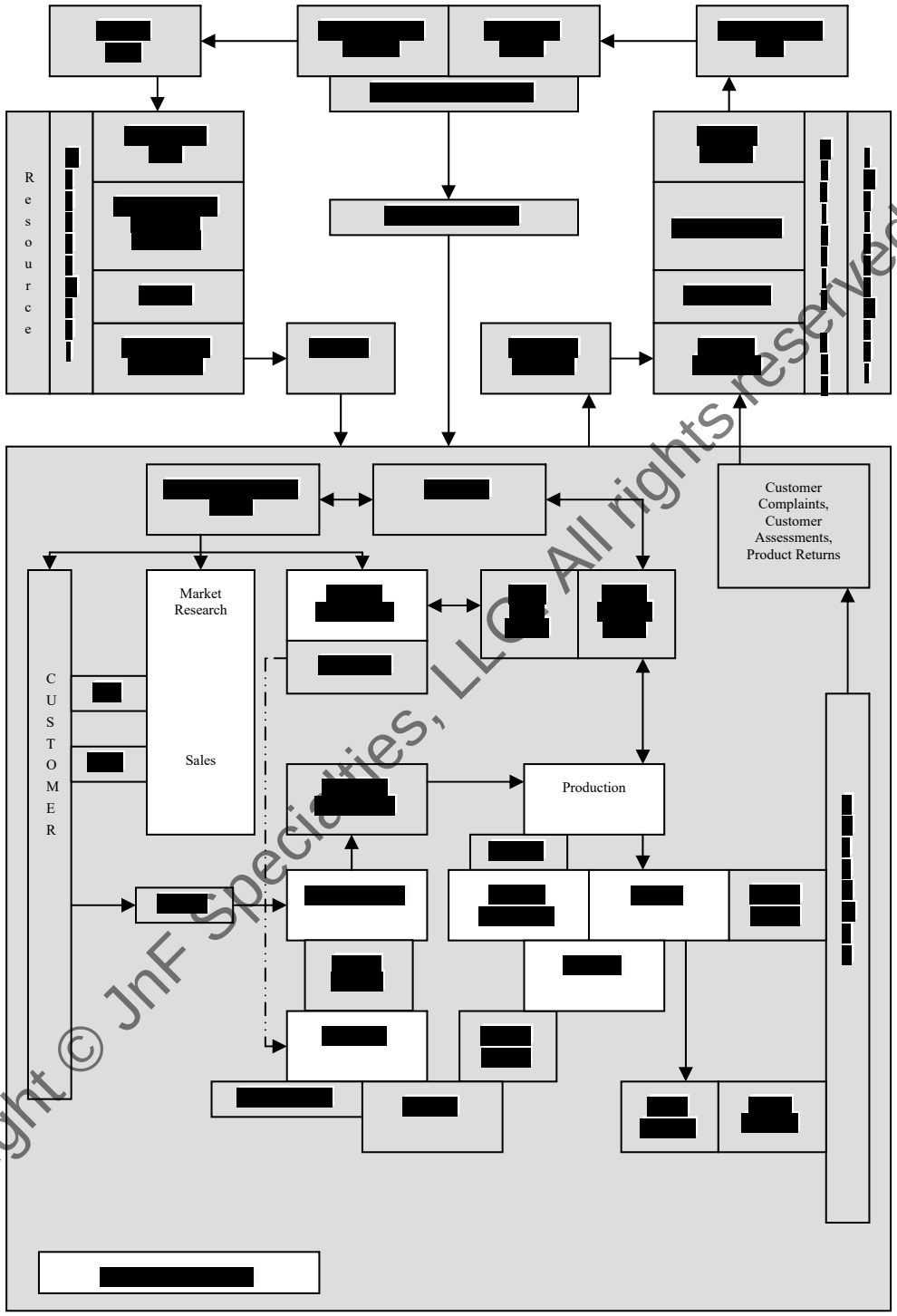
The following processes are outsourced and controlled as indicated:

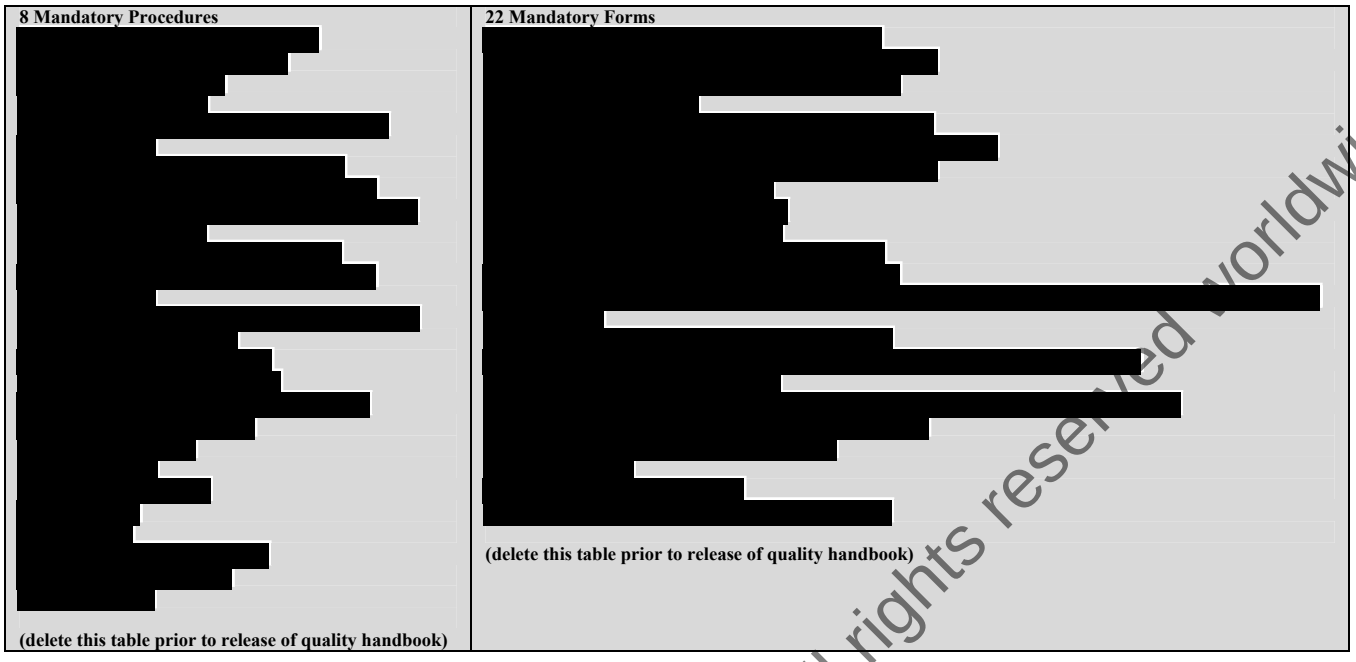
- [redacted]
- [redacted]
- [redacted]

Appendix D: Quality Objectives

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

Appendix E: Identification of Key Realization Processes





Add to Cart