Quality Management System Plan

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Revisions		Rev:	Orig
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Used On	Contract#:		**Your Company Name**
Prepared By:			
			QMS PLAN
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1.0 SCOPE

One lesson learned is the importance of utilizing proper planning when designing and implementing a Quality Management System (QMS). This Plan builds upon that lesson by [redacted]

This Plan utilizes the "Process Approach" for development and improvement by identifying processes; [redacted] This Plan focuses on Customer satisfaction. It is important to design, implement and maintain a quality management system [redacted]
This includes greater attention to [redacted]
It is no longer good enough to [redacted] but also to [redacted]

The intent of a QMS is:

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

This Plan expects Auditors to audit based upon [redacted]
The COP is a model that refers to [redacted]

This is accomplished by [redacted]

2.0 PROCESS APPROACH

For the Company to function effectively, it has to [redacted]

An activity using resources that is managed to enable [redacted]

a system of processes within the Company, together with [redacted] referred to as the **"process approach".** An advantage of the process approach is [redacted] When used within a quality management system, such an approach emphasizes the importance of:

a) [redacted]
b) [redacted]

c) [redacted]
d) [redacted]

This is typically achieved by [redacted] all the requirements in the quality manual. Heritage quality management systems created an elemental structure of policies, procedures and work instructions but often failed to [redacted]

2.1 Quality Management System Requirements

the Company shall:

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

This is typically documented using the "process approach" through [redacted] or [redacted] This Plan focuses on the approach that the Company uses to [redacted]

2.2 QMS Basics

Management commitment

Top management shall provide evidence of [redacted] continuously improve its effectiveness by:

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

Process efficiency

Top management shall review the product realization processes and support processes to assure [redacted]

Quality objectives

Top management shall ensure that quality objectives, including [redacted]

Customer representative

Top management shall designate personnel with responsibility and authority to ensure that Customer requirements are addressed. This includes [redacted]

Internal communication

Top management shall ensure that appropriate communication processes are established and communication [redacted] to promote innovation. The process shall include [redacted]

Infrastructure

the Company shall determine, provide and maintain [redacted] as applicable:

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

Customer communication

the Company shall determine and implement effective arrangements for communicating with Customers in relation to;

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

Product design input

the Company shall identify, document and review the product design input requirements, including the following:

– [redacted]
– [redacted]
– [redacted]

Manufacturing process design input

The Company shall identify, document and review the manufacturing process design input requirements, including:

–
–
–
–

Manufacturing process design output

The manufacturing process design output shall be validated.

The manufacturing process design output shall include:

–
–
–
–
–
–
–
–

Supplier monitoring

Supplier performance shall be monitored through the following indicators:

–
–
–
–

The Company shall promote Supplier monitoring of the performance of their manufacturing processes.

Measurement, analysis and improvement – General

The Company shall plan and implement the monitoring, measurement, analysis and improvement processes needed

a)
b)
c)

This shall include

Internal Auditor qualifications

The Company shall have internal Auditors who are qualified to audit the requirements of the QMS.

Manufacturing process improvement

Manufacturing process improvement shall continuously focus upon [redacted]

Note 1: Controlled characteristics are documented in a control plan.

Note 2: Continuous improvement is implemented once manufacturing processes are capable and stable, and when [redacted]

2.3 Benefits of Using the Process Approach

- [redacted]

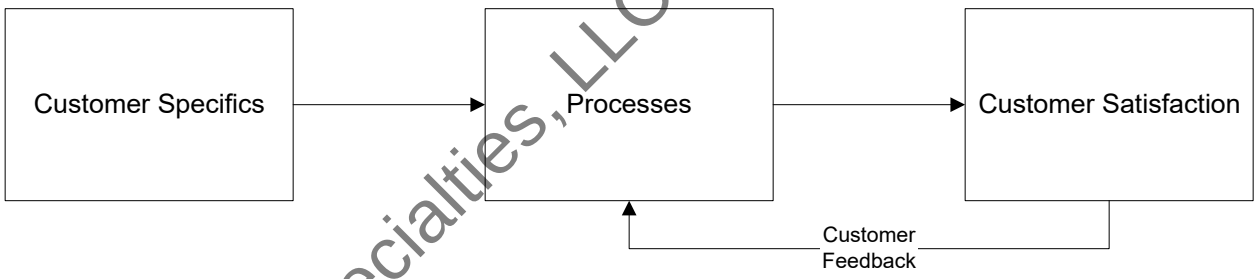

Figure 1: Alignment to Customer Metrics

2.4 What is a Process?

A process is a set of interrelated or interacting activities that transforms inputs into outputs. Inputs to a process are generally outputs from another process. Processes are normally planned and carried-out under controlled conditions.

Figure 2: Simplified Process Model

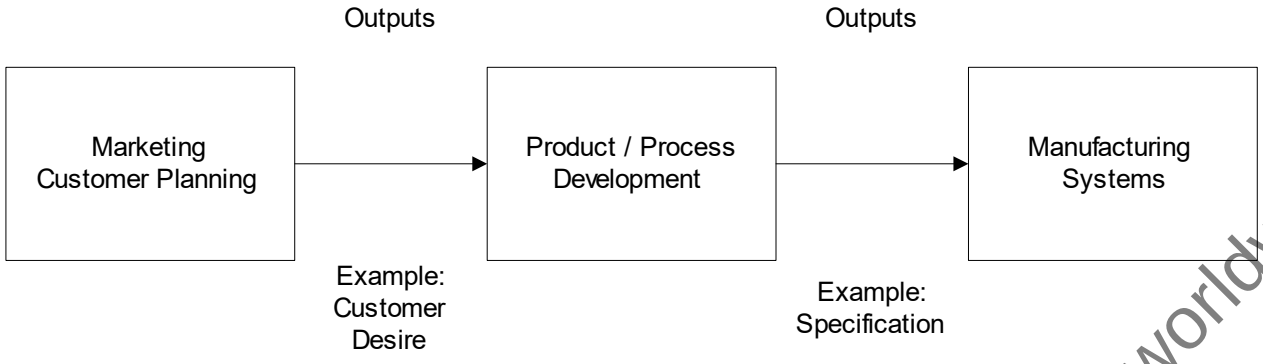

Figure 3: Interactions between Processes

2.5 Building Blocks of a Process

A process is a sequence of actions and responsibilities that include the following areas:

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

Figure 4: Process based QMS

2.6 The Process Approach

The process approach is a methodology for the design, implementation and maintenance of the Quality Management System. This method identifies Methods may include

The heritage elemental approach structures a QMS by element (vertical integration). These elements are then typically audited as described in the *Quality System Assessment Checklist*. This approach typically does not consider This approach is not focused on Customer satisfaction – it is focused on satisfying requirements.

Figure 5: Heritage Process Approach

The modern process approach structures a QMS around [redacted] the sequence and interactions, the QMS can then [redacted] The following figure shows attributes of each process that need to be reviewed during a process audit.

The modern process approach applies a common set of attributes for major processes and interactions: [redacted]
(see Map for Process Based QMS shown above).

[redacted]

Figure 6: Modern Process Approach

3.0 SETTING UP THE QUALITY MANAGEMENT SYSTEM

3.1 Step 1 – Process Identification

The Company shall identify the processes needed for the quality management system and their application throughout the organization. The Company needs to show how [redacted] *Internal Process Mapping* (a Microsoft Excel-based mapping tool) provides step-by-step instructions on how to identify the processes in the Company and how to map internal processes to the requirements of the QMS.

Note: *Internal Process Mapping* is to be used to map processes and is not recommended for [redacted] The tool will assist the Company to identify where in the QMS each requirement is addressed.

The Auditor then focuses on [redacted]

3.2 Step 2 – Process Mapping

The Company shall determine the sequence and interactions of processes. The Company needs to show how its process inputs → process steps → process outputs interact in a logical sequence to meet the requirements of the QMS. Another term for this step is called "process mapping". Once the Company's processes have been mapped to the requirements, the Company will [redacted] through its natural workflow.

Figure 7: Typical Process Flow

3.3 Step 3 – Effectiveness

The Company shall determine criteria and methods needed to ensure that both the operation and control of processes is effective. Effectiveness is defined as, [redacted] When mapping the process, review the process outputs to inputs. Compare the outputs of the process to [redacted] These metrics are used to [redacted]

3.4 Step 4 - Auditing

Three types of audits are required by the QMS:

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

All of these audits must be conducted using the process approach. Internal Auditor qualifications are defined as: [redacted]

The basic steps in a process approach audit can include:

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

If the product / process meet specification with no negative trends:

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

If the product / process do not meet specification nor has negative trends:

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

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- if the process involves manufacturing:
  - [redacted]
  - [redacted]

These three types of audits are interrelated, as shown below:

Internal Audit Plan

[redacted]

Figure 8: Audit Types Build Upon Each Other

- A **Quality Management System Audit** uses [redacted]
- The **Manufacturing Process Audit** focuses on [redacted]
- The **Product Audit** focuses on [redacted]

The three types of audits required by the QMS may be performed as separate or combined events as shown below.

Figure 9: Audit Flow Diagram

3.4.1 Quality Management System (QMS) Audit

The first step in implementing the QMS is to assure that the QMS is in compliance to all requirements including [redacted] This may be accomplished by using *Internal Process Mapping.* The second step is to assure [redacted] An example of this would be [redacted] The complete list of processes can serve as an audit check sheet to ensure [redacted] It is critical to verify [redacted] The audit should include focus on [redacted]

3.4.2 Manufacturing Process Audit

The Company shall audit each [redacted] defined by the Company, often in the form of control plans. The Company also defines [redacted]

[redacted] All types of processes must be audited. For example, if [redacted] provided measurement indicators show no difference [redacted] emphasizes the importance of [redacted] The following key indicators are addressed:

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

The manufacturing process may include interfaces/linkages between or among the following:

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

Note: The manufacturing process audit may use [redacted] An example of a typical manufacturing process audit flow diagram is shown below.

Figure 10: Manufacturing Process Audit Flowchart

3.4.3 Product Audit

The Company shall audit products at appropriate stages of production and delivery at a defined frequency to verify conformity to [redacted] such as [redacted] As shown below, this type of audit [redacted] lead to [redacted] The product audit monitors the product

[redacted] to the next. The physical part measurements of the product audit can be used to [redacted]

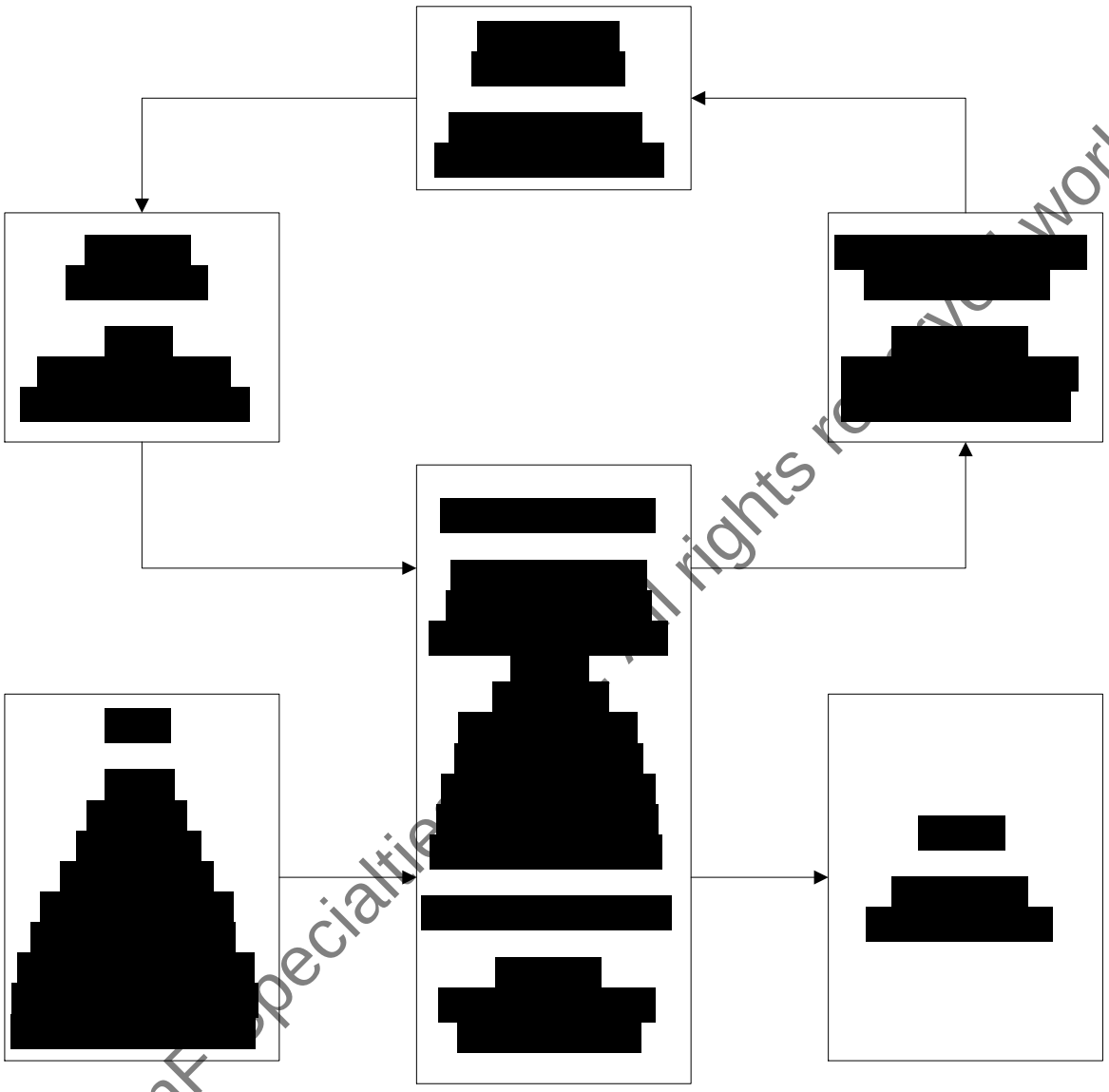

Figure 11: Product Audit

Using the process audit approach, the output of the product audit [redacted] can see how the product audit [redacted]

3.4.4 Internal Audit Plans

Internal audits shall cover all [redacted] according to an annual plan. When internal/external nonconformities or Customer complaints occur, the audit frequency shall be appropriately increased." The annual plan(s) defines [redacted] In determining the frequency of audits, the status and importance of the processes and areas to be audited is taken into account as well as [redacted]

3.5 Step 5 – Documentation to Certification Body

If the Company elects to become registered, the Company must first provide the following information to the Certification Body:

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

Putting the Process Approach into Use

By following the natural flow from function to function and process to process and comparing the actual process with Customer requirements and metrics, the Company can [redacted] The output of the auditing process is the audit report. The audit report is an important input into the management review process.

4.0 STRATEGY FOR IMPLEMENTING THE QMS

Objective: The objective of this section is to [redacted]

Strategy:

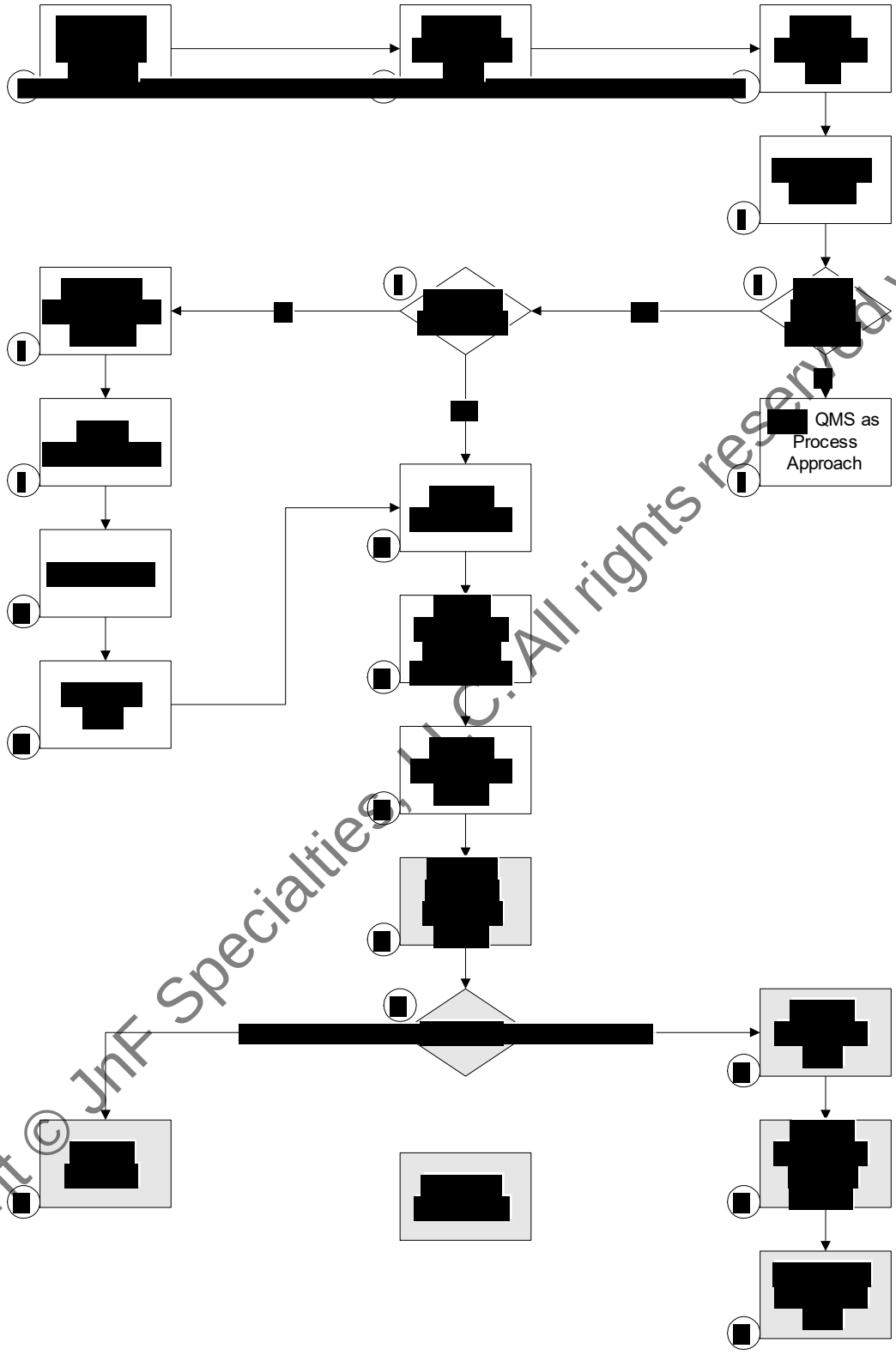

Figure 12: Implementation Map

1. Identify and Understand What Is New: The first step is to identify and understand the new QMS from the Company's current quality management system requirements. It is recommended that key individuals [redacted]

2. Determine the Scope of the Quality Management System: The Company will need to determine what the scope of the quality management system and their certification will be. The following may be considered:

- [redacted]
- [redacted]

The QMS may address many different mandatory requirements for several industries – several certifications may be required.

3. Develop a Transition or Certification Plan: Once the scope of the Company's quality management system has been determined; it is time to develop a plan to guide the Company through the transition and/or certification process. The transition plan should include [redacted] It is recommended that the Company review timeline requirements with their certification body, taking into consideration [redacted]

Note: Not every qualified certification body is recognized to audit every industry standard.

4. Perform a Gap Analysis: A gap analysis should be conducted to determine the conformance of the Company's current QMS to the requirements of the new QMS. *Internal Process Mapping* provides guidance to help the Company [redacted] Use of this tool or equivalent will allow the Company to [redacted]

5. Determine if the QMS Reflects the Process Approach: If the QMS reflects the process approach, proceed to step 7. If not, proceed to Step 6.

6. Align the Quality Management System to Reflect the Process Approach: If the Company's QMS does not reflect the process approach, the Company will need to [redacted] as described in step 5. Although at first impression it may appear that the QMS [redacted] process mapping will identify [redacted]

Hint 1: In realigning the QMS to the process approach, it is recommended that [redacted] since use of those [redacted] reinforce the habit of the heritage elemental approach.

Hint 2: Documentation of processes can be a variety of formats such as [redacted] can also often effectively communicate the needed information.

7. Determine if All Requirements of the new QMS Are Met: Review the results of the gap analysis performed in step 4 and determine [redacted] that the current system reflects the process approach (Step 5) then [redacted]

8. Determine the Documentation Strategy: Some modification to quality system documentation will be necessary to meet the requirements of the new QMS using one or more of the following strategies:

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

Note: These strategies are not listed in any order of preference and the Company should [redacted]

9. Revise, Reference or Create the QMS Documentation: Once the Company's documentation strategy has been determined the documents must be updated. The development or modification of any QMS documents should be done using [redacted]

10. Train Employees on the New QMS: The Company will have to provide training to personnel to ensure [redacted] may require training:

- [redacted]

In general the following applies:

New QMS States	Top Management Role
Top management shall ensure…	[redacted]
Top management shall review…	
Top management shall provide…	
Top management shall define…	
Top management shall appoint / designate…	

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

11. Implement the QMS: After everyone has been trained on the new QMS and their responsibilities, it is time to implement the new system using [redacted]

- **Phased-in Approach:** Implementation of selective QMS processes and procedures during one phase and when they are up and running implementing some more processes and procedures in another phase. This method continues until [redacted]

[redacted] The order of implementation should consider [redacted]

Advantage

- [redacted]

Disadvantage

- [redacted]

- **Complete Implementation Approach:** Complete all QMS processes and procedures and transition [redacted] if applicable, are removed from service simultaneously.

Advantage

- [redacted].

Disadvantage

- [redacted]

12. Conduct Internal Audits: The entire QMS is audited [redacted] to the new QMS and Customer-specific requirements.

13. Correct Deficiencies and Verify the Effectiveness of Solutions: The Company must correct all deficiencies identified during the internal audit. Implement the corrective action process to ensure [redacted] Where deficiencies do not result in nonconformance but [redacted] should be made to [redacted]

14. Conduct Management Review: Once the audit has been conducted and the deficiencies corrected and verified, all [redacted] of the required information and determines if the QMS meets expectations. Expectations include [redacted] For example, quality system metrics may be reviewed monthly with summary reviews conducted as needed.

STEPS 15 THROUGH 20 ARE CONDUCTED BY THE REGISTRAR

15. Document Review: When top management believes that the Company is in conformance with requirements and is operating effectively, it is time to [redacted]

Note: If the Company used Internal Process Mapping to demonstrate equivalence of its Quality Management System to the requirements of the QMS, this information may [redacted]

16. Determine if a Pre-Audit of the QMS Should Be Conducted:
A pre-audit of the QMS prior to a certification audit may be performed. Pre-audits assess [redacted] The pre-audit is strictly optional; however, [redacted]

17. Conduct Pre-Audit (optional): Conduct a pre-audit to determine [redacted]

18. Conduct Certification Audit: When the Company is ready for certification, a recognized certification body conducts the audit.

19. Conduct Surveillance Audit at Appropriate Intervals: The Company shall provide the following documentation to the certification body for review and for use in planning the audit:

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

The certification body analyzes the Company's documentation to plan the audit.

Note: Operational performance trends should include [redacted]

20. Conduct the Re-certification Audit: Most certifications are limited to three years. Recertification audits require [redacted]

5.0 IMPLEMENTATION PITFALLS TO AVOID

Main Issue: Eligibility for Certification
Pitfall to Avoid: [redacted]
Reason to Avoid: [redacted]

Stage/Topic: Pre-Audit
Main Issue: Scheduling of Multiple Sites
Pitfall to Avoid: [redacted]

Reason to Avoid: [redacted]

Stage/Topic: Pre-Audit
Main Issue: Pricing
Pitfall to Avoid: [redacted]

Reason to Avoid: Common things that are overlooked include:
1.) [redacted]
2.) [redacted]
3.) [redacted]

Stage/Topic: Preparing the QMS
Main Issue: Understanding the Process Approach
Pitfall to Avoid: [redacted]

Reason to Avoid: [redacted]

Stage/Topic: Preparing the QMS
Main Issue: Measuring the Process
Pitfall to Avoid: [redacted]

Reason to Avoid: [redacted]

Stage/Topic: Preparing the QMS
Main Issue: Effectiveness

Pitfall to Avoid: [redacted]

Reason to Avoid: [redacted]

Stage/Topic: Preparing the QMS
Main Issue: Proper Training
Pitfall to Avoid: [redacted]

Reason to Avoid: [redacted]

Stage/Topic: Preparing the QMS
Main Issue: Customer Requirements
Pitfall to Avoid: [redacted]

Reason to Avoid: [redacted]

Stage/Topic: Preparing the QMS
Main Issue: Clarification of Requirements
Pitfall to Avoid: [redacted]

Reason to Avoid: [redacted]

Stage/Topic: Preparing the QMS
Main Issue: Using Checklists and other Audit Tools
Pitfall to Avoid: [redacted]

Reason to Avoid: [redacted]

[redacted]

Stage/Topic: During the Audit
Main Issue: Customer Performance Metrics
Pitfall to Avoid: [redacted]

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

Reason to Avoid: [redacted]

Stage/Topic: During the Audit
Main Issue: Management Responsibility
Pitfall to Avoid: [redacted]
Reason to Avoid: [redacted]

Stage/Topic: During the Audit
Main Issue: Documentation Requirements
Pitfall to Avoid: [redacted]

Reason to Avoid: [redacted]

Stage/Topic: During the Audit

[redacted]

Reason to Avoid: [redacted]

Stage/Topic: 3rd Party Auditors
Main Issue: Value Added Audits
Pitfall to Avoid: [redacted]

Reason to Avoid: [redacted]

Stage/Topic: 3rd Party Auditors
Pitfall to Avoid: [redacted]

Reason to Avoid: [redacted]

APPENDIX A – INTERNAL PROCESS MAPPING

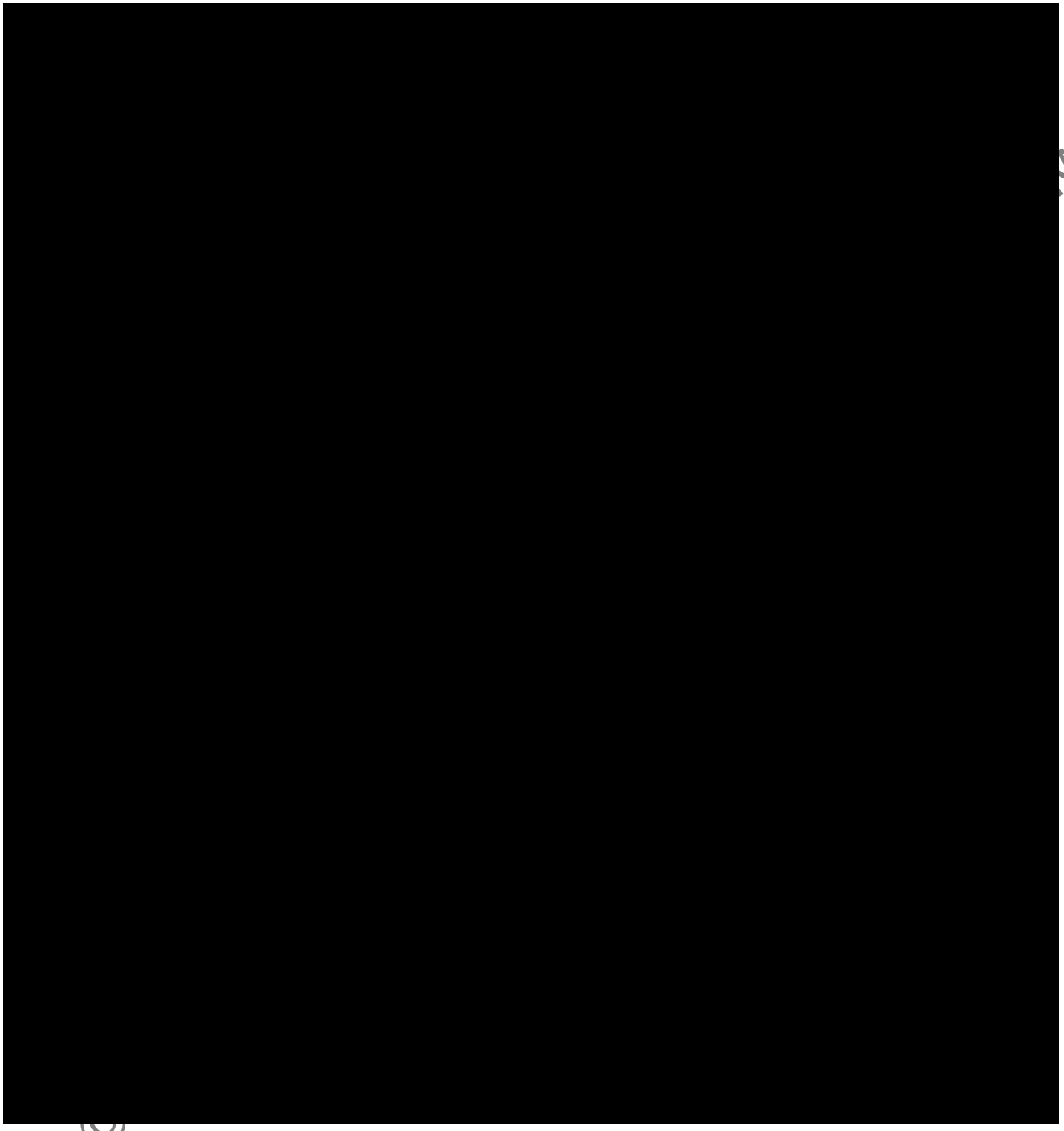

Figure 13: Internal Process Map

The Company shall identify the processes needed for the [redacted] processes in the Company and how to map those [redacted]

DETAILED INSTRUCTIONS

Note: This is only suggested for use in the initial mapping of processes to the requirements of the QMS and not as an audit tool. All QMS summaries are [redacted] Third party Auditors determine compliance to the requirements of the QMS.

Purpose

The purpose of this Tool is to [redacted]

Prerequisite

Before using the Tool, the Company must identify the following:

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

TIP: Not all Customer Oriented Processes are [redacted]

4. For each process:

TIP: These process attributes are shown in the following figures, which are two ways to look at the same process model.

a. [redacted]

b. [redacted]

TIP: Inputs and outputs define the majority of the process interactions. Measurements or other process attributes might also result in interactions (e.g., a measurement in one process might be an input to another).

c. [redacted]
d. [redacted]
e. [redacted]
f. [redacted]

Figure 14: Process Attributes-1

Figure 15: Process Attributes-2

To complete the following steps, the Company must define [redacted] a series of process flowcharts or a graphic of functional structure or a text listing of processes with attributes.

Now we can begin to map the processes to the QMS.

Mapping the Requirements to the Company Processes

1. [redacted]
2. [redacted]

Table 1: Major Sections of the QMS

Section Number from QMS	Title of Section (tab in Excel workbook)	Summary/Intent of the Section
4.0	Quality Management System	The Company documents its requirements as appropriate. The quality system includes quality manual, controlled documents, specifications and records.
5.0	Leadership	Management establishes systems to drive the Company to meet Customer requirements. Significant Management involvement is required (walk the talk).
6.0	Planning	Planning for the quality management system includes consideration of the context of the organization and the needs and expectations of interested parties.
7.1	Resources	Management ensures that the appropriate personnel, skills, infrastructure, facilities, materials and equipment are available to complete the job to specification.
8.3	Design and Development	All processes and product are designed using appropriate planning techniques, including, for example, FMEAs and control plans. All Customer requirements are managed, including special characteristics. All changes to the approved processes and product are to be reviewed by the Customer.
8.4	Control of externally provided	The Company ensures that purchased products and services meet requirements. Compliance

Section Number from QMS	Title of Section (tab in Excel workbook)	Summary/Intent of the Section
	processes, products and services	checks may include incoming quality, onsite reviews and other methods of Supplier monitoring and/or development.
8.5	Production & Service	The Company manages its production processes through control plans, work instructions and job setup, and focuses on preventive measures of production management rather than reactive correction.
9.1	Monitoring, measurement, analysis and evaluation	The Company manages its measurement systems and equipment to ensure that appropriate measurement capability is used. The Company measures process inputs, outputs and applicable process steps using appropriate equipment, audits or other methods. This information is analyzed using appropriate statistical or other techniques.
10.3	Continual improvement	The Company continually improves the suitability, adequacy and effectiveness of the quality management system
Supplemental Requirements	Control Plan	Control plans are managed and contain elements as specified by requirements.

The high-level Customer Oriented Processes and other high-level processes are [redacted]

Copy the high-level process names from [redacted] a more suitable method; there may be advantages or disadvantages.

The next step is to go to each of the 9 natural groupings from Table 1 in turn [redacted] For example, in Quality Management Systems, there are [redacted] processes that address the overall requirements. For example, [redacted] List all the processes or evidence that primarily meets the summarized requirements of each heading.
Note: Not all requirements in the QMS are addressed by processes. Some requirements may be addressed by [redacted]

Each major Section worksheet can be filled-in by identifying the processes by each major (bolded) heading.
TIP: The Example Section tab shows a partially filled out worksheet.

Once all these highlighted headings have been mapped to the Company processes, the next step is to [redacted]

Once this is done for every line item requirement for all 11 natural groupings, there may exist the following:

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

Once all line item requirements have been addressed, [redacted]

The registrar can then use [redacted]

NOTE:
Internal Process Mapping is to be used only [redacted] all audit planning must be conducted by [redacted]

Once complete, the column containing the QMS topics may [redacted] complete QMS coverage.

APPENDIX B - HEAT TREAT PROCESS EXAMPLE

The purpose of this Appendix is to provide an example of the four attributes of a process in the case of the development of the re-arrangement of a heat treat process in an existing manufacturing line:

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

Process: [redacted]
Product: [redacted]
Customer requirement: [redacted]
Customer: [redacted]

Management Responsibility

Definition: [redacted] ABC's management realizes [redacted] within 10 days to meet the plant requirements and have no negative cost implications. ABC management engages the employees to design the process change while meeting the following:

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

Resource Management

Definition: [redacted] The team selects appropriate tools for [redacted] the team must also consider [redacted] The team replaces [redacted]

Note: Knowledge may be developed by

Product Realization

Definition:

The team defines a plan to

represent the other products using the line to

are considered by the team:

Once the Customer

design of the modified line must :

-
-
-
-
-
-

Measurement, Analysis and Improvement

Definition:

In the example of the modified several phases exist where measurement can be applied:

-
-
-
-

- [redacted]
- [redacted]

Not all requirements in the QMS need to [redacted] explain the applicability of each requirement. In general, where measurements are made, the following apply in every case:

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

In addition to the above generally applied requirements:

For this example of the process of designing [redacted] the capability of the line, but are not the product of this example process. The following shows [redacted] Where the specifications are received:

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

Validation checkpoints for the development of the new line:

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

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

APPENDIX C - THE QUALITY MANAGEMENT SYSTEM AUDIT

This Appendix gives some examples and guidance on how to conduct a Quality Management System Audit by using the process approach.

Preparation for the Quality Management System Audit

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

Conducting the Process Audit

A process audit approach follows [redacted] it is likely that the source of the poor Customer satisfaction will [redacted] ask about [redacted]

The basic steps in a process approach are:

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

- [redacted]
- [redacted]

These basic steps are followed for any process to determine if the process is effective.

Reviewing Metrics During the Audit

The audit continues by reviewing the metrics.

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

The right focus will lead the Company to improvement in areas most important to the Customer.

Next, the processes contained within the Company are checked to see that they are assigned, executed and are effective. Effectiveness is judged by [redacted] Organizational metrics must incorporate Customer expectations at a minimum - follow the process flow within the Company.

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

The process audit approach reaches beyond [redacted]
The process needs to be followed throughout the Company to be sure [redacted]
The focus is not on performance within each functional silo, but on [redacted] Under the heritage elemental approach, each function [redacted] only to find out [redacted]

Here is an example of what might happen in the Company:

[redacted] As can be seen from the above example, sub-optimization [redacted] greater inefficiency and loss.

Note: Results of the audit are forwarded for management review.

APPENDIX D - THE MANUFACTURING PROCESS AUDIT

This Appendix gives examples or suggestions on how to conduct a Manufacturing Process Audit. Determine the manufacturing processes within the Company (such as product lines, similar processes within locations).

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

Useful tools: [redacted] ask for recent Customer concerns and ask to be shown where those concerns were addressed by updates to the processes.

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

Another helpful tool during the manufacturing process audit is [redacted] Employee motivation and empowerment [redacted] and importance of their activities and how they contribute to the achievement of quality objectives.

- [redacted]
- [redacted]

Other key steps in reviewing the manufacturing process include [redacted]

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

Review the part certification requirements within the manufacturing process for continued effectiveness.

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

APPENDIX E - PROCESS MAPPING EXAMPLES

Objective: The objective of this section is to provide the Company with some examples of how process mapping can be used to help understand the quality management system and its processes to meet the requirements of the QMS.

Mapping the system versus mapping a process

When considering using process mapping as a tool [redacted] the Company should understand [redacted] the second level is then using process mapping of the key processes themselves and their sub-processes if necessary.

Mapping the QMS

The Company shall identify the processes needed for its QMS and its application throughout the organization. The Company shall also determine [redacted] Process mapping the QMS, illustrating the sequence and the key inputs (Customer requirements) and outputs (input to the next process) of each process, is an excellent way for the Company to meet the requirements. Additionally, this allows the Company to [redacted]

Note: Complete process definition should consider: [redacted]

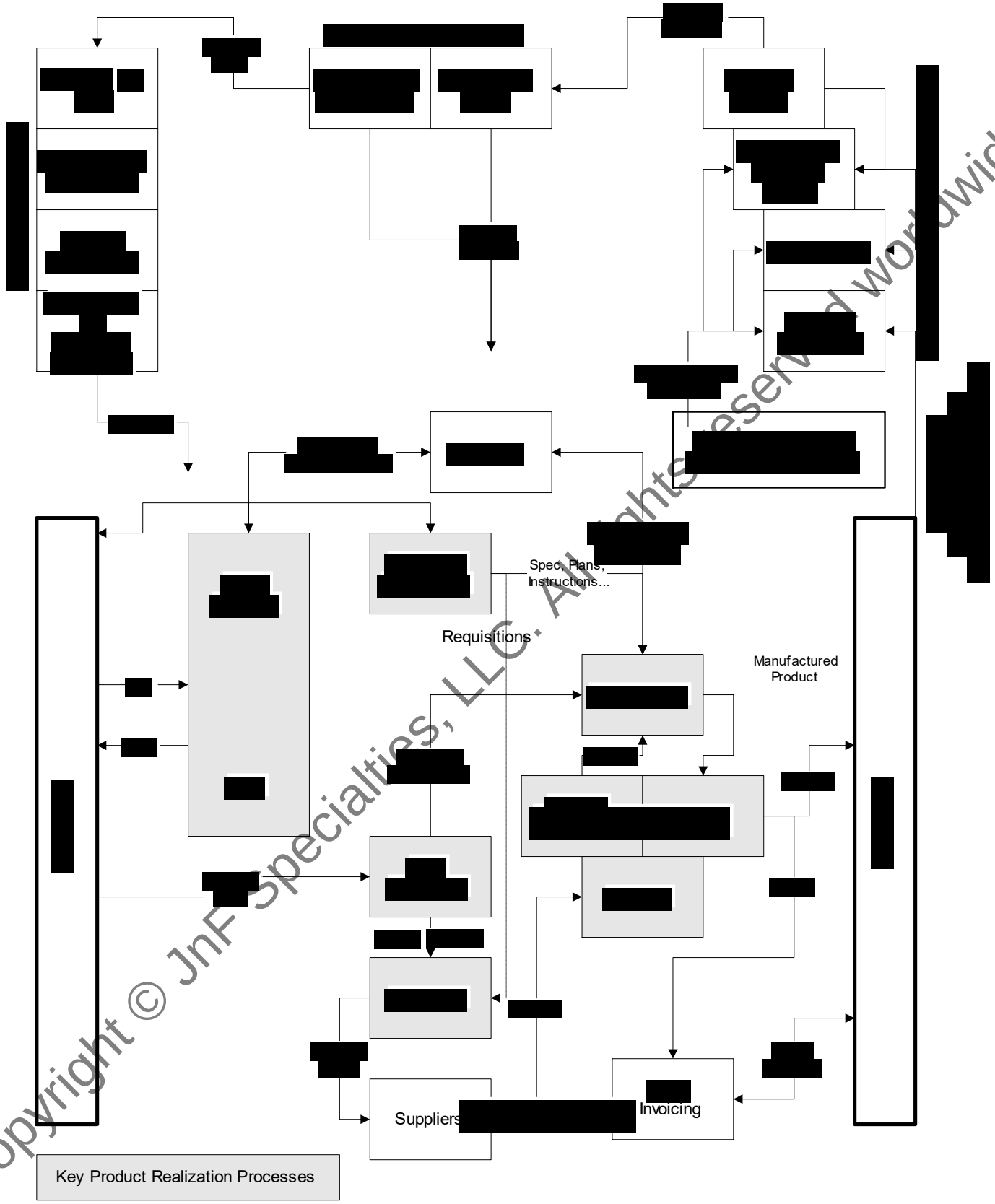

Figure 16: QMS Map

Figure 17: Manufacturing Map

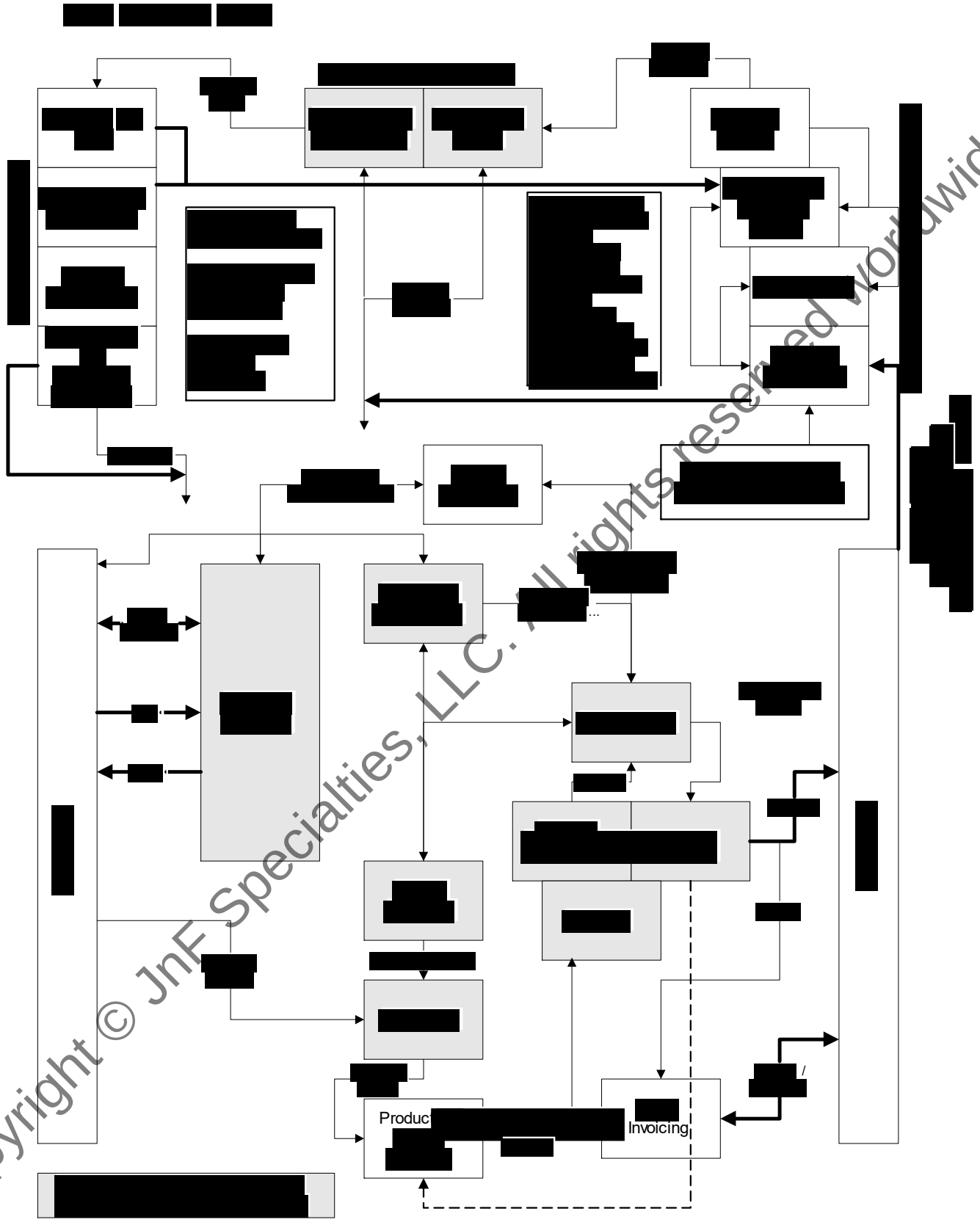

Figure 18: Product Realization Map

Mapping individual processes: Mapping processes can help the Company understand [redacted] redundant steps and other inefficiencies that can [redacted] process improvements and cost reduction. Below is an example of a map at the process level.

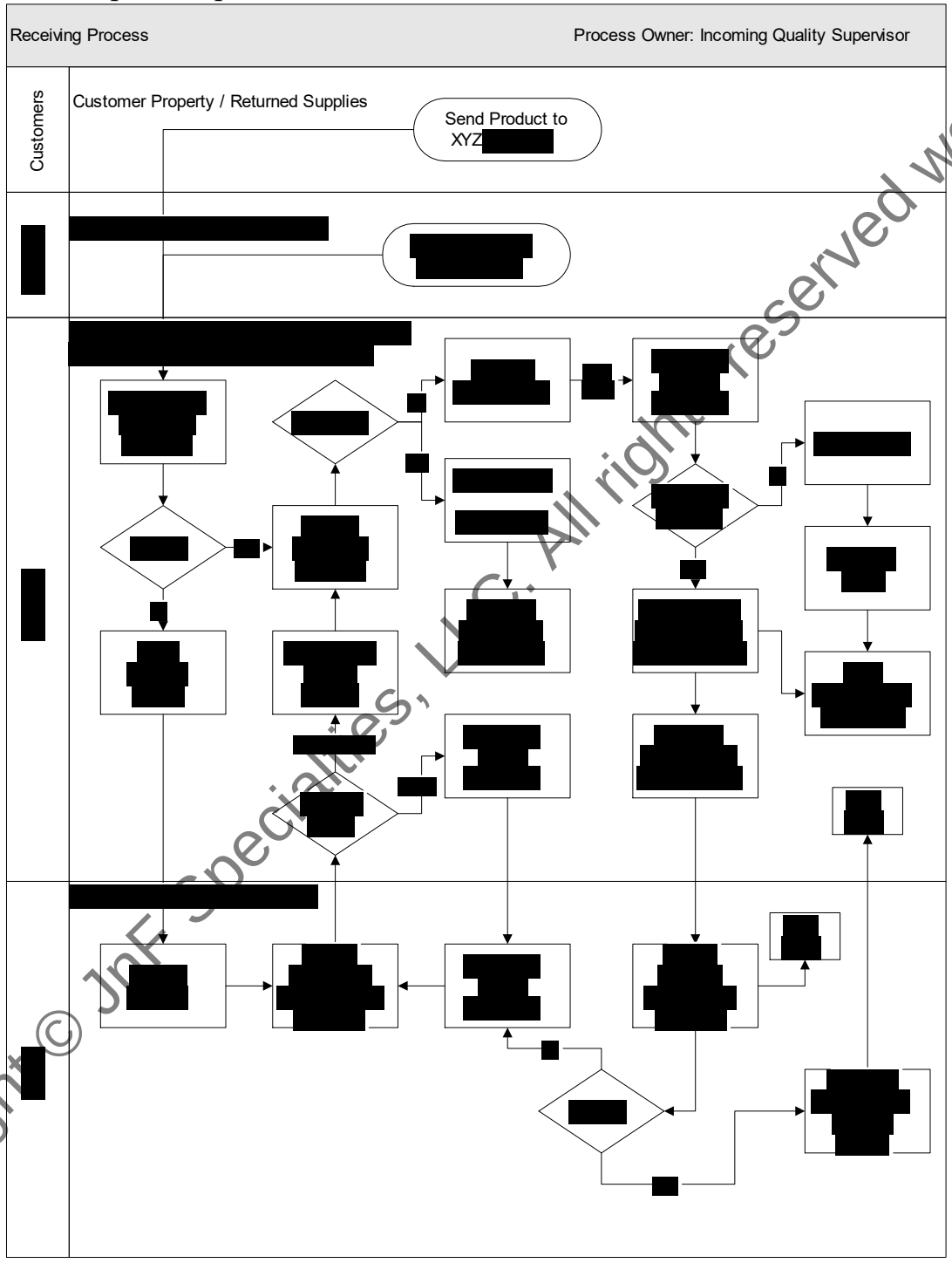

Figure 19: Process Level Map

Key Considerations: There are many different ways to do process mapping and it is up to [redacted] graphical flowcharts [redacted] define a standard set of symbols to be used in all process maps. This will ensure [redacted]

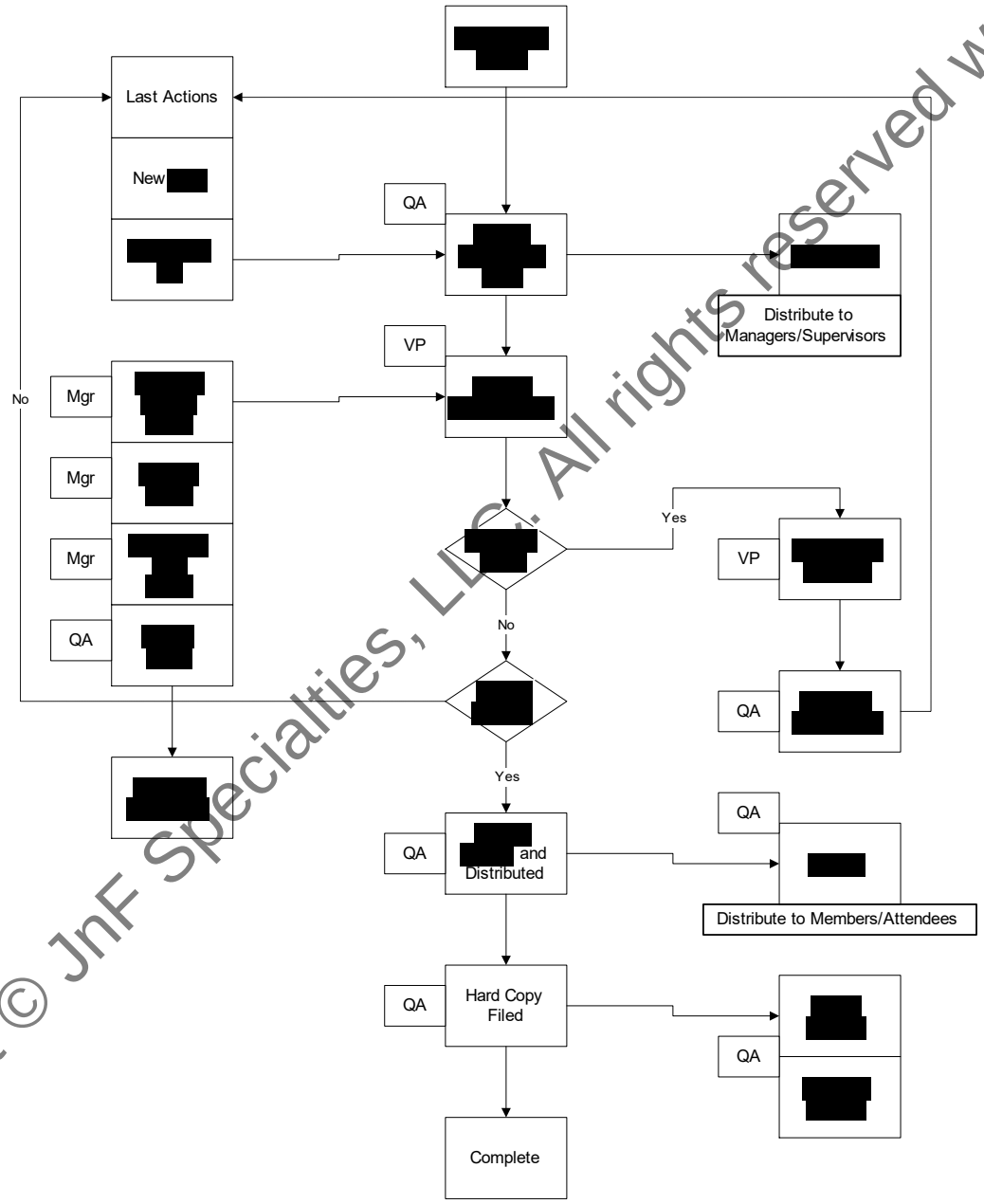

Figure 20: Management Review Map

Figure 21: Request for New Process Map

Process Approach Analysis

Includes information about the following:

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

Explanation

This analysis addresses three important facets of understanding and applying the Process Approach to Management. They include the following:

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

The sequence of and the reasons for the inclusion of the information provided are as follows:

1) [redacted]

2) [redacted]

3) [redacted]

4) [redacted]

5) [redacted]

6) [redacted]

Process Defined

A process is a chain of added value activities that deliver [redacted] the diagram below:

Figure 22: Basic Process

A process has a chain of activities between the two limits as shown by the diagram below:

Figure 23: Expanded Process

Customer Oriented Process Defined

Internal/external interactions between an organization and a Customer:

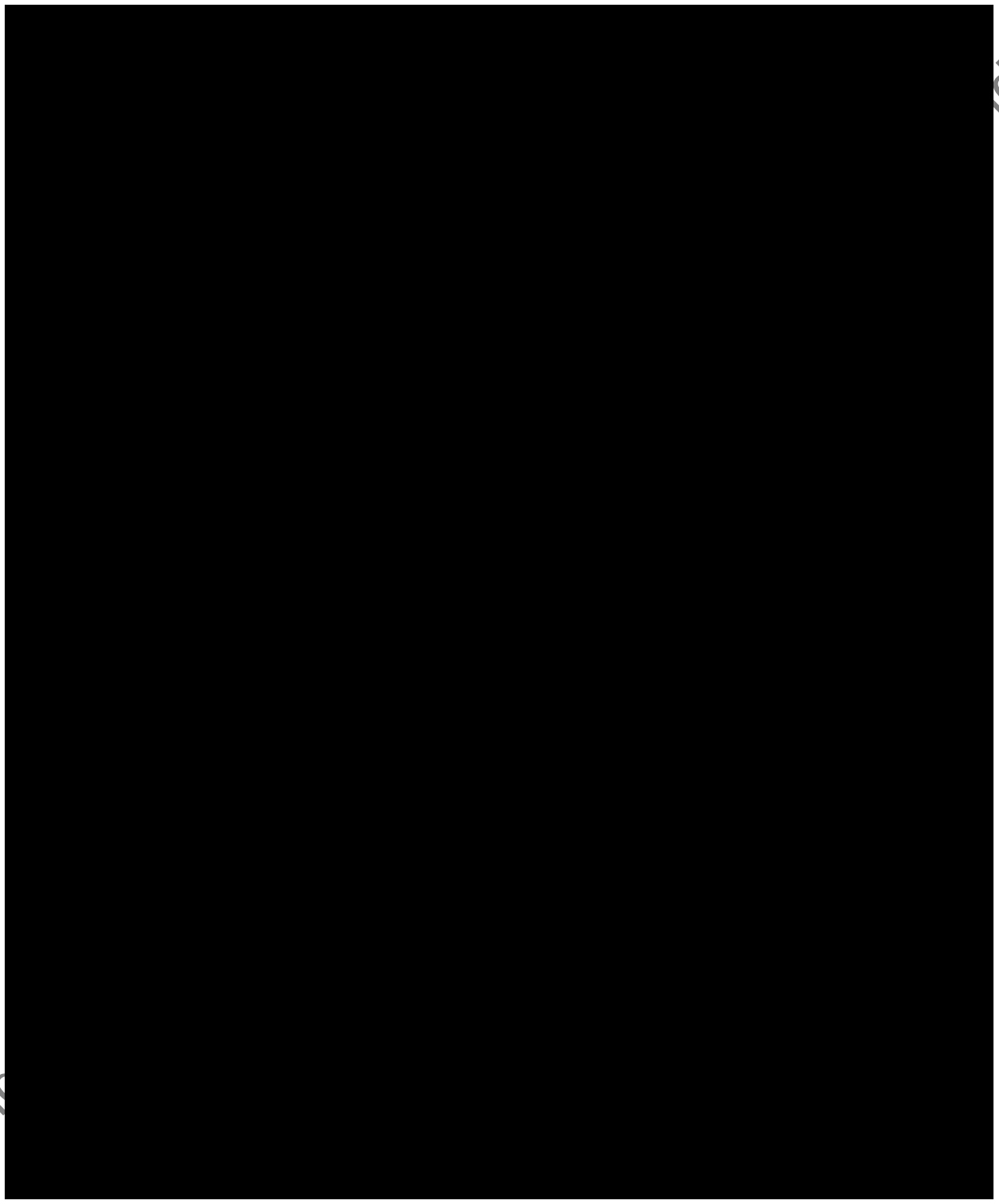

Figure 24: Customer Interactions

List of Customer Oriented Processes:

The following ten COP's are certainly not the only ones an observer would find in a manufacturing organization but they are universal enough to be a good benchmark to begin an identification process with other COP's added as required.

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

Customer Oriented [redacted]

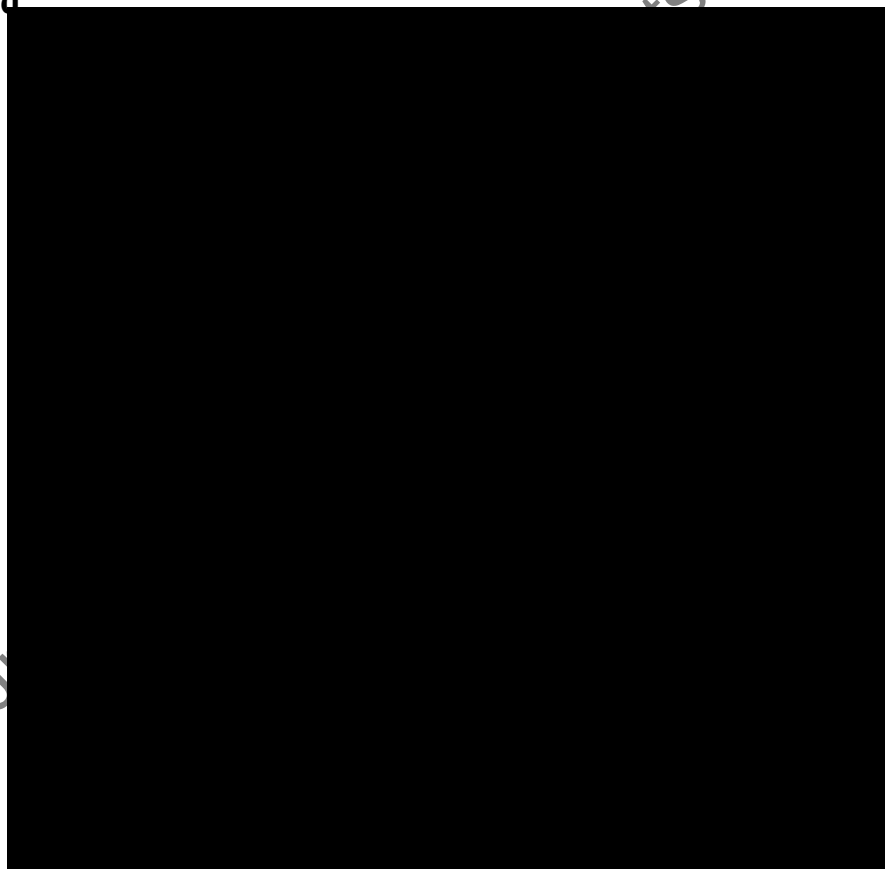

Figure 25: Customer Oriented Process (COP)

The illustration above graphically illustrates [redacted] The number of Customer oriented processes (COP's) depicted in the above diagram [redacted] to illustrate the multiple natures of Customer/organization interactions; [redacted] The model is provided to [redacted]

Example COP Analysis

The following example is provided to obtain a sense of what an application of the process approach might look like.

1: [redacted]

2: [redacted]

2: [redacted]

2: [redacted]

3: [redacted]

3: [redacted]

4: [redacted]

4: [redacted]

5: [redacted]

5: [redacted]

6: [redacted]

6: [redacted]

Process Approach for example:

[redacted]

Figure 26: COP Example

Four Questions about a Process

A useful tool for analyzing processes is displayed below. The tool is often referred to as [redacted]

[redacted] related to the input and output [redacted]

The tool is helpful for both implementation and auditing.

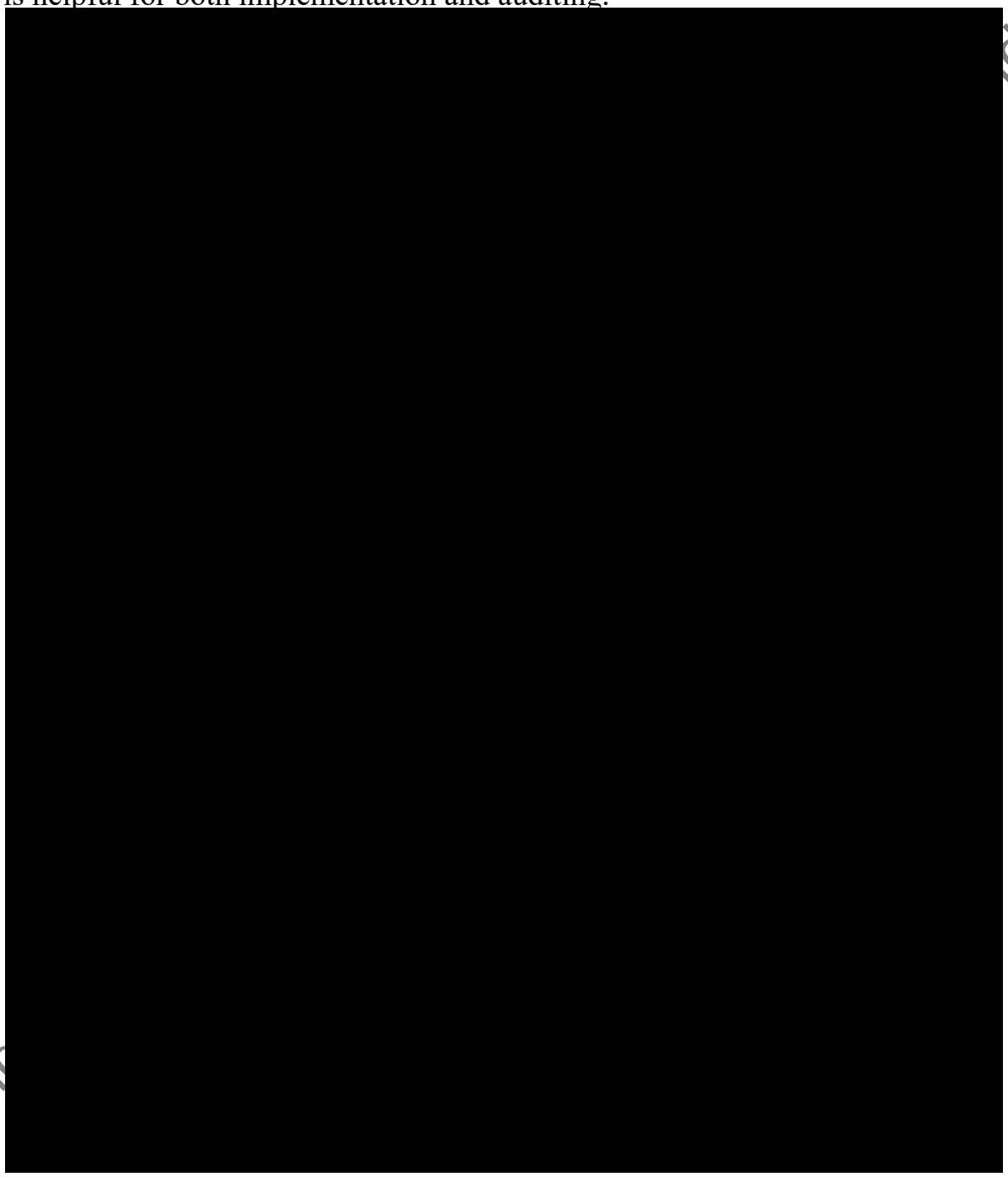

Figure 27: Turtle Map

Four Questions about a Process

Depicted below are four questions applied to one of the COP's from the example - Process 6, Finance - the two questions pertaining input and output are also summarized.

Figure 28: Turtle Example

Process Approach "Turtle" Diagram:

An Analytic Tool for Auditing and Implementation

Below is a simplified version of the tool, which indicate [redacted] the page gives a brief explanation of what is intended for each box.

Section	Details
1	Enter [redacted].
2	Enter [redacted]
3	Enter [redacted]
4	Enter [redacted]
5	Enter [redacted]
6	Enter [redacted] et.
7	Enter [redacted]

Figure 29: Turtle Diagram

Process Approach Audit Worksheet

Below is an explanatory version of the Process Approach Audit Worksheet, which includes [redacted]

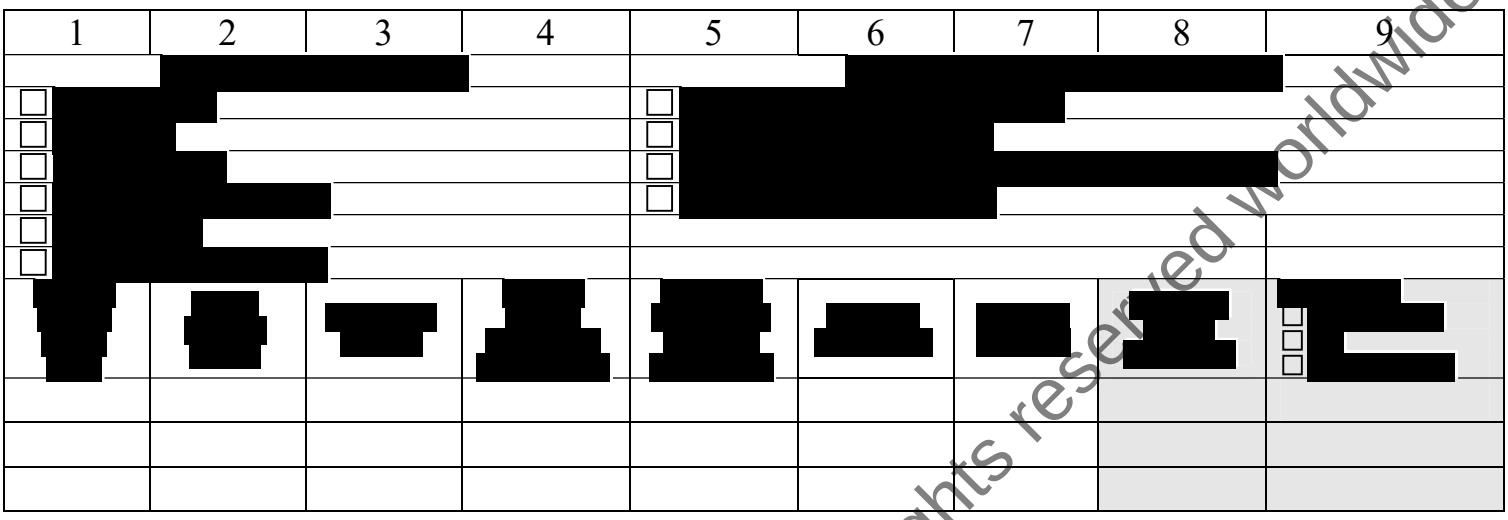

Figure 30: Process Approach Audit Worksheet

Comments about the intent of the Worksheet

[redacted]

[redacted]

The vision for the worksheet is to [redacted] by breaking the audit into [redacted] Once completed this audit "map" could provide information for [redacted]

Other uses of the worksheet could be:

1) [redacted]

2) [redacted]

Either use of the worksheet would provide value to the Company and would take much of the guesswork out of the audit.

Figure 31: Completed Audit Worksheet

APPENDIX F - CERTIFICATION/SURVEILLANCE AUDIT PLAN INSTRUCTIONS

Scope:

The purpose is to provide [redacted] a minimum, [redacted] by an *.

Company Information:

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

Support Site Information:

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

Audit Information:

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

Audit Times:

- [redacted]

Special Items/Issues to be audited:

- [redacted]

Top Management Availability:

- [redacted]

Customer Satisfaction Input:

- [redacted]
- [redacted]

- [redacted]

Update to Customer Satisfaction Input:

- [redacted]

The intent of the process approach is to [redacted] focus on [redacted]

QMS Certification/Surveillance - Process Approach Audit Plan

Company Information	Management Representative
Customer:	
[redacted]	
Debriefs will be scheduled as needed:	
Tentative for Work Lunch:	
[redacted]	

3:00pm	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted] Client Debrief
	Day 2		
Time	Auditor A	Time	Auditor B
6:00am	[redacted]	6:00am	Manufacturing Validation of Process and Product
		[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]		
[redacted]	[redacted]	[redacted]	[redacted]
2:30pm	Auditor Debrief and Caucus		
[redacted]	[redacted]		
[redacted]			
	[redacted]		[redacted]
[redacted]		[redacted]	
	[redacted]		
[redacted]		[redacted]	
	Audit Information		
[redacted]		[redacted]	
[redacted]			
[redacted]			

Audit Times		
Audit Arrival – Opening Meeting:	Day 1	Day Two
Closing Meeting:		

Figure 32: Audit Plan

APPENDIX G - DOCUMENTATION STRATEGY

Strategy One

The Matrix Approach: This documentation approach is an option for the Company to transition from its existing QMS to the new QMS. Many previously certified organizations created [redacted] new standards do not require the Company to change the structure of its existing documentation system. The existing quality system and numbering system for the QMS document and data control can remain the same; however, [redacted]

Benefits

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

Disadvantages

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

Steps to accomplish the matrix approach

a. [redacted]

Note: Ideally, this should be completed to the "shall" level of each requirement. The Internal Mapping Tool may be useful to [redacted]

b. [redacted]

c. [redacted]

Hint: It is a good practice to highlight the new additions.

The following is an example of how Internal Process Mapping may be used to create a matrix that cross-references a system to requirements:

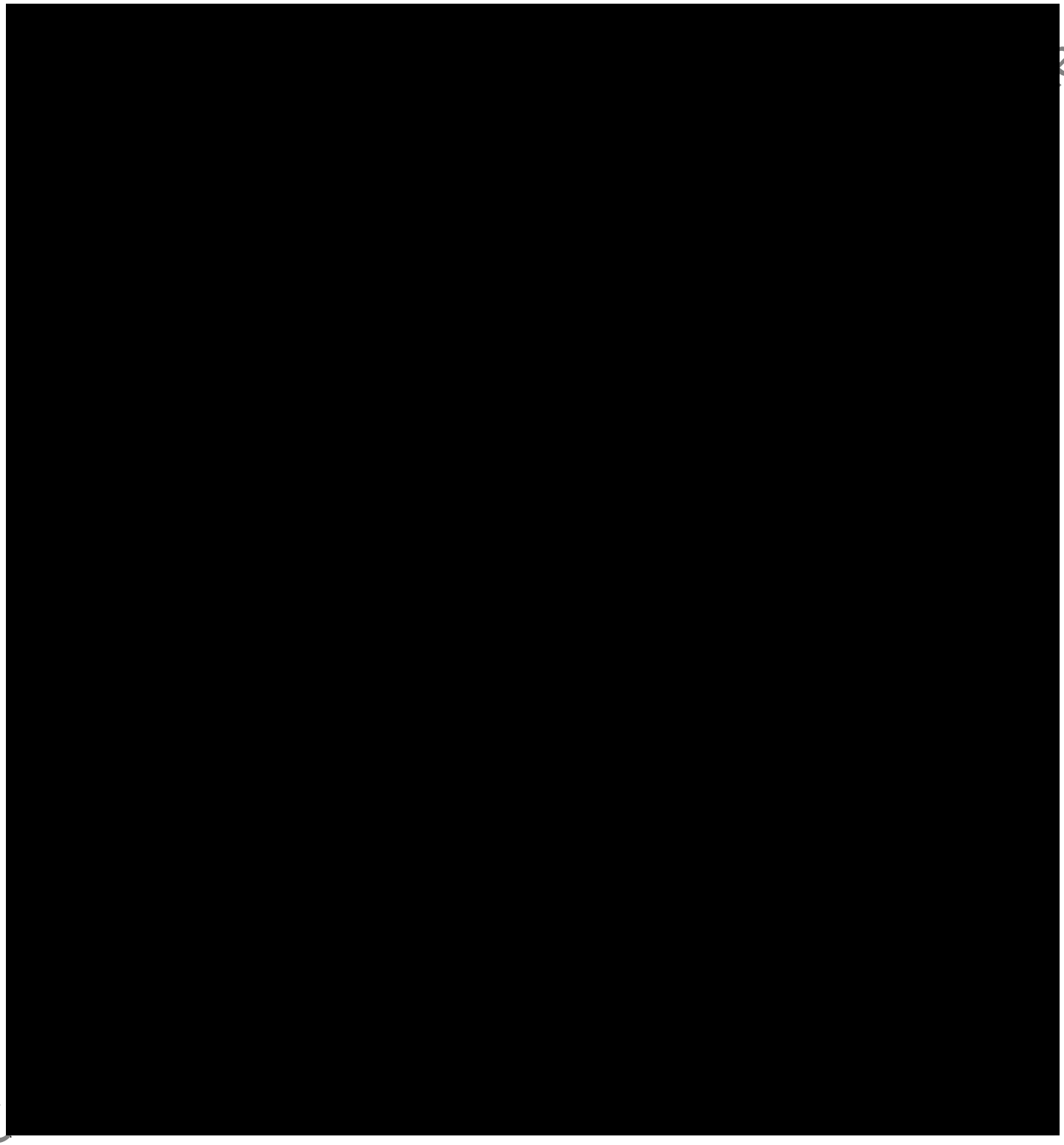

Figure 33: Example of Completed Internal Process Map

Strategy Two

Revise Current Documentation: This is another option for the Company to transition from the old QMS to the new QMS. This approach may work well for the Company to make its document system "lean". The new QMS has [redacted]

Benefits

- [redacted]

Disadvantages

- [redacted]
- [redacted]

Steps to revise documentation

a. [redacted]

b. [redacted]

c. [redacted]

Strategy Three

Create New or Reinvigorate the Existing System:

The Company shall identify where in its processes it is meeting the requirements of the new QMS.

This can be accomplished by [redacted] compliance to

the new QMS, it will show where gaps exist. Any documents or processes or requirements "left over" after this exercise should be reconsidered for relevance to the new QMS or Customer requirements.

Benefits

- [redacted]
- [redacted]

Disadvantages

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

Add to Cart