ISO 9001:2015

Quality Management Systems Documentation

Quality Manual / Documented Information

Document No. QM-001

Street Address

City, State, Zip

Tel,

Cell Phone:

Email:

Web Site:

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Introduction

Your Company developed and implemented a Quality Management System in order to document the company’s best business practices, better satisfy the requirements and expectations of its customers and improve the overall management of the company.

To fully understand the organization and its external and internal issues that are relevant and that affect its ability to achieve the intended results of the quality management system.

The Quality Management System of Your Company meets the requirements of the international standard ISO 9001:2015. The system addresses the design, development, production, installation, and servicing of the company’s products. It incorporates the process approach where consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes.

This process approach provides for the management of the quality system and its processes through the application of a “Plan-Do-Check-Act” methodology and a focus on “Risk-Based-Thinking” leading to the prevention of undesirable outcomes.

The manual is divided into sections that correlate to the Quality Management System sections of ISO 9001:2015. The manual describes the Quality Management System, delineates authorities, inter relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides the documented information with procedures or references for all activities comprising the Quality Management System that ensures the compliance to the necessary requirements of the standard.

This manual is used internally to guide the company’s employees through the various requirements of the ISO standard that must be met and maintained in order to ensure customer satisfaction, continuous improvement and provide the necessary instructions that create an empowered work force.

This manual is used externally to introduce our Quality Management System to our customers and other external organizations or interested parties. The manual is used to familiarize them with the controls that have been implemented and to assure them that the integrity of the Quality Management System is maintained and focused on customer satisfaction and continuous improvement.

The manual is approved by a top management representative.

President: ___________________________ Date: ______________
Section 01  Scope of the Quality Management System

General

To determine and establish the scope of the QMS, Your Company determined the boundaries and applicability of the QMS and considered the external and internal issues, the requirements of relevant interested parties, and the products and services of the company. The scope is available and maintained as documented information stating the products and services covered by the QMS. Your Company applies all the requirements of ISO 9001:2015 when they are applicable within the determined scope of the QMS.

As developed with procedure P-400 for Organizational context, include the scope of your QMS here:

_________________________________________________________________________
_________________________________________________________________________
_________________________________________________________________________

For example, if you are a manufacturer of toys, the scope of your QMS may be:

The scope of the Quality Management System includes the major product and service categories associated with the primary functions of manufacturing wooden toys at the North Pole location and distributing the product to children of all ages.

Conformity to ISO 9001:2015 may only be claimed if the requirements determined as not being applicable do not affect the organization’s ability or responsibility to ensure conformity of its products and services and the enhancement of customer satisfaction.

In the event that any requirement is not applicable at Your Company, justification for any instance where a requirement cannot be applied is documented.

Your Company has determined that the following requirement(s) is/are not applicable to the operations at this site:

_________________________________________________________________________
_________________________________________________________________________

As determined with procedure P-400, identify the requirement(s) that do not apply and document the justification here:

_________________________________________________________________________
_________________________________________________________________________

For example, if you are a manufacturer of toys, a requirement that does not apply may be:

Clause 8.5.5 for post-delivery activities does not apply to the company. Customer feedback has shown that conformity to post-delivery services is achieved with the initial delivery activities.

Section 02  Normative References

There are no normative references.

Section 03  Definitions

Applicable definitions are included in documented procedures and instructions at par 3.0 to enhance the understanding of the process.
Control of External Providers

1.0 Purpose/Scope

1.1 This procedure describes the process for controlling the procurement process at Your Company to ensure that purchased products and services, and outsourced processes conform to requirements.

1.2 The procedure applies to situations where the control of external providers is required (as defined in par 5.2.1).

2.0 Responsibilities and Authorities

2.1 The Materials manager has the prime responsibility and approval authority for this procedure.

2.2 In support of the Materials / purchasing manager, the Quality team / ISO steering committee is responsible to identify the situations where the requirements for the control of external providers apply.

2.3 Additional responsibilities for the materials manager / quality manager / purchasing department staff / receiving personnel are detailed in relevant paragraphs of section 5.0 below.

3.0 References and Definitions

3.1 References

3.1.1 This document relates to clause 8.4 of the ISO 9001:2015 standard, Control of external providers.

3.2 Definitions

3.2.1 Supplier / Provider: Person or organization such as a producer, distributor, retailer or vendor that provides a product or a service.

4.0 Resources

4.1 None

5.0 Instructions

5.1 In support of the planning procedures P-810 for Operational planning and control, and P-910 for Monitoring, measurement, analysis and evaluation, this procedure addresses the control of external providers.

5.2 The Quality team / ISO steering committee identifies the situations where the requirements for the control of external providers apply.

5.2.1 Control of external providers is required when:
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<td>Part / Item:</td>
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<tr>
<td>Dept. / Provider:</td>
<td>Job No. / PO No.:</td>
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<tr>
<td>Qty. Rejected:</td>
<td>Serial / Batch Nos.:</td>
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**DESCRIPTION OF NONCONFORMANCE**

| Date: | Identified By (Signature / Date): |

**DISPOSITION**

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**CLOSEOUT**

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