

**Documents are in Microsoft Word for ease of editing**

**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:**

**Blue text throughout the manual highlight areas for customization**

**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 and internal issues that are relevant and the of the quality management system. **Provides general purpose and description of Quality Manual**

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 or 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 for all products and services covered by the QMS. **Your Company** applies all the requirements of ISO 9001:2015 within the determined scope of the QMS.

You can search and replace "Your Company" with your own company name

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

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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 to be 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 in the instance where a requirement cannot be applied is documented.

Blue text gives guidance for customization

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

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

Related documents are referenced

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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

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### 1.0 Purpose/Scope

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- 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

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- 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

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- 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

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- 4.1 None

### 5.0 Instructions

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- 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:

