



*Organization of this manual is the same as the sectional organization of ISO 9001:2000. Close correspondence between the manual and the standard helps to demonstrate compliance of the system and ensures that all clauses and requirements are being addressed systematically.*

*Note that each section of the manual is an independent document with its own page numbering, approval and release signatures, and revision level.*

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Jack Kanholm - 00/00/00	



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## 1.1 QUALITY POLICY

### QUALITY POLICY

**<COMPANY> is committed to meeting customer requirements and enhancing customer satisfaction through continual improvement of its products, services and the quality management system.**

*This policy is too general, and it should not be considered as an example of a fully developed policy. It is included here only to illustrate how the policy could be presented in the manual.*

## 1.2 INTRODUCTION

*This section includes an introduction, a definition of operations and products to which the quality system applies, and statement of any exclusions of ISO 9001 requirements (per Clause 1.2 of the standard).*

- 1.2.1 **<COMPANY>** developed and implemented a quality management system to demonstrate its ability to consistently provide product that meets customer and regulatory requirements, and to address customer satisfaction through the effective application of the system, including continual improvement and the prevention of nonconformity.

*The introductory paragraph is taken form ISO 9001:2000 Section 1.1. If you feel that it is too generic, edit it to better communicate the reasons for implementing the quality system.*

- 1.2.2 The quality system complies with the international standard ISO 9001:2000.

*List any other standard with which your quality system complies, for example, federal standards, military standards, industry standards, customer standards, etc. Most of these sector-specific standards are now based on ISO 9001, so there is a good chance*

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*that you may comply with those that apply to your industry, if there are any.*

- 1.2.3 The manual is divided into eight sections modeled on the sectional organization of the ISO 9001:2000 standard. Sections are further divided into several subsections representing main quality system processes. Each subsection defines general policies and basic principles for the pertinent quality system process; summarizes responsibilities and methods; and references relevant operational procedures and other documents.
- 1.2.4 The purpose of this manual is to define and describe the quality system, to define authorities and responsibilities of the management personnel involved in the operation of the system, and to provide a general description of all processes comprising the quality system.
- 1.2.5 Another purpose of this manual is to present the quality system to customers, suppliers, regulators and other external interested parties, and to inform them what specific controls are implemented at <COMPANY> to assure quality.

### 1.3 APPLICATION

*Define the products and/or services for which this quality system applies. Where applicable, in addition to manufacture and delivery you may add design, development, distribution, installation, servicing, etc., of the products. If you don't apply the system to all categories of products, name specifically these products to which the system applies. Here, you can also directly use the scope of your ISO 9001 certification.*

- 1.3.1 The quality management system defined in this manual applies to the design, manufacture and distribution of products offered by <COMPANY>.

*Instead of "products" name the products specifically (or generally by categories or types of products).*

### 1.4 EXCLUSIONS

*This section pertains to ISO 9001 Clause 1.2, Application, allowing for claiming exclusions from certain requirements of the standard. Under previous editions, organizations could choose between ISO 9001 and ISO 9002, depending on the nature of their operations and needs. Now there is only one specification of requirements, ISO 9001, but organizations may claim exclusions from various requirements that do not apply to their operations.*

*The intention is primarily to allow exclusions of design control requirements where there are no design activities (old ISO 9002). But you can also exclude other requirements that don't apply, for example, 7.5.4, Customer property.*

*This clause starts with a short procedure explaining briefly the rules for taking exclusions, who makes these determinations and who approves them, and how exclusions are documented. Although not explicitly required, the procedure helps to demonstrate that there is a deliberate process for identifying applicable exclusions, and thus adds credibility to the validity of the claimed exclusions.*

- 1.4.1 The quality management system shall be relevant to the nature of our organization and

products, and to customer and regulatory requirements. For this reason, those requirements of ISO 9001 that do not apply are excluded from the scope of our quality system.

- 1.4.2 An ISO 9001 requirement may be excluded only when the following three conditions are met:

*The following two conditions are identical to those stated in ISO 9001 Clause 1.2.*

- The requirement must be within ISO 9001 Clause 7, Product Realization;
- The exclusion may not affect our ability, nor absolve us from the responsibility, to provide product that meets specified requirements; and
- The exclusion may not affect our ability to carry out corrective action.

- 1.4.3 Processes which are applicable, but which are performed by outside contractors, do not qualify for exclusion. They are accounted for in the quality system to ensure control over such outsourced processes.

- 1.4.4 The QA Manager is responsible for identifying those requirements of ISO 9001 that do not apply to our organization or products, and to propose to the top management that such requirements be excluded from the scope of the quality system.

- 1.4.5 Top management evaluates the proposed exclusions and determines whether they are appropriate. The evaluation and approval of exclusions are conducted within the framework of management reviews of the quality system (refer to Operational Procedure QOP-56-01, Management Review).

*Formal approval of exclusions by the top management is not explicitly required in the standard. Thus, you may delete this paragraph if you feel that it is not appropriate, or does not apply in your company. I included it here because decisions regarding the scope of the quality system are generally sufficiently important to warrant direct involvement of the top management, and because these decisions may have direct bearing on the compliance status of the company.*

- 1.4.6 Any exclusions taken are documented in this section of the quality manual. The excluded requirements are precisely identified with reference to specific clauses and/or statements in the standard. There is also a brief justification why the exclusion is taken and why it is appropriate.

### CLAIMED EXCLUSIONS

*If all requirements of ISO 9001 Section 7 apply, write here "No exclusions taken." You still need this section in the manual to define how exclusions will be identified, should this become relevant in the future.*

*If you identified any exclusions, document them as in the two examples below. The first example illustrates how you could justify exclusion of design and development requirements. The second example may be relevant to a company that does not receive any products or documents from its customers.*

- I. **Exclusion:** ISO 9001:2000 Section 7.3, Design and Development, including all subsections

**Justification:** <COMPANY> does not design or develop products. All principal product characteristics are specified by the customers or their consultants. Our engineering activities are limited to developing methods and means of production, fabrication, or installation.

- II. **Exclusion:** ISO 9001:2000 Section 7.5.4, Customer Property

**Justification:** <COMPANY> does not receive from customers any tangible or intellectual property that is intended for incorporation into, or in any way associated with products.



## 4.1 GENERAL REQUIREMENTS

*A customary way to satisfy Clause 4.1 in an ISO 9001 quality system is to include a process map in the form of a Plan-Do-Check-Act (PDCA) diagram (as on the next page) depicting quality system processes and their sequence and interrelation; and further define these processes and their sub-processes in a process map matrix.*

### 4.1.1 Quality system processes

4.1.1.1 The quality management system is designed as a system of interrelated processes. All main activities of the system are defined as Quality System Processes (QSPs) and are grouped into the following four categories (refer to the Quality System Processes Map on next page):

- Product Realization Processes (PRP),
- Measurement, Analysis and Improvement Processes (MIP),
- Management Responsibility Processes (MRP), and
- Resource Management Processes (RMP)

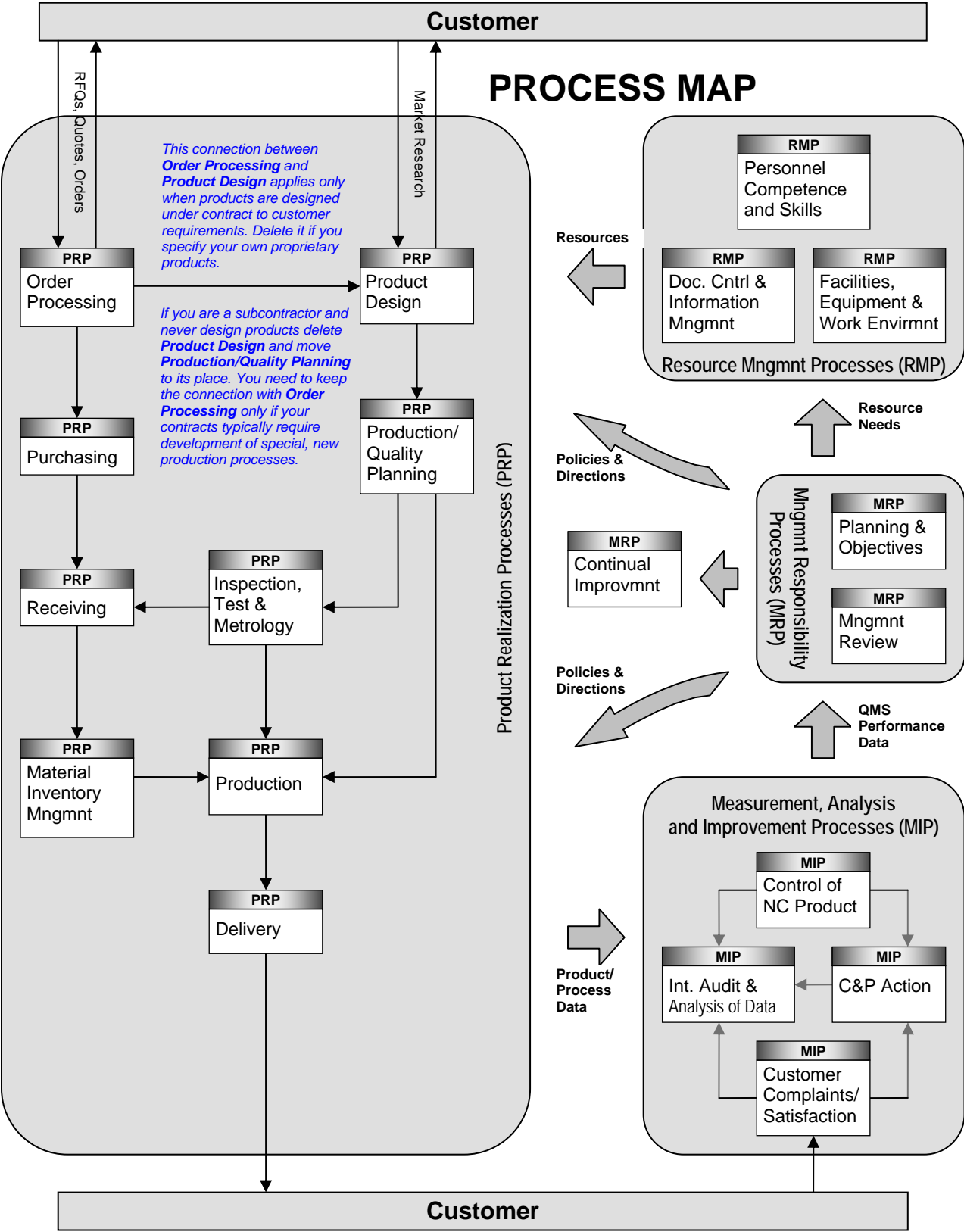
And are organized into a Plan-Do-Check-Act loop.

4.1.1.2 The sequence and interrelation between the four groups and individual QSPs are illustrated in the Processes Map diagram. Each QSP is further broken down into its sub-processes, as defined in the Process Map Matrix included after the diagram.

4.1.1.3 QSPs and their sub-processes are documented in this quality manual and in associated operational procedures and work instructions. This documentation defines the quality system processes and their sequence and interaction, and instructs on how to implement and apply them throughout the organization.

4.1.1.4 Quality system documentation also defines criteria and methods needed to ensure that the operation and control of quality system processes are effective. This includes assignment of responsibilities and allocation of resources for the process, instructions on how to carry out (or operate) the process, and definition of methods for monitoring and/or measuring the effectiveness of the process.

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## PROCESS MAP MATRIX

*Processes identified in this documentation are limited to include only those processes for which there are explicit requirements in the ISO 9001 standard. For example, processes for market analysis, payments, financing, etc., are not included because the ISO 9001 standard does not have any explicit requirements for these processes. This opens the QMS documentation to the criticism that not all business and operations processes are considered, and thus the process approach is compromised. However, if you identify all your processes, you will need to control (document) them all, and thus end up having a quality system that goes beyond the scope of ISO 9001 requirements.*

*While this is not necessary for compliance, you may want to include marketing, payments, and whatever else is important and relevant. I didn't do it here in this generic documentation because I don't know what those additional processes would be in your company, and also because this is a minimalist documentation that is committed not to go beyond requirements of the standard.*

<b>PRODUCT REALIZATION PROCESSES (PRPs)</b>	
<b>Order Processing</b>	
<b>Purpose</b>	To determine customer requirements, prepare bids and quotations, submit tenders, and take orders from, or enter into contracts with, customers.
<b>Process Owner</b>	<Sales>
<b>Sub-Processes</b>	<ul style="list-style-type: none"> <li>• Determining product requirements</li> <li>• Determining customer requirements</li> <li>• Evaluating capability and capacity to meet requirements</li> <li>• Preparing quotations, bids and tenders</li> <li>• Entering orders (or signing contracts)</li> <li>• Receiving, entering and processing change orders</li> <li>• Providing product information</li> </ul>
<b>Product Design</b>	
<i>Delete this process if you don't design products (read note on the Process Map)</i>	
<b>Purpose</b>	To design products meeting the design input requirements.
<b>Process Owner</b>	<Engineering>
<b>Sub-Processes</b>	<ul style="list-style-type: none"> <li>• Planning and scheduling design projects</li> <li>• Reviewing and controlling design input</li> <li>• Performing design activities</li> <li>• Conducting design reviews</li> <li>• Establishing design output documents</li> <li>• Verifying and validating product designs</li> <li>• Controlling design changes</li> </ul>
<b>Production/Quality Planning</b>	
<b>Purpose</b>	To plan and develop processes needed for manufacturing and verification of product.
<b>Process Owner</b>	<Production Engineering>





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<b>Sub-Processes</b>	<ul style="list-style-type: none"><li>• Determining quality objectives and requirements for products</li><li>• Developing, validating and documenting production processes (process flowcharts, process sheets, equipment setup instructions, tooling specifications, operator instructions, etc.)</li><li>• Establishing product acceptance criteria and product verification requirements (measuring, inspections, tests, etc)</li></ul>
<b>Purchasing</b>	
<b>Purpose</b>	To select qualified vendors and to purchase from them materials, components, and services necessary for the manufacture and delivery of the product (for full scope of application refer to QOP-74-01, Purchasing).
<b>Process Owner</b>	<Purchasing>
<b>Sub-Processes</b>	<ul style="list-style-type: none"><li>• Evaluating and selecting suppliers and subcontractors</li><li>• Maintaining a list of approved suppliers</li><li>• Preparing, reviewing and issuing purchasing documents</li><li>• Communicating with suppliers regarding their quality performance (notifications, requests for corrective actions, etc.)</li></ul>
<b>Receiving</b>	
<b>In the full version of the software the <i>Purpose, Process Owners and Sub-processes</i> are fully specified for this and all the following processes.</b>	
<b>Material Inventory Management</b>	
<b>Production</b>	
<b>Delivery</b>	
<b>Inspection, Test and Metrology</b>	
<b>MEASUREMENT AND IMPROVEMENT PROCESSES (MIPs)</b>	
<b>Control of Nonconforming Product</b>	
<b>Internal Audits and Analysis of Data</b>	
<b>Corrective and Preventive Action</b>	
<b>Customer Complaints &amp; Satisfaction</b>	
<b>MANAGEMENT RESPONSIBILITY PROCESSES (MRPs)</b>	
<b>Planning and Objectives</b>	
<b>Management Review</b>	
<b>Continual Improvement</b>	
<b>RESOURCE MANAGEMENT PROCESSES (RMPs)</b>	
<b>Personnel Competence and Skills</b>	
<b>Document Control and Information Management</b>	
<b>Facilities, Equipment and Work Environment</b>	



#### 4.1.2 Resources and information

- 4.1.2.1 <Quality> is responsible for determining resource and information requirements necessary to support the operation and monitoring of quality system processes, and for communicating these requirements to <Management>. <Management> is responsible for ensuring the availability of necessary resources and information. **QM Section 6.1 Provision of Resources** explains in more detail how resource requirements are identified and satisfied.

*If your <Quality> and <Management> function is the same person, rework this paragraph so that it makes sense. For example “<Management> is responsible for determining resource and information requirements necessary to support the operation and monitoring of quality system processes, and for ensuring the availability of necessary resources and information.”*

#### 4.1.3 Monitoring and measurement

- 4.1.3.1 Performance of quality system processes is systematically monitored and measured. This is to ensure their effectiveness and identify opportunities for improvement.
- 4.1.3.2 Performance of quality system processes is monitored through internal quality audits (refer to **QM Section 8.2** and Operational Procedure **QOP-82-02 Internal Quality Audits**).
- 4.1.3.3 The overall performance of the quality system is monitored by measuring customer satisfaction (refer to **QM Section 8.2**).
- 4.1.3.4 Quality system processes are reviewed and analyzed by the management review of the quality system (refer to **QM Section 5.6** and Operational Procedure **QOP-56-01 Management Review**).

#### 4.1.4 Continual improvement

- 4.1.4.1 Quality management system processes are regularly reviewed by <Management> to identify any possible failures or breakdowns, as well as opportunities for improvement. Actions necessary to address actual or potential problems and to improve the quality system are implemented through corrective and preventive actions and through quality objectives.
- 4.1.4.2 **QM Section 8.5** and Operational Procedures **QOP-56-01 Management Review** and **QOP-85-03 Corrective and Preventive Actions**, define how the quality management system itself ensures its own compliance and continual improvement.

#### 4.1.5 Outsourced processes

*If this sounds more natural, use the phrase 'subcontracted processes' instead of 'outsourced processes'.*

- 4.1.5.1 When processes that affect product conformity are outsourced, special controls are

implemented to ensure that these processes meet specified requirements. Such controls include, as applicable:

*Edit this list to reference the actual types of controls used in your company.  
Mandatory items are marked with (ISO)*

- Evaluation and pre-qualification of suppliers;
- Assessment of subcontractor's manufacturing processes and their quality system;
- Flow-down of customer (contract) requirements,
- Monitoring of supplier quality performance;
- Requirements for process control, inspection, testing and other such records demonstrating product conformity; and
- Receiving inspection of the supplied product.

**QM Section 7.4** and Operational Procedures **QOP-74-01 Purchasing**, and **QOP-74-02 Verification of Purchased Product**, define these purchasing control processes.

- 4.1.5.2 Ensuring control over outsourced processes does not absolve <COMPANY> of the responsibility to conform to all customer and other applicable requirements.

## 4.2 DOCUMENTATION AND RECORDS

*This section defines the scope of the quality system and related documentation, sets out some general policies regarding the quality manual, and refers to operational procedures for document control and quality records.*

### 4.2.1 Documentation

- 4.2.1.1 <COMPANY> quality system documentation comprises the following categories of documents:

- Quality system manual;
- Quality system operational procedures;
- Quality system forms;
- Work instructions;
- Product, labeling and packaging specifications;
- Manufacturing, installation and servicing specifications;
- Quality assurance/control procedures and specifications; and
- Standards and codes.

These categories are further defined in Operational Procedure **QOP-42-01 Control of Documents**.

### 4.2.2 Document control

*This section will have a different feel when documents are established and distributed*

*on paper, and for strictly electronic systems. This generic text tries to do both, assuming that the company is in transition from paper to electronic document distribution.*

*While document control requirements stated in Clause 4.2.3 apply to both paper and electronic systems equally, the means to achieve the required control will be different. Edit this section, and the corresponding operational procedure QOP-42-01, to reflect the specific arrangements as applicable to your company.*

- 4.2.3.1 **<COMPANY>** is gradually transitioning from paper to electronic documentation. As this transition progresses, new categories of documents are transferred from paper to electronic document control system. Both systems are currently used, and are defined in Operational Procedure **QOP-42-01 Control of Documents**.

*You can edit or delete this 'transition' statement if it does not apply. The quality manual does not need to specifically define which documents are paper and which are electronic, as this may be changing rather quickly.*

- 4.2.3.2 The document control system defined in Operational Procedure **QOP-42-01 Control of Documents** ensures that:

- Documents are reviewed for adequacy and are approved prior to release;
- Documents are reviewed and updated as necessary, and revised documents are re-approved;
- Documents are identified, to include their current revision status and changes;
- Documents are distributed to, and are available at locations where they are used;
- Document distribution is controlled; and
- Obsolete documents are withdrawn from points of use, and/or are clearly identified to prevent their unintended use.

### 4.2.3 Control of records

*Although records are addressed in ISO 9001 in the same section dealing with documents, they are very different in some respects. For example, records do not need to be reviewed and approved for issue, and should never be revised (revision of records would be falsification). Conceptually, the difference between a document and a record is that a document instructs or informs, while a record is a statement of actual facts or events.*

*The scope of records shall be such as to provide complete evidence of product and process conformity, and the conformity and effectiveness of the quality system.*

*Records can be paper or electronic, and the specific methods for control of records will obviously depend on the media. As written, this section refers rather to paper records. Edit to reflect the specific conditions in your company.*

- 4.2.4.1 Records are established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.

- 4.2.4.2 Records are organized into the following four categories:



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- Product Design Records,
- Production and Product Quality Records
- Sales and Distribution Records
- Quality System Records

*These four groups are just an example. The standard does not require that records be grouped in any specific categories. You can change the categories or even delete this sub-clause altogether.*

- 4.2.4.3 Operational Procedure ***QOP-42-02 Control of Records*** defines more specifically what records are maintained in each category and designates their storage locations and retention periods. It also defines the process for ensuring that records are clearly identified, are stored in appropriate locations and conditions, are adequately protected, and are easily retrievable.

