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*Paid version includes all the contents listed in the table of contents.*

*Sample for manufacturers*

# Quality manual

Application of ISO 9001 : 2015

Approval	Creation

**Sample Inc.**

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## 1 Scope

Our company establishes quality management systems based on "Quality management systems — Requirements" (hereinafter referred to as ISO9001).

This manual specifies the framework of establishment, introduction, operation, monitoring, review, maintenance, and improvement of our company's quality management system.

(1) applicable business

- production and assembly of industrial machinery parts
- design and manufacture of jig, attachment, mold

(2) applicable organization

organizations listed in the organizational chart on a separate piece of paper

(3) applicable office

【name of office】 ○○

【address of office】 ○○

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## 2 Normative references

ISO9000:2015      Quality management systems — Fundamentals and vocabulary

## 3 Terms and definitions

For the purposes of this manual, the definitions of terms given in ISOQ9000:2015 apply. Terms that need definition are defined as follows.

- (1) Employee : All the members of our corporation within the Scope of ISO9001, including board members, employees, contract employees, fixed-term employees, part-time employees, and part-timers
- (2) Management team : Company president and board members
- (3) Committee for the Promotion of ISO : Committee that discuss and shape quality management policies

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## 4 Context of the organization

### 4.1 Understanding the organization and its context

Our company discusses and determines in ISO promotion committee external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended results of its quality management system. Our company also monitors and reviews information about these external and internal issues in ISO promotion committee.

### 4.2 Understanding the needs and expectations of interested parties

Our company determines the following requirements, and monitors and reviews information about these interested parties and their relevant requirements in ISO promotion committee.

interested parties	requirements of interested parties
customers	Contractual obligation (contract document) Supplying products that meet legal and regulatory requirements
employees	Using business resources appropriately Securing education and training
suppliers (procurement source)	Providing information properly and appropriately

### 4.3 Determining the scope of the quality management system

When determining the scope, our company takes the following factors into consideration, and the scope determined is kept available as documented information.

- (1) the external and internal issues referred to in 4.1
- (2) the requirements of relevant interested parties referred to in 4.2
- (3) the products and services of the organization

## 4.4 Quality management system and its processes

### 4.4.1 General requirements

Our company establishes, implements, maintain and continuously improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of ISO9001:2015. Our company also determines the processes needed for quality management system and their application throughout the organization, and:

- (1) determines the inputs required and the outputs expected from these processes;
- (2) determines the sequence and interaction of these processes;
- (3) determines and applies the criteria and methods (including monitoring, measurements

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and related performance indicators) needed to ensure the effective operation and control of these processes;

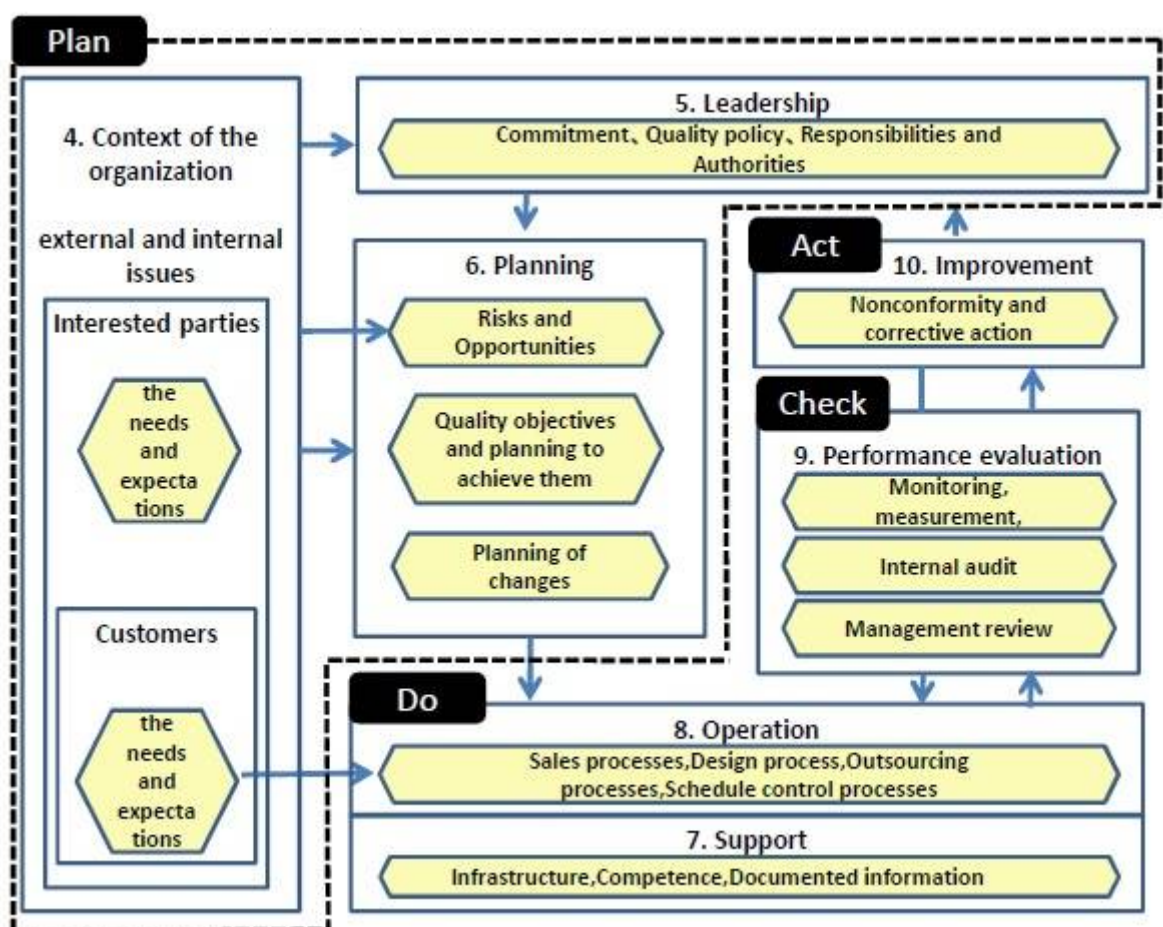
- (4) determines the resources needed for these processes and ensure their availability;
- (5) assigns the responsibilities and authorities for these processes;
- (6) addresses the risks and opportunities as determined in accordance with the requirements of 6.1;
- (7) evaluates these processes and implement any changes needed to ensure that these processes achieve their intended results;
- (8) improves the processes and the quality management system.

#### 4. 4. 2 Implementation of processes

To the extent necessary, our company:

- (1) maintains up-to-date documented information to support the operation of its processes;
- (2) retains information as quality records to have confidence that the processes are being carried out as planned.

#### Process correlation diagram





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## Quality Policy

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### 【Company creed】

Our company,●●, tries to develop our employees' capacity and improve their welfare through machine processing and component manufacturing, and, while making efforts to achieve conformity of our company's development to individual happiness, aims to be a unique company where each person has strong beliefs in technology, humanity, knowledge, and unity.

### 【Fundamental policy】

1. All employees work together to improve customer satisfaction.
2. Our company sets a quality goal in order to implement the quality policy concretely, and carries out and examines the activities to achieve it.
3. Our company observes relevant regulatory requirements.
4. All employees take part in educational and training courses to make sure that each of them can develop competencies.
5. Our company tries to improve quality management system continuously by periodically evaluating and reviewing this quality policy and relevant rules and management system.

Sample Inc.  
President ○○

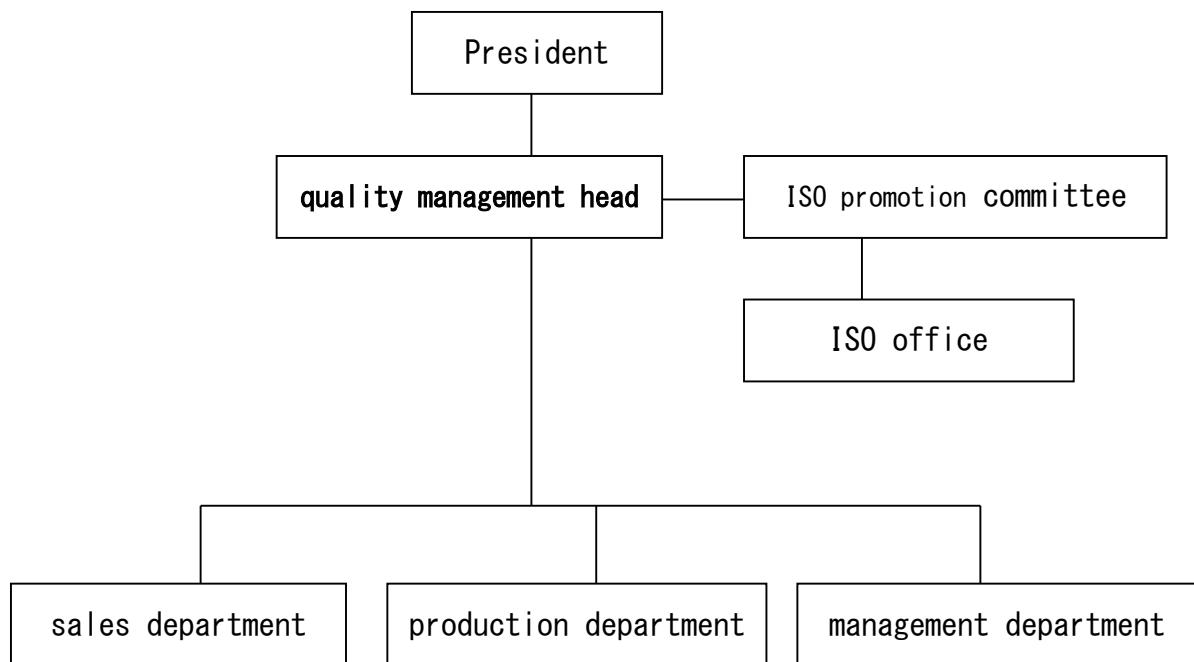
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### 5.3 Organizational roles, responsibilities and authorities

Our president ensures that the responsibilities and authorities for relevant roles are assigned, communicated within the organization.

#### 5.3.1 Promotion organization

An organization to promote quality management system (QMS) is outlined below.



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### 5.3.2 Responsibilities and authorities

Responsibilities and authorities to promote quality management system(QMS) are described below.

Position	Responsibilities and authorities	Remarks
President	(1) appoints a quality management head and an internal auditing head. (2) establishes and maintains quality policy. (3) provides enough business resources to establish, introduce, operate, monitor, review, maintain, and improve the quality management system. (4) conduct management reviews.	—
Quality management head	(1) ensures that the quality management system meets the requirements of ISO9001:2015. (2) ensures that the processes produce the intended output. (3) reports the performance and improvement possibilities of quality management system to the president. (4) ensures that customer-focused strategy is promoted throughout the organization. (5) plans to switch to the quality management system, and when implementing it, ensures that the quality management system is kept perfectly appropriate. (6) presides over the ISO promotion committee.	Appointed by the president
ISO promotion committee	collects and organize the problems in promoting ISO of our company, and then, takes measures, makes plans, and make an assessment.	—
ISO Office	follows the direction given by the quality management head, and conducts practical operations to promote the quality management system.	—
Internal auditing head	(1) draws up internal auditing programs, appoints the leader and members of internal auditing team, and reports the result of auditing to the president. (2) ensures that internal auditing is carried out.	Appointed by the president
Department head	(1)ensures that department members follow this quality manual and other procedures. (2) checks the department's achievement on a daily basis and tries to improve it.	—

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## 7 Support

### 7.1.3 Infrastructure( equipment management)

Our company determines, provide and maintain the infrastructure necessary for the operation of its processes to achieve conformity of products and services based on the table below.

categories	resources	methods of maintenance and management
buildings, equipment	factories, water-purifier tank	daily checking, management by contracting companies
machinery	machine tools, measuring equipment	daily checking, management by contracting companies
utilities	electricity, gas, water	management by contracting companies
support service	information-communication(WEB management)	management by contracting companies
	company PC	daily checking

#### (1) Procedure of equipment management

##### ① Installation and updating of equipment

Installation of new equipment and updating of existing equipment are carried out with the approval of president.

##### ② Tasks to maintain equipment

The person in charge in the relevant department conducts daily checking on specified equipment.

##### ③ Response to equipment abnormality

When abnormality of equipment is found in the course of checking or daily work, the person in charge reports it to the department head, and writes "equipment break-down reports".

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### 7.3 Awareness ( education and training)

ISO office conducts the following employee training.

Segment	Time of implementation	Subject	Training content
Awareness education	Based on annual training roadmap	All employees	(1) Publication of quality policy (2) Publication of relevant quality objectives (3) Their contribution to the effectiveness of the quality management system, including the benefits of improved performance (4) the implications of not conforming with the quality management system requirements
	When assigning new employees	New employees	
Professional training	Right time	Employees who need professional competence in certain fields or tasks	(1) acquisition of professional knowledge and skills that influence the performance and validity of quality management system (2) training and follow-up education of internal auditors

### 7.4 Communication

Our company determines the internal and external communications relevant to the quality management system, including:

- (1) on [for] what it will communicate;
- (2) when to communicate;
- (3) with whom to communicate;
- (4) how to communicate;
- (5) who communicates (the person in charge).

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#### 7.4.1 Internal communication

Our company determines the following communications and ensures that information on the improvement of the quality management system is exchanged.

Communications	Content (Purpose)	Subject	Method	Time of implementation	Host (Person in charge)
General meeting	Explaining the company policy, future plans and achievement; Enlightening employees on quality management	All employees	Meeting	Annual	Management department
ISO promotion committee	Acquiring, organizing, addressing, planning, reviewing the quality problems ( addressing deficiency, operational problems, and risks; managing the progress)	Department head and ISO promotion committee	Meeting	Monthly	Quality management head
Production meeting	Managing deadlines appropriately	Department head	Meeting	Daily (every operating day)	President
Morning meeting	Communicating the information on customers and deadlines for appropriate operations	All employees	Each department	Daily (every operating day)	Department head
Business contact	Explaining the company policy, future plans and achievement; Enlightening employees on quality management	All employees	Circular and notice	Timely	Management department

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## 8 Operation

### 8.2 Requirements for products and services (Sales processes)

#### 8.2.1 Customer communication

Communication with customers includes the following activities, and the ISO promotion committee reviews them as necessary.

Category of information	Method	Person in charge
Provision of information on products and services	pamphlet, HP	President
Handling of inquiries, contracts, or orders (including changes)	estimate sheet, sales documents, etc.	Sales staff
Customers feedbacks on products and services including claims	mails, deficiency reports, etc.	Sales staff Factory director
Handling or control of customers' belongings	receipt, mails	Sales staff
Agreement on how to address contingencies	contracts, sales documents, etc.	Sales staff

#### 8.2.2 Determining the requirements for products and services

When determining the requirements for the products and services to be offered to customers, our company ensures, before receiving official inquiries, that:

- (1) the requirements for the products and services are defined, including:
  - ① any applicable statutory and regulatory requirements;
  - ② those considered necessary by the organization;
- (2) our company can meet the claims for the products and services it offers.

#### 8.2.3 Review of the requirements for products and services

##### 8.2.3.2 Contract procedure

The sales staff conducts the following tasks:

- (1) Consideration of inquiries
  - ① When receiving an inquiry, the sales staff checks whether its content(ability) is our company's sales item, and determines delivery deadline, the place, processes, budget, and the terms of payment, etc.
  - ② The sales staff prepares "estimate sheets" based on the meeting with customers, and submits them after the president's approval. Original copies of "estimate sheets" are filed by the sales staff.
- (2) Confirmation before acceptance of order
  - ① After receiving an order, the sales staff checks the information materials of inquiries, and clarify the points that are unclear or different from those at the time of inquiries.

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The sales staff also checks the load status of the manufacturing department (whether manufacturing by the deadline is feasible).

- ② In the case of an oral order, the order is double-checked by such means as e-mail and fax.

(3) Acceptance of order

An order is accepted when checking before acceptance of order has been conducted, the sales staff contacts the management staff, and the management staff puts the order into the computer. Then a "manufacturing instruction" is issued.

(4) Changes to the content of contracts

1) Notification of confirmation to a customer

The sales staff consults with the factory director, and checks technical and time availability, prepares a new "estimate sheet", and contacts the customer by such means as telephone, e-mail, and FAX.

2) Implementation of changes

- ① Following the changed "manufacturing instruction", the sales staff contacts the management staff, and the management staff puts the changes into the computer.
- ② The sales staff issues a new "manufacturing instruction", and distinguishes it from the previous one. These two are sent with a drawing to the manufacturing department.
- ③ The factory director checks the new "manufacturing instruction", and orders the suspension or change of operation associated with the changes.

### 8.2.3.3 Control of records

The sales staff retains documented information as quality records, as applicable:

- (1) on the results of the review;
- (2) on any new requirements for the products and services.

### 8.2.4 Changes to requirements for products and services

Our company ensures that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.



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### 8.5.2 Identification and traceability

Our company uses suitable means ( described below) to identify outputs when it is necessary to ensure the conformity of products and services.

#### (1) Identification of the types of products and other spot goods

Object of identification	Method of identification	Person in charge
Identification of material types	Display on spot goods or differentiation of storage space	Manufacturing staff
Identification of purchased product types	Description in marker pen etc. on outer cases at the time of delivery or shipping	Manufacturing staff
Identification of half-finished product types		
Identification of customer-supplied product types	Display on spot goods	Sales staff
Identification of product types	Storage in the specified area in a card-board box or in a package	Manufacturing staff

#### (2) Identification of inspection and examination status

##### ① Identification in receiving inspections

Object of identification	Method of identification	Person in charge
materials, purchased product, supplied products	<u>Identification of inspection status</u> Spot goods of materials and outsourced processed products that have not received inspections are identified as such.	Receiving staff
Outsourced processed products	<u>Identification of inspection results</u> Non-conforming items as a result of inspections and examinations are placed in the specified area or display their status.	Receiving staff

##### ② Identification in shipping inspections

The inspection staff allocates production numbers to the products, puts them in the specified area, puts his stamp on the drawing, and identifies them as accepted and inspected products. Non-conforming items are placed in the specified area, or display their status.

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## 9 Performance evaluation

### 9.1.3 Analysis and evaluation

On the matters described below, our company analyzes and evaluates appropriate data and information arising from monitoring and measurement.

Object of analysis and evaluation	Method for analysis and evaluation	Time of monitoring and measurement	Time of analysis and evaluation	Department in charge
Conformity of products and services	Trend analysis on the rate and content of deficiency	Accordingly	Monthly	Management Department
Customer satisfaction	Questionnaire of main customers to receive their evaluation	Every November	Every November	Sales department
Performance and validity of quality management system	Evaluated by internal audit	Every November	Every November	Internal auditing head
Implementation of the plan	Evaluation of each plan in the ISO promotion committee	Monthly	Every November	Quality management head
Validity of the handling of the risks and opportunities	Evaluated by internal audit	Every November	Every November	Internal auditing head
Performance of external providers	Evaluated in the " procurement / outsourcing source reviews"	Accordingly	Every November	Management department
Need for improving quality management system	Evaluated by internal audit	Every November	Every November	Internal auditing head

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### 9.3 Management review

#### 9.3.1 General

- (1) The president evaluates and reviews (management reviews) of our company's quality management system (QMS) to ensure its suitability, adequacy, effectiveness, and alignment with the strategic direction of the organization.
- (2) The president performs management reviews every December. If the president finds it necessary, reviews are conducted temporarily.
- (3) The quality management head prepares the information described in 9.3.2 as inputs to ensure the effectiveness of management reviews.

#### 9.3.2 Management review inputs

The quality management head reports to the president the following information as inputs.

No	Input items	Reference records
1	Status of actions taken as a result of previous management reviews	Conference note of the previous QMS management review
2	Change in external and internal problems related to the quality management system (QMS)	Conference note of ISO promotion committee and others
3	Customer satisfaction and feedback from interested parties	Results of questionnaires
4	Extent to which quality goals are achieved	Quality goal control sheet
5	Process performance and conformity of products and services	Conference note of ISO promotion committee Deficiency reports
6	Nonconformity and corrective actions	Deficiency reports Reports on corrective actions
7	Results of monitoring and measurement	Rates of deficiency and others
8	Monitoring results	Internal monitoring reports, External monitoring reports, Reports on corrective actions
9	Performance of external providers	procurement / outsourcing source reviews
10	Validity of business resources	Conference note of ISO promotion committee and others ISO
11	Effectiveness of actions taken to deal with risks and opportunities	Conference note of ISO promotion committee and others ISO
12	Improvement opportunities	Conference note of ISO promotion committee and others ISO

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