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# Quality management — Guidelines on people involvement and competence

*Management de la qualité — Lignes directrices pour l'implication et les compétences du personnel*

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# Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 10018 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 3, *Supporting technologies*.


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# Introduction

## 0.1 General

The overall performance of a quality management system and its processes ultimately depends on the involvement of competent people and whether they are properly introduced and integrated into the organization. The involvement of people is important in order for an organization's quality management system to achieve outcomes which are consistent and aligned with their strategies and values. It is critical to identify, develop and evaluate the knowledge, skills, behaviour and work environment required for the effective involvement of people with the necessary competence.

This International Standard provides guidelines for human factors which influence people involvement and competence, and creates value that helps to achieve the organization's objectives.

## 0.2 Relationship with quality management systems

The quality management system standards developed by ISO/TC 176 are based on the quality management principles described in ISO 9000.

The correlation between this International Standard and ISO 9001 facilitates people's involvement and competence within the quality management system. However, this International Standard can also be used with other management systems.

## 0.3 Process-based approach to people involvement and competence

This International Standard is based on a strategic process-based approach (see Figure 1) for developing the involvement and competence of people at all levels of the organization.

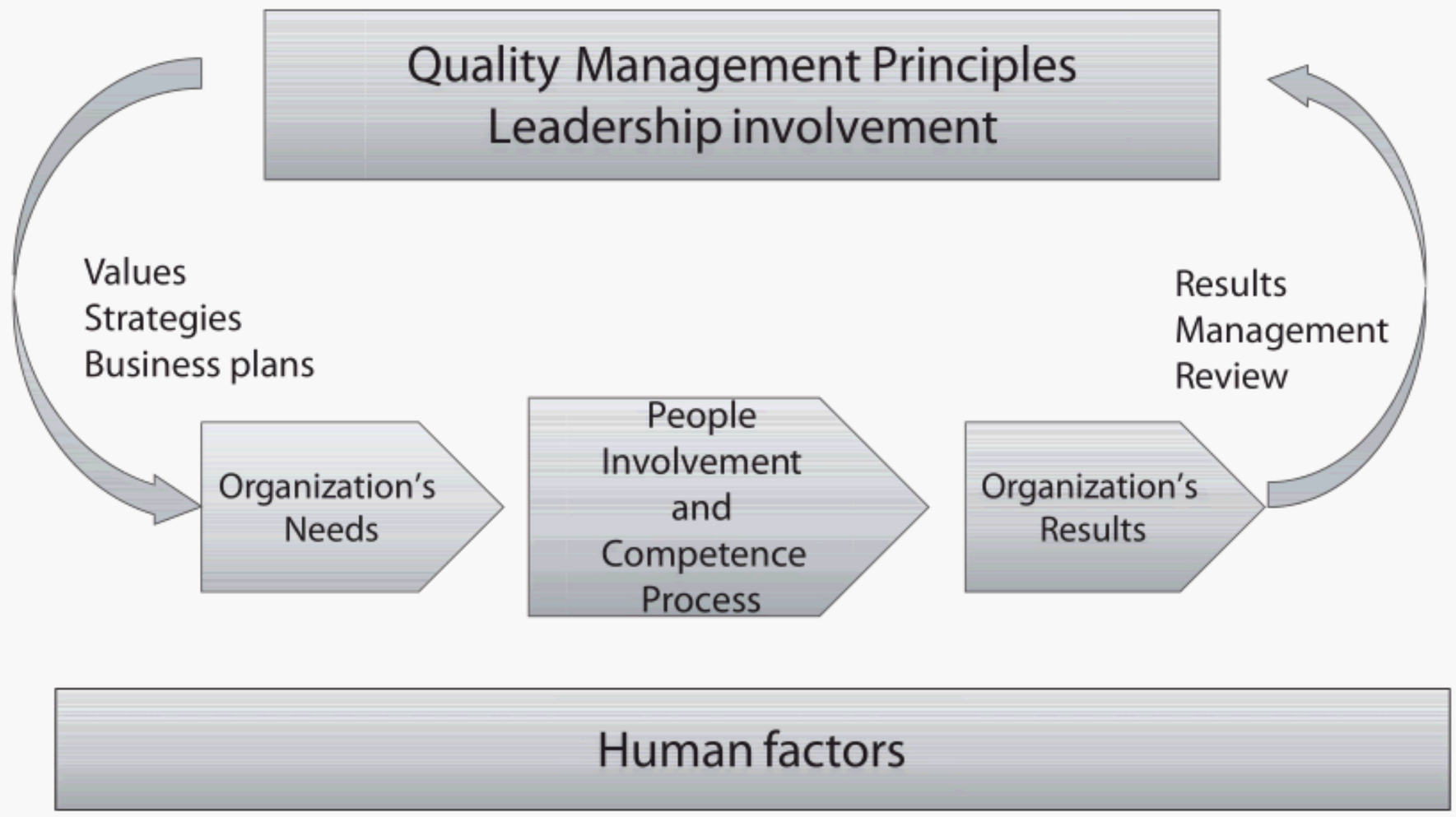


**Figure 1 — Strategic process for people involvement and competence**

The process model (see Figure 2) illustrates tactical actions, results and plans for people involvement and competence.

If people involvement and competence are monitored, measured and analysed within the quality management system, this produces results which enable top management to make decisions for improvement, thus leading to enhanced levels of customer satisfaction.

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## 0.4 Using this International Standard

Clause 4 describes the processes which an organization can use to implement and maintain people involvement and competence in quality management systems.

The factors described in 4.6 provide actions which may be taken to strengthen people involvement. The guidelines in Clauses 5 to 8 provide the specific actions which can be taken to meet individual quality management system requirements, such as those specified in ISO 9001.

This International Standard provides guidance to leaders, managers, supervisors, quality practitioners, quality management representatives and human resources managers.


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# Quality management — Guidelines on people involvement and competence

## 1 Scope

This International Standard provides guidance on engaging people in an organization's quality management system, and on enhancing their involvement and competence within it. This International Standard is applicable to any organization, regardless of size, type, or activity.

## 2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000, *Quality management systems — Fundamentals and vocabulary*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000 and the following apply.

**3.1**
**competence**
ability to apply knowledge and skills to achieve intended results

NOTE 1 Continuing application of competence can be affected by the work environment with all its variations, pressures, relationships and conflicts that can affect, for example, attitude and commitment to apply the relevant knowledge and skills.

NOTE 2 Competence requirements are more than academic qualifications, training and experience. They define the results or outcomes to be achieved for a particular job, the performance criteria or standards to be achieved, the evidence required and the method of obtaining it.

NOTE 3 Competences referenced in this International Standard apply both to people within an organization and those outsourced.

**3.2**
**competence acquisition**
process to ensure that **competence** (3.1) is attained by a person, a group of people, or an organization

NOTE In order to ensure the needs and objectives of the organization are being met, it can be necessary to have a continual programme of competence acquisition.

**3.3**
**competence development**
process to increase the competence of a person, a group of people, or an organization

**3.4**
**human factors**
physical or cognitive characteristics, or social behaviour, of a person

NOTE Human factors can have a significant influence on the interaction within, and the functioning of, management systems.

**3.5**
**involvement**
engagement in, and contribution to, shared objectives

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# 4 Management of people involvement and competence

## 4.1 General

This clause provides a process and guidelines for developing people involvement and competence. Organizations can use these guidelines to ensure long-term commitment to involvement and competence.

## 4.2 Leadership involvement and strategy

Effective quality management systems require leaders to be visibly involved in achieving the people involvement and competence objectives.

Leaders should encourage people to assume responsibilities and create conditions which enable people to achieve desired results, ensuring relevant statutory and regulatory requirements are met.

Leaders should demonstrate their commitment to people involvement and competence by:

a) establishing strategies, policies and objectives;

b) defining responsibilities and authorities;

c) ensuring understanding of customers' needs and expectations;

d) determining personnel requirements, such as knowledge, skills and behaviour;

e) assessing resource requirements, such as infrastructure, work environment and work conditions;

f) providing the resources required;

g) encouraging communication.

## 4.3 People involvement and competence acquisition process

Competence can be addressed in development plans which also contribute to people involvement. The process for people involvement and competence acquisition is described in Figure 2.

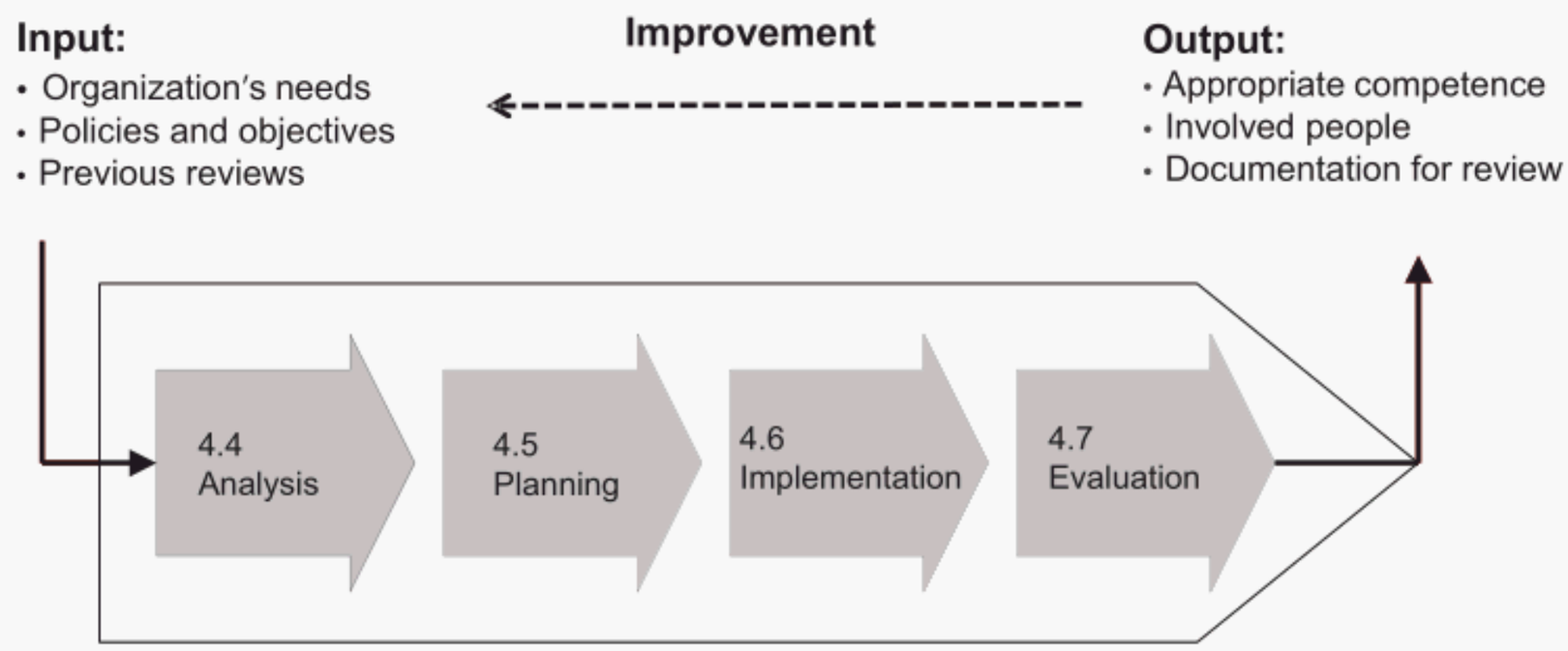


**Figure 2 — Development process of people involvement and competence acquisition within an organization**

The process is based on the four steps outlined below:

a) analysis (see 4.4): data are collected and analysed in relation to the organization's short- and long-term objectives for people involvement and competence;

b) planning (see 4.5): procedures are established and maintained to plan the people involvement and competence acquisition process on an organizational, group and individual level;


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c) implementation (see 4.6): the plans and associated actions are implemented in order to achieve the objective of people involvement and competence;

d) evaluation (see 4.7): plans, actions and outcomes are reviewed and evaluated for continual improvement.

There should be a review carried out at every step to ensure that the input and output data are correct. These steps apply to all levels of the organization, group and individual.

## 4.4 Analysis of people involvement and competence acquisition

### 4.4.1 Needs identification

The organization should identify its short- and long-term people involvement and competence needs at planned intervals. The identification of needs may include organizational strategies, values, business plans, policies and input from interested parties, such as customers.

The identification process will begin by evaluating the current levels of people involvement and competence, identifying any limitations or gaps. The process will therefore involve the following stages of assessment:

a) identifying involvement and competence needs;

b) identifying the conditions and resources needed for people to be effective in the workplace.

The organization should also consider whether special arrangements are necessary to reduce or manage risks associated with deficiencies in current activities. Such risks can occur, for example, where there are new or complex tasks, language barriers or organizational changes.

### 4.4.2 Assessment

The organization should assess people involvement and competence at the individual, team and organizational levels. In order to assess the level of people involvement, leaders should define specific methods for evaluating the manner in which the people work, communicate, collaborate and network.

The assessment should be consistent with development activities. The output of the assessment should enable analysis of the fulfilment of objectives that have been established relating to people involvement and competence. A record of this assessment should be maintained.

The output of the assessment defines the gaps between the existing people involvement and competence and the needs which have been identified. The gaps show the areas to be developed and create the inputs to the next step.

## 4.5 Involvement and competence planning

### 4.5.1 General

Upon completion of the gap analysis, the organization should follow and maintain procedures to plan its people involvement and competence acquisition. This includes developing and establishing short-term and long-term competence objectives at both the organizational and individual level. The objectives should be approved and documented.

The plans should be integrated into the annual organizational and financial planning, in order to ensure that there are planned resources to reach the objectives of people involvement and competence.

### 4.5.2 Organizational planning

Competence acquisition and people involvement plans should be based on the strategic roadmap which influences the future needs. These plans should be documented and should include the following:

— objectives and requirements based on the organization's strategic direction;

— defined activities and responsibilities;

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— a timeframe for people involvement and competence acquisition;

— required resources.

There should be agreement between the leadership and people concerning the plans, which should be recorded, reviewed and updated at defined intervals. Such a plan is a strategic document based on the previously described analyses and should be adopted by the leadership of the organization. A plan should define activities, responsibilities and timeframes to accomplish the development objectives.

### 4.5.3 Planning of the involvement and competence of individuals

Individual involvement and competence development plans should be established for each person. These plans should define activities, resources, responsibilities and timeframes to accomplish the development objectives, and they should be agreed between the people, their managers and leaders. These plans should also be recorded, reviewed and updated at defined intervals.

## 4.6 Implementation

### 4.6.1 General

The organization should carry out the planned activities developed in 4.5 for people involvement and competence acquisition. The outcomes of those planned activities should be recorded and reviewed.

### 4.6.2 Implementation of people involvement plans

Leadership actions to enhance people involvement should address factors such as communication, teamwork, responsibility, innovation and recognition. These are described more fully in Annex A.

Involvement requires an environment in which people participate in planning and may influence decisions and actions which affect their jobs. The environment should enable the engagement of people to achieve the organizational goals.

The people involvement process includes a number of factors, as described below.

— Communication: integrates the factors and should be addressed to promote shared understanding and involvement. Managers should communicate key information and expectations to people and listen to their views about the current direction on a continual basis (see Clause A.4).

— Recruitment: the process of sourcing, screening and selecting people for a position in an organization. Managers can undertake some part of the recruitment process, but larger organizations often use professional recruiters (see Clause A.12).

— Awareness: once communication objectives and methods are established, people should be made aware that ISO 9001 requires an organization to establish and implement a quality management system. Managers should ensure that their people are aware of those processes for which they are responsible (see Clause A.3).

— Engagement: employer engagement is the company's commitment to improving the partnership and developing shared understanding between the people and their managers (see Clause A.8).

— Teamwork and collaboration: occurs when people work together for a common goal. This is a way of organizing workload which strongly contributes to people involvement. This creates common goals, shared knowledge, values and behaviour, thus increasing the probability that quality objectives can be achieved (see Clause A.14).

— Responsibility and authority: managers are accountable for creating systems which provide people with the authority to assume responsibility to make decisions about their work. They should be consistent with competence requirements defined within their quality management system. The managers create a work environment which fosters the ability of people to control their own work and make decisions for which they are accountable (see Clause A.13).


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— Creativity and innovation: success results from a high degree of creativity. Allowing creativity creates a higher sense of personal fulfilment and consequently enhances involvement. Creativity is the process of producing new ideas, while innovation is the process of applying such these ideas. In the context of an organization, the term innovation refers to the entire process by which individuals or groups generate creative new ideas and convert them into products, services, or business practices (see Clause A.5).

— Recognition and rewards: the organization should take actions to continually improve people involvement. This is achieved through recognition and rewards as well as feedback for individuals or teams that have been involved in achieving results to the benefit of the organization (see Clause A.11).

In addition to the above factors, other factors described in Annex A also affect the level of people involvement, i.e. leadership (see Clause A.9), empowerment (see Clause A.7), attitude and motivation (see Clause A.2), and education and learning (see Clause A.6).

EXAMPLES Examples of methods for measuring the extent to which some of these human factors are implemented are given below. These measurements can be obtained through staff surveys, focus groups or individual interviews.

— Awareness: the degree of understanding of the policies and objectives of the organization's quality management system.

— Networking: the effectiveness of how groups of people work together and support each other in critical tasks.

— Engagement: the level of satisfaction people have in activities such as communication, learning and management.

— Teamwork: the extent to which a team reaches its objectives in key project milestones and process requirements.

— Creativity and innovation: the numbers of ideas generated when compared to their implementation rates.

### 4.6.3 Implementation of competence plans

The organization should carry out planned activities for competence acquisition. The input to this step is the competence acquisition plan.

Activities in an acquisition plan for the organization could be education and training, recruitment, establishing partnerships and outsourcing.

For the individual, a competence development plan can be comprised of activities such as education and training, both classroom or on-the-job, networking, teamwork, reading and self-study.

Activities that have been carried out should be recorded.

## 4.7 Evaluation

The organization should follow procedures for evaluation of the effectiveness of people involvement and competence acquisition activities that have been completed.

The evaluation should compare results of people involvement and competence acquisition with the previously prepared plans, and the outcomes should be communicated to all affected parties. Improvements should then be implemented.

Evaluations should be conducted at planned intervals, and the outcomes should be recorded and used as an input to the management review process.

Most of the activities listed in Clauses 5 to 8 can be used as a checklist to assess the current status of an organization regarding people involvement and competence. The levels of people involvement and competence can be checked by comparing the completed actions against the items listed in each clause.

Annex B also provides a method of organizational self-assessment.

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# 5 Management responsibility

## 5.1 Management commitment

When demonstrating their commitment to people involvement, management should:

a) explain to the people in the organization the value created by the quality management systems;

b) ensure that quality management objectives are set and deployed throughout the organization;

c) ensure awareness of the relationship between the quality management systems and financial performance.

## 5.2 Customer focus

In enhancing customer satisfaction, top management should help people understand the following:

a) the relationships between their jobs and the needs and expectations of interested parties;

b) the importance of customer satisfaction.

## 5.3 Quality policy

When creating the policy and ensuring this is understood, top management should:

a) discuss the policy to promote understanding;

b) ensure that the policy balances the needs and expectations of all interested parties;

c) encourage people to understand the policy's relevance and explain the relationship between the policy and each person's activity;

d) show people the relationship between policies and business or operational plans.

## 5.4 Quality objectives and planning

When ensuring that measurable quality objectives are established in the organization, top management should:

a) explain the objectives to people;

b) monitor their achievement;

c) align people activities with the organizational objectives;

d) involve people in the creation and updating of objectives which impact on them.

## 5.5 Responsibility, authority and communication

### 5.5.1 Responsibility and authority

When ensuring that responsibilities are defined and communicated, top management should:

a) specify the roles and responsibilities of managers and supervisors for people involvement and competence;

b) provide individuals with an explanation of their roles and responsibilities;

c) ensure that people have the responsibility and authority they need to perform their duties effectively within the quality management system.


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### 5.5.2 Management representative

In selecting a management representative, top management should:

a) choose a representative with the competences to coordinate the establishment, implementation, maintenance and improvement of the quality management system;

b) select a representative with the competences which include leadership, coaching and clear communication skills;

c) provide the necessary authority, responsibility and time needed to carry out their role effectively;

d) if the organization is large, select a representative from each department and form a cross-functional team to report to the overall management representative.

### 5.5.3 Internal communication

In communicating the effectiveness and efficiency of the quality management system with the people, top management should:

a) establish “top down” and “bottom up” communication systems;

b) use techniques such as “team briefing” to communicate information;

c) monitor the effectiveness of communication systems.

## 5.6 Management review

When evaluating the effectiveness and efficiency of the quality management system, top management should address the review inputs at planned intervals and do the following:

a) take decisions and actions to improve the involvement and competence of people;

b) set involvement and competence objectives and communicate these to all concerned;

c) establish mechanisms to ensure the successful achievement of people involvement and competence objectives;

d) provide resources to develop the competence of people;

e) involve people in the operation of the quality management system and be aware of people’s difficulties and opportunities;

f) provide a platform for the exchange of people’s ideas.

# 6 Resource management

## 6.1 Provision of resources

When providing the resources needed to continually improve the quality management system, top management should:

a) be aware of and provide the resources that people need to succeed in their work;

b) manage the knowledge resource within in the organization.

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## 6.2 Human resources

### 6.2.1 General

Human resources planning should be both strategic (long-term) and tactical (short-term) and should include a recruitment and selection process which:

a) is transparent to candidates and emphasises the importance of their competence;

b) provides applicants with information on organizational values and attitudes;

c) identifies how well a person will fit in with the organization's culture (e.g. alignment with values and attitudes);

d) establishes competence criteria for each role, which should be defined by managers together with the people concerned during a structured discussion.

### 6.2.2 Competence, training and awareness

In evaluating competence requirements and developing competence needs, top management should:

a) follow the competence acquisition process described in 4.3;

b) ensure that training is provided based on competence requirements;

c) ensure the existence of professional or trade certification, when necessary;

d) explain people roles and competence requirements needed for achieving quality objectives (see 5.4);

e) make people aware of how they contribute to the results of the organization.

NOTE ISO 10015 provides a method of planning, delivering and monitoring training.

## 6.3 Infrastructure

In establishing, providing and maintaining the infrastructure, the organization should:

a) involve appropriate people at all levels in the planning of infrastructure;

b) ensure that all staff are aware of the available resources;

c) ensure that staff are competent to use resources effectively;

d) identify the means of rectifying any problems.

## 6.4 Work environment

In managing the work environment, organizations should consider that people are:

a) aware of their roles and responsibilities in fulfilling the relevant statutory and legal requirements;

b) aware of their personal rights in terms of local, national and international agreements;

c) involved in identifying environmental deficiencies and health and safety risks related to their roles;

d) trained in the organizational systems for the environment and health and safety;

e) competent in reporting and recording hazards, and able to take corrective action.


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# 7 Product realization

## 7.1 Planning of product realization

In planning and developing processes linked to product realization, the organization should ensure that:

a) relevant people are involved in the process design;

b) awareness is maintained of risks associated with any limitations in competence;

c) when fully competent people are unavailable, the ensuing risks are managed;

d) process owners should understand that process ownership includes taking responsibility for the process outcomes;

e) process designers should understand the importance of cross-functional processes;

f) cross-functional teamwork should enable processes to link to form a system.

## 7.2 Customer-related processes

### 7.2.1 Determination of requirements related to the product

In determining product requirements, the organization should ensure that:

a) those responsible for product realization/service delivery understand customer needs and expectations, as well as product requirements;

b) people understand statutory and regulatory requirements;

c) operational staff are given an understanding of legal obligations and statutory requirements for consumer protection.

### 7.2.2 Review of requirements related to the product

In reviewing product requirements, the organization should ensure that:

a) people who are responsible for product realization and delivery should be consulted when identifying customer requirements to ensure process capability;

b) people have a clear understanding and possess the skills to resolve differences with customers.

### 7.2.3 Customer communication

In communicating with customers on product information, order handling and customer feedback, the organization should ensure that:

a) people engage with customers to obtain feedback and resolve any unmet needs;

b) people handling complaints are aware of the relevant policies and processes;

c) meetings addressing complaints involve people in departments affected by the complaint;

d) people handling complaints have the competence to communicate customer complaints to those people who can improve the affected processes;

e) feedback is provided to the customer regarding complaints resolution, as well as to all people in the organization who have been involved with the complaints handling (see ISO 10001, ISO 10002, ISO 10003);

f) customers are engaged in activities for the development and improvement of products and services through meetings, such as focus groups.

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## 7.3 Design and development

### 7.3.1 Design and development planning

In planning the design and development of a product, the organization should:

a) identify the design and development stages in which people connected to the design process are engaged;

b) ensure that people involved in the design and development processes possess the necessary competences;

c) define design and development responsibilities and authorities for those involved;

d) ensure that there is communication between the people in the design and development process (see 7.3.2 and 7.3.3);

e) ensure that people are trained in design change and risk identification processes as related to design and development.

### 7.3.2 Design and development inputs

Design and development inputs requirements should be clearly determined and recorded, and inputs should be reviewed for adequacy. These inputs should not be conflicting. The organization should ensure that:

a) customer needs and expectations are communicated between designers and sales people;

b) design and development activities involve people from areas outside the design department (e.g. sales, marketing or production) to ensure agreement on design inputs;

c) design and development activities engage expertise from all functions of the organization;

d) relevant inputs are obtained.

### 7.3.3 Design and development outputs

Design and development outputs are verified against the inputs and approved prior to release, in order to ensure that:

a) both internal and external customers (including end-users) are consulted;

b) products under design and development meet requirements for people's safety and for ease of use by customers.

### 7.3.4 Design and development review

Design and development reviews are performed in accordance with the plan, and any issues that require action are addressed by the following:

a) involvement of the most appropriate people to identify design and development problems and solutions including the end users;

b) the results of the review being communicated to all those affected by the design and development decisions including the operations, sales and purchasing departments, end users and suppliers.

### 7.3.5 Design and development verification

In verifying design and development outputs to ensure that they have met input requirements, the organization should:

a) verify the design and development for usability with internal and external customers;

b) explain the design and development verification process to people in operations and sales prior to launch of a new product or service;


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c) ensure that the operations and sales teams are kept informed as necessary at all stages of the verification process.

### 7.3.6 Design and development validation

Validation is performed in accordance with the plan (see 7.3.1). Where practicable, validation of product or service will be completed prior to delivery and should:

a) be explained to people in operations and sales prior to launch;

b) ultimately occur with the internal or external customer;

c) be conducted by people with the competence to analyse the feedback from internal and external customers and suppliers, so that necessary modifications can be made.

### 7.3.7 Control of design and development changes

When identifying changes and maintaining records, changes should be reviewed, verified, validated and approved before implementation, and the following should apply:

a) design and development change meetings should involve those people who were part of the processes, including product users;

b) design and development changes should be explained to all those people affected by the change;

c) changes that affect customers and suppliers should be communicated to them during the change process.

## 7.4 Purchasing

### 7.4.1 Purchasing process

When applying control to a supplier, the type and extent of control depends on the impact of the purchase on product realization. Suppliers are evaluated and selected based on their ability to supply goods and services. In addition, the following should be considered:

a) people within the organization should understand and be able to apply the quality management principle relating to suppliers;

b) users of the purchased goods/services should be involved in supplier selection;

c) the organization's management should ensure that people who work in the organization, but are employed by an external organization, are competent and aware of the organizational processes and goals relevant to their function.

NOTE This can be accomplished through training, briefings and other appropriate communication.

### 7.4.2 Purchasing information

The supplier should be provided with appropriate information which adequately describes the product to be purchased, including applicable quality management systems requirements. In order to enable this:

a) the person issuing the purchasing requisition should know the specific information to provide to purchasing;

b) the person issuing the purchase order should know what information to provide to the supplier;

c) the organization's processes should be made known to the relevant people within the supplier's organization.

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### 7.4.3 Verification of purchased product

When ensuring the purchased product meets requirements, the organization should ensure that:

a) people have necessary competence for the verification of purchased product;

b) supplier performance is explained to staff, as necessary.

## 7.5 Production and service provision

### 7.5.1 Control of production and service provision

In planning and carrying out production and service provision under controlled conditions, the organization should ensure that:

a) people are involved in creating their own work instructions to ensure understanding;

b) work instructions are explained to new people and followed up with mentoring;

c) training programmes are developed for introduction of new processes;

d) critical product characteristics are explained to the workforce, and required measurements are agreed with those performing the work.

### 7.5.2 Validation of processes for production and service provision

The organization should validate any process for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. An explanation should be provided of the following:

a) the concept of being unable to verify process output;

b) the need to control process inputs such as material, information and documentation, so that the processes can be predictable.

### 7.5.3 Identification and traceability

When identifying the product and its status throughout the product realization process, the organization should:

a) ensure that people understand the meaning and importance of identification and traceability of product;

b) consider developing a process flowchart in order to explain traceability.

### 7.5.4 Customer property

Care should be taken with customer property while it is under the organization's control. People should understand the following:

a) the requirements relating to identification, verification and protection;

b) the concept of the customer's intellectual property and how to protect it.

### 7.5.5 Preservation of product

The quality management system is required to preserve product conformance during the internal processing and delivery to the intended destination. People should:

a) receive an explanation of critical product characteristics;

b) be involved in developing procedures where there is a high risk of deterioration of product;

c) be informed about responsibilities for monitoring product.


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### 7.6 Control of monitoring and measuring equipment

In cases where the quality management system requires the organization to determine the monitoring and measuring equipment needed to provide evidence of conformity of product, the people should:

a) understand the requirements relating to calibration and equipment control when using measuring equipment;

b) check the calibration status before using equipment and be aware of the consequences of the failure to control;

c) be competent to perform calibration.

## 8 Measurement, analysis and improvement

### 8.1 General

The organization should plan and implement monitoring, measurement, analysis and improvement processes. In addition, the following should apply:

a) the responsibilities in 5.5.1 should be defined for people who are measuring, evaluating and monitoring;

b) the persons responsible for a process should be involved in the selection of the key aspects to be measured in order to determine quality;

c) the persons responsible for measurement should be competent in measurement, analysis and improvement;

d) people should be provided with information on how measurements contribute to the measurement of the overall performance of the organization;

e) people should be enabled to improve the performance of their processes by selected measures.

### 8.2 Monitoring and measurement

#### 8.2.1 Customer satisfaction

The organization should monitor information relating to customer perceptions of whether the organization has met customer requirements. The following guidelines apply:

a) people should receive an explanation of the value of measuring and monitoring customer satisfaction (see ISO 10004);

b) results of customer satisfaction monitoring and measurement and the subsequent actions taken should be explained to people.

#### 8.2.2 Internal audit

The organization should conduct internal audits at planned intervals to determine whether the quality management system is effectively implemented and should ensure the following:

a) internal auditors are trained, competent and independent of those activities being audited;

b) people from all business functions are engaged on the audit team, and represent different levels of seniority, to enable the team to be seen as representative of the entire organization;

c) an explanation is provided to people being interviewed during an audit that the audit involves assessing the process and not the person;

d) people understand the purpose of the audit in reporting the effectiveness and efficiency of the quality management system to top management;

e) top management has an understanding of the audit process and has competence in monitoring the results.

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NOTE See ISO 19011 for guidance on internal auditing.

### 8.2.3 Monitoring and measurement of processes

The organization should monitor and measure the quality management system processes. When planned results are not achieved, correction or corrective action should be taken. In addition, the following should be considered:

a) process owners should monitor the process for which they are responsible;

b) indicators for measurement should be developed by the people involved in a given process;

c) the relationship should be explained between process measurement that people undertake and subsequent corrective actions.

### 8.2.4 Monitoring and measurement of product

The organization should monitor and measure the characteristics of a product to verify that the product requirements are met. In addition, the following should apply:

a) partnership should be encouraged between the process owner and verifier where the process owner is not responsible for monitoring the product;

b) people should have the necessary competence in, and should be provided with the work environment to perform, monitoring and measuring activities.

## 8.3 Control of non-conforming product

The organization should ensure that product which does not conform to specified requirements is identified and controlled to prevent its unintended use or delivery. The organization should ensure that:

a) those responsible for the process that identifies nonconforming product are involved in developing the required procedure;

b) people are provided with criteria for identifying and disposing of a non-conforming product or service;

c) people understand the risks resulting from product or service failure;

d) people attend information sharing sessions which provide feedback and analysis on non-conformity and which facilitate learning that prevents recurrence.

## 8.4 Analysis of data

Organizations should evaluate data to enable continual improvements and should:

a) develop people's competence in collection, analysis, interpretation and evaluation of data;

b) communicate the results of data analysis as soon as possible to the appropriate levels of management and other interested parties;

c) explain the results of data analysis to people thoroughly, so that necessary action may be taken.

NOTE ISO/TR 10017 provides information on statistical techniques and data analysis.


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## 8.5 Improvement

### 8.5.1 Continual improvement

The organization should continually improve the effectiveness of the quality management system and involve its people by:

a) developing a flowchart of the relationships between management review and measurement, corrective or preventive action, and continual improvement;

b) encouraging leaders to establish and implement improvement programmes involving people across functions;

c) encouraging leaders to train people in the continual improvement process.

### 8.5.2 Corrective action

The organization should take action to eliminate the causes of non-conformity in order to prevent their recurrence. In addition, the following should apply:

a) a structured methodology should be followed, which people can understand and apply to identify the root causes of problems;

b) root causes should be identified by ensuring people are competent in using the knowledge gained from measurement;

c) an understanding should be developed of the concept of collective knowledge to be used in problem solving;

d) cross-functional teams should be used for improvement projects, in order to gain benefit from collective knowledge.

### 8.5.3 Preventive action

The organization should determine action to eliminate potential causes of non-conformities, in order to prevent their occurrence, by ensuring that:

a) people understand the concept that preventive action is appropriate when there is tendency for a process to go in the wrong direction;

b) the importance of the relationship between preventive action and data analysis is explained;

c) there is an understanding of the value of preventive action as opposed to corrective action.

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# Annex A
(informative)

# Factors that impact on people involvement and competence

## A.1 General

The following factors are addressed in this annex:

— attitude and motivation (see Clause A.2);

— awareness (see Clause A.3);

— communication (see Clause A.4);

— creativity and innovation (see Clause A.5);

— education and learning (see Clause A.6);

— empowerment (see Clause A.7);

— engagement (see Clause A.8);

— leadership (see Clause A.9);

— networking (see Clause A.10);

— recognition and rewards (see Clause A.11);

— recruitment (see Clause A.12);

— responsibility and authority (see Clause A.13);

— teamwork and collaboration (see Clause A.14).

The description of factors provides an explanation of why each is important and the benefits gained from implementation.

## A.2 Attitude and motivation

Leaders should ensure that people have the attitude and motivation to achieve the outcomes desired by the organization. The key benefits of positive attitudes and motivation are that they foster a work environment that is conducive to achieving planned results.

People's behaviour should be consistent with the aims of the organization's strategies, policies and procedures. This involves people demonstrating values and behaviour that lead them to act in a manner oriented towards achieving organizational objectives. A person's views regarding the organization's policies, procedures, processes, product, suppliers, staff, customers, top management, or other elements of the management system give purpose and direction to their behaviour.

Positive attitudes develop as a result of leadership behaviour (see Clause A.9), providing education and competence development (see Clause A.6) and through structured recognition programmes (see Clause A.11).


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## A.3 Awareness

People should understand the policies and objectives of the quality management system and their role in helping to achieve them. To achieve this, people should be made aware that ISO 9001 requires an organization to establish a quality management system in which processes are identified and effective process operation ensured. People should understand their individual responsibilities in achieving effective process operation.

Leaders should ensure that people in the organization understand the purpose of the quality management system and their role in the system. They should also ensure that people are aware that the quality management system includes documents for policy and objectives, a manual and procedures, planning documents and records, that should be known and controlled. People should be involved at all stages of identifying process and controls they work with and they should be aware of their process responsibilities.

Awareness is often provided during a person's induction when joining the company (see Clause A.12). Methods by which this awareness is provided can be by explanation from a person's supervisor, group presentation in slide format or by video presentation. However, it should be regarded as a continuous activity with information being provided at regular intervals about results related to the quality management system.

## A.4 Communication

Effective communication is necessary in order for people inside and outside the organization to work with common objectives. As organizations grow and become more complex, communication becomes more difficult.

Accuracy, brevity and clarity make communication effective. The objective of any communication needs to be clear, and unnecessary content should be avoided. A message should be delivered in the simplest terms and should be in a form that will be understood by the receiver. Verbal messages are not always clearly understood first time and key points should be repeated.

Communication may be delivered through media which may be verbal or non-verbal. The correct media for a message should be chosen by considering the audience. The media and methods will depend on the purpose and nature of the communication. Complex messages should be documented and simple messages may be provided verbally. Important messages will usually be provided in multiple media, e.g. visually, verbally and in written form. Media examples include face-to-face meetings, newsletters, blogs, e-mails, conferences and videoconferences.

In a hierarchical organization, internal communication may be "top down" from leaders and managers, and may be "bottom up" when information on performance is provided. A matrix organization would also have cross-functional communication between groups and between people sharing information (see Clause A.10).

Communication is necessary to provide information about the quality management system and organizational strategies (see Clause A.3). It is also necessary for asking people their views, so they can influence plans and decisions, and for providing an understanding of which issues are important to each individual's work (see Clause A.14).

## A.5 Creativity and innovation

Creativity and innovation inside the organization helps to improve existing processes and products and to create new products and services for the market.

Creativity is the process of producing new ideas, while innovation is the process of both creating and applying these ideas. In the context of an organization, the term "innovation" refers to the entire process by which people or groups generate new ideas and convert them into commercial products, services and business practices. Innovation is frequently obtained as a result of sharing collective knowledge. Successful innovation results from a high degree of people involvement (see also Clauses A.10 and A.14).

The nature of the contribution that people make to the innovation process changes through the process. Changing needs in the modern workplace require individuals to both work within existing stable processes and to operate effectively in a changing work environment using new competences of creativity and innovation.

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To develop creativity and innovation, leaders should recognize and encourage innovation (see Clause A.11). This is achieved by identifying opportunities to innovate and by encouraging people to create practical solutions.

## A.6 Education and learning

Competence is the ability to apply knowledge and skills to achieve intended results. The benefit of education and learning is the increase in competence, which leads to an increase in a person's ability to create value for the organization and its customers. Education and learning are essential factors in people involvement and competence. Successful organizations apply the knowledge and skills of their people in a way that creates value for the organization and its customers.

Learning is the process of acquiring knowledge or skills through experience, from study, or from instruction. Formal learning will often result in a person receiving qualifications. Learning processes may apply to a person or collectively to an organization. An organization should recognise that people learn in different ways. Adults learn differently from children. Some people are more suited to a classroom environment and others to a mentoring environment. Others learn better in a web based environment.

The learning organization focuses on increasing its knowledge to continually increase the organization's capacity for performance. Organizations need to be competent to be competitive. To achieve the necessary flow of information and knowledge and become a learning organization, the organization's processes need to form a management system. An organization's ability to learn enables it to be more competitive. The learning organization focuses on increasing its knowledge to continually increase the organization's capacity for performance.

Benefits of an effective learning process are an increase in the sense of achievement, job satisfaction and job security. This leads to an improvement in attitude and motivation (see Clause A.2). Improvement in competences such as communication leads to improvement in product quality and better customer service. For the organization, this leads to increased competitiveness and profitability.

## A.7 Empowerment

Empowerment enables people to take responsibility for their work and its results. It is achieved by providing people with the necessary information, authority and freedom to take decisions related to their own work. This results in a reduction in the need for centralized control and enables an organizational to operate with greater agility.

To achieve this, leaders should define individual objectives, delegate authority and responsibility, and create a work environment in which people control their own work and decision making (see Clause A.9). The organization should provide the incentive for people to act autonomously, recognizing good performance, rewarding results and celebrating the goals reached (see Clause A.11).

Resources should be provided to develop people's competence (see Clause A.6). Complete knowledge and information should be provided about their work and also about the organization's overall performance and trends. Empowerment enhances learning. A critical feature of successful teams is that they are invested with the authority to make decisions (see Clause A.14).

Empowerment enables a leader and a manager to invest more time in strategy and planning.

## A.8 Engagement

When people are fully engaged in the activities of an organization, they experience more personal fulfilment and the organization consequently conducts its activities more effectively. Engagement is the outcome of effective recruitment (see Clause A.12), followed by an introduction to the workforce through an awareness process (see Clause A.3). Successful engagement then requires both engagement of leadership and engagement of people.

Leadership engagement is necessary to show a company's commitment to improving the partnership between people and leaders. Leaders should become engaged with their people by understanding the expectations of their people. This is achieved by obtaining regular feedback (see Clause A.4). The level of engagement a person experiences is a direct relationship of how people relate to their leaders managers and colleagues (see Clause A.10).


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A person's perception of their job's importance directly impacts customer satisfaction. The level of importance to the organization will be shown by the availability of resources for a person to carry out their work. Improvements and changes are more likely to be produced by people who are fully engaged.

## A.9 Leadership

Leaders establish unity of purpose and the direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives [see ISO 9000:2005, 0.2, bullet b)]. Leadership provides a clear focus for people throughout an organization and enables them to follow a path to achievement of the organizational objectives. A leader needs to possess the necessary competences to achieve this.

Leaders define objectives and designate resources, and they act in a more strategic role. Managers organize resources to achieve a result by engaging the people in the organization, and they act in a more tactical role. Managers coordinate activities to direct and control an organization.

## A.10 Networking

Networking promotes the transfer of information, knowledge and ideas.

There are two main types of networks:

— the open network is more suited to sharing knowledge;

— the closed network is for achieving results.

The open network is suited to finding opportunities and conceptual solutions. To be effective, this network should be diverse and dispersed. It should contain customers, business partners and people in other disciplines. Innovative breakthroughs frequently occur at the intersection of different bodies of knowledge.

The closed network is easier to form and is more effective for achieving results. People naturally gravitate to people with similar backgrounds and form closed networks. This network is also vulnerable to "groupthink". The knowledge exchanged between such small groups of familiar people is more focused and higher volume. Closed networks usually lack diversity.

Small organizations are easily networked, but as organizations grow, communication becomes more difficult (see Clause A.4). Networks can be developed by electronic means through an intranet. However, the rate of information transfer in such networks in a given time is much lower than in person-to-person networking.

## A.11 Recognition

Recognition and reward reinforce people's behaviour and their understanding of the value their efforts have provided for the organization. Recognition should reinforce behaviour that is to be encouraged. It also demonstrates that the organization values its people and cares about their success, which reinforces the pride and esteem of the people.

Some organizations also recognize the contribution of others outside, such as suppliers and outsourced workers. The principles apply in the same way.

Non-monetary recognition can often be valued more by people than money or gifts. To address recognition, the organization should establish clear and understandable criteria for what performance or contribution will be rewarded by the organization, and it should provide systematic feedback to the people inside organization.

The organization should supply its people with specific information about the behaviour or actions being recognized. The recognition should ideally occur as close to the performance of the actions as possible, so that the recognition reinforces behaviour the organization wishes to encourage.

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## A.12 Recruitment

Recruitment is the process of sourcing, screening and selecting people for a position in an organization. Managers can undertake some part of the recruitment process, but larger organizations may use professional recruiters.

Sourcing for candidates involves identification of people with relevant competences through advertising or through agency searches. This results in a list of prospects, which can then be evaluated to identify those with the appropriate qualifications and any necessary personality fit with the organization.

Competences should be evaluated prior to the interview to identify competence levels. Tests can include: cognitive aptitude tests, job knowledge tests and personality tests. Interviews can then be unstructured or structured.

The information the applicant has provided in his application should be verified, and there may be a need for security clearances in some work situations. This can be an extensive task and should be restricted to the final two or three applicants if there is a close decision on selection. The physical ability of a person to perform the work may also need to be verified.

The final decision on selection is normally made by the person who will supervise the future employee. The decision might also include the opinions of future co-workers if the applicant has met those people during the selection process. This depends on the culture of the organization.

The legal process of engaging the people is then completed. There may also be a new starter induction, or a probationary period.

## A.13 Responsibility and authority

When people have a clear understanding of their role and responsibilities in the organization, they are more effectively engaged in the organization (see Clause A.8).

The organization should provide people with the appropriate authority to assume responsibility for making decisions about their work, which is consistent with their competence and with requirements defined in the quality management system. For responsibility and authority to be accepted in an organization, it should create a work environment which fosters the desire and ability of people to control their own work and decision making (see Clause A.2).

Leaders should assign appropriate responsibility to the organization's people and develop the skills necessary for them to fulfil their responsibilities. Leaders and managers should endeavour to delegate control of processes and the authority for individuals to make decisions and thus increase the organization's agility.

## A.14 Teamwork

The ability to work in a team is acknowledged as being a requirement for people in organizations of any size. Teamwork results from the ability of people to work together in a creative and productive relationship within a process, leading to enhanced and assured quality in products and services. Teamwork develops when there is mutual trust and respect between members of a team.

Processes frequently cross departments and functions, as well as national boundaries in an organization. Teamwork helps to focus and optimize the efforts required of people. Teamwork reduces risk by avoiding overdependence on one person, and it provides the added assurance that quality objectives can be achieved. However, organizations should assess people's aptitude for roles within teams.

An effective team increases the probability of achieving set results for any project, process, product or service. For effective teamwork, a leader should create an appropriate environment in which people can work together by defining common goals and team targets. Teamwork is encouraged by rewarding the team rather than the individual, by recognizing positive influences and by creating incentives for collaboration in the group (see Clause A.11).


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# Annex B
(informative)

# Self-assessment

Most of the considerations in Clauses 5 to 8 can be used as a checklist to assess the situation regarding people involvement and competence in an organization. The level of people involvement and competence could also be checked by comparing the completed actions against the items listed under each clause. Various adjustments are possible when determining the level of involvement, e.g. assessing the degree to which separate actions are completed, or putting different weightings to the actions.

**Table B.1 — Self-assessment of people involvement**

| Maturity level | | | | |
|---|---|---|---|---|
| **Level 1** | **Level 2** | **Level 3** | **Level 4** | **Level 5** |
| People are informed through meetings or e-mails, etc. about those actions listed in Clauses 5 to 8 relevant to their area of work, and about the possibility of individuals and teams influencing the actions.<br><br>Suggestions from people are welcomed. | People discuss with their immediate supervisors about those actions listed in Clauses 5 to 8 relevant to their area of work, in particular of the endeavour for continual improvement.<br><br>They suggest improvements in some of the actions.<br><br>The suggestions are dealt with promptly. | People are active in implementing and improving relevant actions listed in Clauses 5 to 8 within their area of work.<br><br>Support is given by supervisors. | People are active in transferring experience of implementing and improving actions listed in Clauses 5 to 8 from their area of work to other parts of the organization.<br><br>There is good support from management. | People initiate and develop new actions connected to those listed in Clauses 5 to 8 within their area of work and apply this also in other parts of the organization or with customers and suppliers.<br><br>The involvement and commitment are visibly recognized by management. |

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**Table B.2 — Self-assessment of competence**

| Maturity level | | | | |
|---|---|---|---|---|
| **Level 1** | **Level 2** | **Level 3** | **Level 4** | **Level 5** |
| People have knowledge and skills to perform assigned routine tasks without supervision of instructor. Other assigned tasks need such supervision.<br><br>People sometimes ask for training within their area of work. | People have knowledge and skills to perform all tasks assigned to them without supervision of instructor.<br><br>They request in-house and/or external training for development of their competence.<br><br>They give ideas for improvement. | People have knowledge and skills to act as instructors in their work area.<br><br>They take responsibility for the processes where they are active.<br><br>They develop and implement ideas for improvement.<br><br>They ask for mentoring or coaching to obtain qualifications for other assignments or positions. | People have knowledge and skills to act as mentors and coaches.<br><br>They are eager to share their knowledge and skills for improvement of the organization.<br><br>They take part in internal and external benchmarking activities.<br><br>They give background for the organization's strategic development.<br><br>They are active in implementing new processes.<br><br>They request a well defined career plan. | People have knowledge and skills to take responsibility for some major part of the organization.<br><br>They are active in the development of the organization's strategy, policy and objectives.<br><br>They initiate and are active in the development of new processes.<br><br>They have an extended network and act as important representatives externally. |


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# Bibliography


[1] ISO 9001, *Quality management systems — Requirements*

[2] ISO 9004, *Managing for the sustained success of an organization — A quality management approach*

[3] ISO 10001, *Quality management — Customer satisfaction — Guidelines for codes of conduct for organizations*

[4] ISO 10002, *Quality management — Customer satisfaction — Guidelines for complaints handling in organizations*

[5] ISO 10003, *Quality management — Customer satisfaction — Guidelines for dispute resolution external to organizations*

[6] ISO 10004, *Quality management — Customer satisfaction — Guidelines for monitoring and measuring*

[7] ISO 10015, *Quality management — Guidelines for training*

[8] ISO/TR 10017, *Guidance on statistical techniques for ISO 9001:2000*

[9] ISO 19011, *Guidelines for auditing management systems*

[10] *Quality management principles*, ISO, 2001[1)]


1) Available at http://www.iso.org.

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