

INTERNATIONAL STANDARD

ISO 9004-4

First edition
1993-06-15

Quality management and quality system elements —

Part 4:

**Guidelines for quality improvement
(standards.iteh.ai)**

Gestion de la qualité et éléments de système qualité —

Partie 4: Lignes directrices pour l'amélioration de la qualité
<https://standards.iteh.ai/catalog/standards/sist/d756c80d3934/iso-9004-4-1993>



Reference number
ISO 9004-4:1993(E)

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International Organization for Standardization
Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

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iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO 9004-4:1993

<https://standards.iteh.ai/catalog/standards/sist/47fa0ca7-f87c-4869-856b-d756c80d3934/iso-9004-4-1993>

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.

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.

International Standard ISO 9004-4 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Sub-Committee SC 2, *Quality systems*.

ISO 9004 consists of the following parts, under the general title *Quality management and quality system elements*:

- Part 1: *Guidelines*
- Part 2: *Guidelines for services*
- Part 3: *Guidelines for processed materials*
- Part 4: *Guidelines for quality improvement*
- Part 5: *Guidelines for quality plans*
- Part 6: *Guide to quality assurance for project management*
- Part 7: *Guidelines for configuration management*

Part 1 is a revision of ISO 9004:1987.

Annex A forms an integral part of this part of ISO 9004. Annex B is for information only.

Introduction

When implementing a quality system (e.g. as described in ISO 9004), the management of an organization should ensure that the system will facilitate and promote continuous quality improvement. A constant goal of management at all levels of an organization should be to strive for customer satisfaction and continuous quality improvement.

The quality of products and services is important for competitiveness. Continuous quality improvement is necessary to enhance an organization's competitive position. It should be emphasized that innovative strategies for the introduction of new product, service, or process technologies and continuous quality improvement all need to be considered.

The motivation for quality improvement comes from the need to provide increased value and satisfaction to customers. Every member of an organization should develop a conscious awareness that each process can be performed more effectively and more efficiently with less waste and resource consumption.

Increases in effectiveness and efficiency benefit customers, the organization and its members, and society in general. Continuous quality improvement enhances the ability of an organization to compete and the opportunity for its members to contribute, grow and excel.

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Quality management and quality system elements —

Part 4: Guidelines for quality improvement

1 Scope

This part of ISO 9004 gives management guidelines for implementing continuous quality improvement within an organization.

The ways of adopting and implementing these guidelines depend upon factors such as the culture, size, nature of the organization, the types of products or services offered, and the markets and customer needs served. Therefore, an organization should develop an improvement process suited to its own needs and resources.

This part of ISO 9004 is not for contractual, regulatory or certification use.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this part of ISO 9004. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this part of ISO 9004 are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8402:—¹⁾, *Quality management and quality assurance — Vocabulary*.

3 Definitions

For the purposes of this part of ISO 9004, the definitions given in ISO 8402 and the following definitions apply.

3.1 process: A set of inter-related resources and activities which transforms inputs into outputs.

NOTE 1 Resources may include personnel, facilities, equipment, technology and methodology.

3.2 supply chain: A set of inter-related processes that accepts inputs from suppliers, adds value to these inputs, and produces outputs for customers.

NOTES

- Input and outputs can be either products or services.
- Customers and suppliers can be either internal or external to the organization.
- A unit of a supply chain is illustrated in figure 1.

3.3 quality improvement: Actions taken throughout the organization to increase the effectiveness and efficiency of activities and processes to provide added benefits to both the organization and its customers.

3.4 quality losses: Losses caused by not realizing the potential of resources in processes and activities.

NOTE 5 Some examples of quality losses are the loss of customer satisfaction, loss of opportunity to add more value for the customer, the organization or society, as well as a waste of resources. Quality losses are a subset of quality costs (see 4.3).

1) To be published. (Revision of ISO 8402:1986)

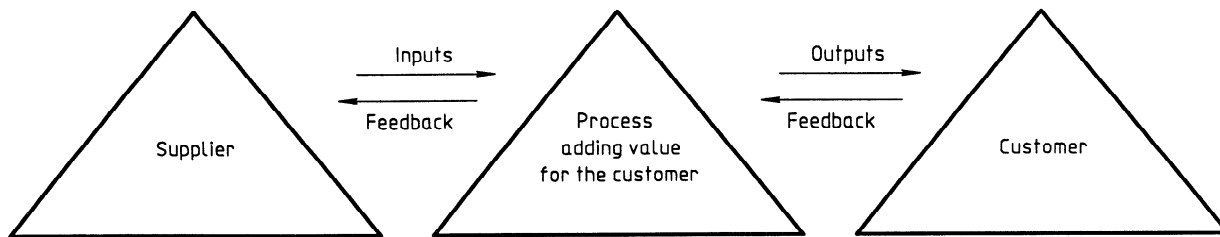


Figure 1 — A unit of a supply chain

3.5 preventive action: An action taken to eliminate the causes of a potential nonconformity, defect or other undesirable situation in order to prevent occurrence.

3.6 corrective action: An action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence.

NOTE 6 Actions for correcting process outputs include repair, rework or adjustment taken to rectify nonconforming, defective or other undesirable process outputs.

4 Fundamental concepts

4.1 Principles of quality improvement

The quality of an organization's products, services and other outputs is determined by the satisfaction of the customers who use them and results from the effectiveness and efficiency of the processes that create and support them.

Quality improvement is achieved by improving processes. Every activity or item of work in an organization comprises one or more processes.

Quality improvement is a continuous activity, aiming for ever higher process effectiveness and efficiency.

Quality-improvement efforts should be directed towards constantly seeking opportunities for improvement, rather than waiting for a problem to reveal opportunities.

Correcting process outputs reduces or eliminates a problem which has occurred. Preventive and corrective actions eliminate or reduce the causes of a problem, and hence eliminate or reduce any future occurrence. Thus, preventive and corrective actions improve the processes of an organization and are critical to quality improvement.

4.2 Environment for quality improvement

4.2.1 Management responsibility and leadership

The responsibility and leadership for creating the environment for continuous quality improvement belong to the highest level of management. Managers convey the leadership and commitment necessary for creating the environment for quality improvement by their own actions, constancy and deployment of resources. Managers lead quality improvement by communicating purpose and goals, by continuously improving their own work processes, by fostering an environment of open communication, teamwork and respect for the individual, and by enabling and empowering everyone in the organization to improve their work processes.

4.2.2 Values, attitudes and behaviour

The environment for quality improvement often requires a new set of shared values, attitudes and behaviour focusing on satisfying customer needs and setting ever more challenging goals. Values, attitudes and behaviour that are essential for continuous quality improvement include:

- focusing attention on satisfying the needs of both internal and external customers;
- involving the entire supply chain from suppliers to customers in quality improvement;
- demonstrating management commitment, leadership and involvement;
- emphasizing quality improvement as a part of everyone's job, either by teamwork or individual activities;
- addressing problems by improving processes;
- continuously improving all processes;
- establishing open communication with access to data and information;

- promoting teamwork and respect for the individual;
- making decisions based on the analysis of data.

4.2.3 Quality-improvement goals

Quality-improvement goals should be established throughout the organization. They should be closely integrated with the overall business goals and provide focus for increasing customer satisfaction and process effectiveness and efficiency. Quality-improvement goals should be defined so that progress can be measured. They should be clearly understandable, challenging and pertinent. Strategies to achieve these goals should be understood and agreed to by all who must work together to achieve them. Quality-improvement goals should be regularly reviewed and should reflect changing customer expectations.

4.2.4 Communications and teamwork

Open communication and teamwork remove organizational and personal barriers that interfere with effectiveness, efficiency and continuous improvement of processes. Open communication and teamwork should be extended throughout the whole supply chain, including suppliers and customers. Communication and teamwork require trust. Trust is essential if everyone is to be involved in identifying and following up on opportunities for improvement.

4.2.5 Recognition

The recognition process encourages actions consistent with values, attitudes and behaviour necessary for quality improvement (see 4.2.2).

Successful recognition processes emphasize the development and growth of individuals and consider the factors which influence an individual's work performance (e.g. opportunity, organization, environment). Furthermore, successful recognition processes emphasize group performance and group recognition, and encourage frequent and informal feedback.

NOTE 7 Reward systems should be consistent with the recognition process. In particular, reward systems should avoid promoting destructive internal competition.

4.2.6 Education and training

On-going education and training are essential for everyone. Education and training programmes are important in creating and maintaining an environment for quality improvement. All members of an organization, including the highest levels of management, should be educated and trained in quality principles and practices and in the application of appropriate methods for quality improvement. This includes the use of quality-improvement tools and techniques (see

annex A). All education and training programmes should be reviewed for consistency with quality principles and practices. The effectiveness of education and training should be regularly assessed. Training separated from application is rarely effective (see 7.3).

4.3 Quality losses

Opportunities to reduce quality losses guide quality-improvement efforts. Quality losses should be linked with the processes causing them. It is important at least to estimate even those quality losses which are difficult to measure, such as the loss of customer goodwill and the failure fully to utilize human potential. Organizations should reduce quality losses by using every opportunity to improve quality.

5 Managing for quality improvement

Although the application of any of the techniques described in annex A will give some incremental improvement, their full potential can only be realized if they are applied and coordinated within a structured framework. This requires organizing, planning, measuring for quality improvement, and reviewing all quality-improvement activities.

5.1 Organizing for quality improvement

An effective way of organizing quality improvement identifies opportunities for quality improvement both vertically within the organizational hierarchy and horizontally in the processes that flow across organizational boundaries. In organizing for quality improvement, the following should be addressed:

- a means for providing policy, strategy, major quality-improvement goals, overall guidance, support and broad coordination of the organization's quality-improvement activities;
- a means of identifying cross-functional quality-improvement needs and goals and assigning resources to pursue them;
- a means to pursue quality-improvement goals by team activities within areas of direct responsibilities and authorities;
- a means for encouraging every member of the organization to pursue quality-improvement activities related to their work and for coordinating these activities;
- a means of reviewing and assessing the progress of quality-improvement activities.

Within the organizational hierarchy, responsibilities for quality improvement include:

- management processes such as defining the mission of the organization, strategic planning, clarifying roles and responsibilities, acquiring and assigning resources, providing education and training, and recognition;
- identification and planning of continuous improvement of the work processes of the organization;
- identification and planning of continuous improvement of the administrative-support processes of the organization;
- measurement and tracking of reduction of quality losses;
- development and maintenance of an environment that empowers, enables and charges all members of the organization continuously to improve quality.

Within the processes that flow across organizational boundaries, responsibilities for quality improvement include:

- defining and agreeing on the purpose of each process and its relationship with the objectives of the organization;
- establishing and maintaining communication among departments;
- identifying both internal and external customers of the process and determining their needs and expectations;
- translating customer needs and expectations into specific customer requirements;
- identifying suppliers to the process and communicating to them their customer needs and expectations;
- searching for process-improvement opportunities, allocating resources for improvement, and overseeing implementation of these improvements.

5.2 Planning for quality improvement

Quality-improvement goals and plans should be a part of an organization's business plan.

Management should set quality-improvement goals in the broadest sense including reducing quality losses. Plans should be developed within the business planning cycle to provide strategic guidance and direction for meeting these quality-improvement goals and implementing the quality policy. These plans should address the most important quality losses and should be deployed throughout all functions and all levels of the organization.

The development of quality-improvement plans should involve everyone in the organization, together with the suppliers and customers of the organization. Involving everyone greatly increases the opportunities for improvement.

Quality-improvement plans are often implemented through a set of specific quality-improvement projects or activities. Management should take care to monitor and control such implementation activities to ensure their integration into the overall goals and business plans of the organization.

Plans for quality improvements focus on newly identified opportunities and on areas where insufficient progress has been made. The planning process has inputs from all levels of the organization, from reviews of achieved results, and from customers and suppliers.

5.3 Measuring quality improvement

An organization should develop a measurement system that fits the nature of its operations. A system of objective measurements should be established for identifying and diagnosing improvement opportunities and for measuring the results of quality-improvement activities. A well-developed system includes measurements at unit, department, cross-functional and total organizational levels. The measurements should relate to quality losses associated with customer satisfaction, process efficiencies and societal losses.

- a) Measures of quality losses associated with customer satisfaction may be based on information from surveys of current and potential customers, surveys of competing products and services, product or service performance records, changes in revenues, routine inspections by service personnel, information from sales and service staff, and customer complaints and claims.
- b) Measures of quality losses associated with process efficiency may be based on labour, capital and material utilization, producing, sorting, correcting or scrapping unsatisfactory process output, process readjustments, waiting times, cycles times, delivery performance, unnecessarily redundant designs, size of inventories and statistical measures of process capability and process stability.
- c) Measures of societal quality losses may be based on failure to realize human potential (e.g. as indicated by employee satisfaction surveys), damage caused by pollution and disposal of waste and depletion of scarce resources.

The phenomenon of variability is common to all measurements. Trends displayed by measurements should be interpreted statistically.

Measuring and tracking trends from a "baseline" of past performance are important, in addition to establishing and meeting numerically given targets. Measuring enhances problem identification based on fact.

The measurements should be reported and reviewed as an integral part of the management accounting and control practices of the organization. The people and organizations involved in the improvement process should be informed of their progress in terms that are meaningful and measurable from their perspective.

5.4 Reviewing quality-improvement activities

Regular reviews of quality-improvement activities should be conducted at all levels of management to ensure that:

- the organization for quality improvement is functioning effectively;
- plans for quality improvement are adequate and are being followed;
- measurements for quality improvement are appropriate and adequate, and indicate satisfactory progress;
- results of the review are fed into the next planning cycle.

Appropriate actions should be taken where any discrepancies have been identified.

6 Methodology for quality improvement

Quality-improvement benefits will accumulate steadily when an organization pursues quality-improvement projects and activities in a consistent, disciplined series of steps based on data collection and analysis.

6.1 Involving the whole organization

When an organization is well motivated and managed for quality improvement, a number of quality-improvement projects or activities of varied complexity will be continuously undertaken and implemented by all members and levels of the organization. Quality-improvement projects and activities will become a normal part of everyone's work and will vary from those necessitating cross-functional or management teams to those which will be selected and implemented by either individual members or teams.

A quality-improvement project or activity usually starts with the recognition of an improvement opportunity. This recognition can be based on measures of quality

losses and/or on competitive comparisons (benchmarks) against organizations recognized as leaders in a particular field. Once defined, the quality-improvement project or activity progresses through a series of steps and is completed with the implementation of preventive or corrective actions taken on the process in order to reach and maintain the new, improved level of performance. As quality-improvement projects or activities are completed, new quality-improvement projects or activities are selected and implemented.

6.2 Initiating quality-improvement projects or activities

All members of the organization are involved in initiating quality-improvement projects or activities. The need, scope and importance of a quality-improvement project or activity should be clearly defined and demonstrated. The definition should include the relevant background and history, the associated quality losses and the current status, if possible expressed in specific, numerical terms. A person or a team, including the team leader, should be assigned to the project or activity. It is necessary to establish a schedule and allocate adequate resources. Provisions should be made for periodic reviews of scope, schedule, resource allocation and progress.

6.3 Investigating possible causes

The purpose of this step is to increase the understanding of the nature of the process to be improved by collection, validation and analysis of data. Data collection should always be carried out according to a carefully constructed plan. It is important to carry out the investigation of the possible causes with the utmost objectivity, without any preconceptions of what the causes or preventive or corrective actions might be. Decisions will then be based on facts.

6.4 Establishing cause-and-effect relationships

The data are analysed to gain insight into the nature of the process to be improved and to formulate possible cause-and-effect relationships. It is essential to distinguish between coincidence and cause-and-effect relationships. The relationships that appear to have a high degree of consistency with the data need to be tested and confirmed based on new data collected according to a carefully constructed plan.

6.5 Taking preventive or corrective actions

After cause-and-effect relationships are established, alternative proposals for preventive or corrective ac-

tions to address the causes should be developed and evaluated. Advantages and disadvantages of each proposal should be examined by the members of the organization who will be involved in implementing these actions. Successful implementation depends on the cooperation of all those involved.

NOTE 8 Quality improvements are obtained by taking preventive or corrective actions on the process to produce either more satisfactory outputs and/or reduce the frequency of unsatisfactory outputs. Relying solely on correcting process outputs such as repairing, reworking, or sorting perpetuates quality losses.

6.6 Confirming the improvement

After implementing preventive or corrective actions, appropriate data must be collected and analysed to confirm that an improvement has been made. The confirmatory data should be collected on the same basis as the data collected to investigate and establish cause-and-effect relationships. Investigations also need to be made for side effects, either desirable or undesirable, that may have been introduced.

If, after preventive or corrective actions are taken, the undesirable results continue to occur at approximately the same frequency as before, it will be necessary to redefine the quality-improvement project or activity by returning to the initiation step.

6.7 Sustaining the gains

After the quality improvement has been confirmed, it needs to be sustained. This usually involves a change of specifications and/or operating or administrative procedures and practices, necessary education and training, and making sure that these changes become an integral part of the job content of everyone concerned. The improved process then needs to be controlled at the new level of performance.

6.8 Continuing the improvement

If the desired improvement is obtained, new quality-improvement projects or activities should be selected and implemented. Since additional quality improvements are always possible, a quality-improvement project or activity may be repeated based on new objectives. It is advisable to set priorities, and to assign time limits for each quality-improvement project or activity. Time limits should not constrain effective quality-improvement activities.

NOTE 9 The "plan-do-check-act cycle" is used for continuous quality improvement. The quality-improvement methodology in this part of ISO 9004 emphasizes the check-act phases of this cycle.

7 Supporting tools and techniques

Decisions based on the analysis of situations and data play a leading role in quality-improvement projects and activities. Success of quality-improvement projects and activities is enhanced by proper application of tools and techniques developed for these purposes.

7.1 Tools for numerical data

Where possible, quality-improvement decisions should be based on numerical data. Decisions regarding differences, trends and changes in numerical data should be based on proper statistical interpretation.

7.2 Tools for non-numerical data

Some quality-improvement decisions may be based on non-numerical data. Such data play an important role in marketing, research and development, and in management decisions. Appropriate tools should be used to process properly this kind of data to transform them into useful information for decision making.

7.3 Training in applying tools and techniques

All members of the organization should receive training in applying quality-improvement tools and techniques to improve their work processes. Training separated from application is rarely effective. Annex A describes some of the numerous tools and techniques which have been developed. Table 1 lists these tools and techniques and their applications in quality improvement. Other tools or techniques may be appropriate for specific applications.