BRITISH STANDARD

Quality management systems — Guidelines for quality plans

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BSi

British Standards

National foreword

This British Standard reproduces verbatim ISO 10005:2005 and implements it as the UK national standard. It supersedes BS ISO 10005:1995 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee QS/1, Quality management and quality assurance procedures, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Summary of pages

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INTERNATIONAL STANDARD

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Quality management systems — Guidelines for quality plans

Systèmes de management de la qualité — Lignes directrices pour les plans qualité

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Contents

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 10005 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

This second edition cancels and replaces the first edition (ISO 10005:1995). It constitutes a technical revision of that edition, taking into account ISO 9000:2000, ISO 9001:2000 and ISO 9004:2000.

Introduction

This International Standard was prepared to address the need for guidance on quality plans, either in the context of an established quality management system or as an independent management activity. In either case, quality plans provide a means of relating specific requirements of the process, product, project or contract to work methods and practices that support product realization. The quality plan should be compatible with other associated plans that may be prepared.

Among the benefits of establishing a quality plan are the increased confidence that requirements will be met, greater assurance that processes are in control and the motivation it can give to those involved. It may also give insight into opportunities for improvement.

This International Standard does not replace the guidance given in ISO 9004 or in industry-specific documents. Where quality plans are required for project applications, the guidance provided in this International Standard is intended to be complementary to the guidance provided in ISO 10006.

In terms of the process model shown in Figure 1, quality management system planning applies to the whole model. Quality plans, however, apply primarily to the path from customer requirements, through product realization and product, to customer satisfaction.
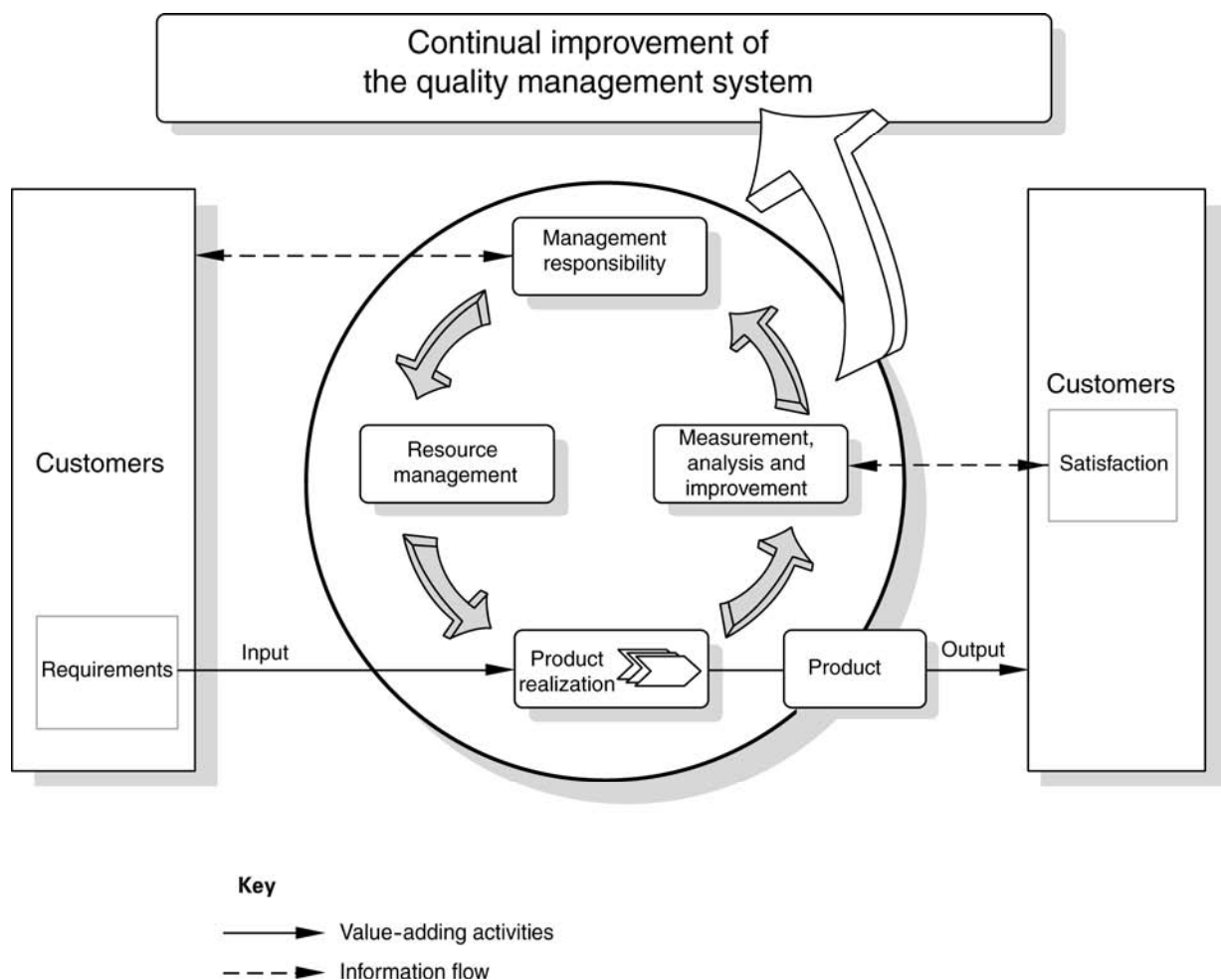

Figure 1 — Model of a process-based quality management system

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Quality management systems — Guidelines for quality plans

1 Scope

This International Standard provides guidelines for the development, review, acceptance, application and revision of quality plans.

It is applicable whether or not the organization has a management system in conformity with ISO 9001.

This International Standard is applicable to quality plans for a process, product, project or contract, any product category (hardware, software, processed materials and services) and any industry.

It is focused primarily on product realization and is not a guide to organizational quality management system planning.

This International Standard is a guidance document and is not intended to be used for certification or registration purposes.

NOTE To avoid undue repetition of "process, product, project or contract", this International Standard uses the term "specific case" (see 3.10).

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 9000:2000, *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. Some of the definitions below are quoted directly from ISO 9000, but notes are in some cases omitted or supplemented.

3.1
objective evidence
data supporting the existence or verity of something

NOTE   Objective evidence may be obtained through observation, measurement, test, or other means.

[ISO 9000:2000, definition 3.8.1]

3.2
procedure
specified way to carry out an activity or a **process** (3.3)

NOTE 1   Procedures can be documented or not.

NOTE 2   When a procedure is documented, the term "written procedure" or "documented procedure" is frequently used. The document that contains a procedure can be called a "procedure document".

[ISO 9000:2000, definition 3.4.5]

3.3

process

set of interrelated or interacting activities which transforms inputs into outputs

NOTE   Adapted from ISO 9000:2000, definition 3.4.1 (the Notes have not been included).

3.4

product

result of a **process** (3.3)

NOTE 1   There are four generic product categories, as follows:

— services (e.g. transport);

— software (e.g. computer program, dictionary);

— hardware (e.g. engine mechanical part);

— processed materials (e.g. lubricant).

Many products comprise elements belonging to different generic product categories. Whether the product is then called service, software, hardware or processed material depends on the dominant element. For example the offered product "automobile" consists of hardware (e.g. tyres), processed materials (e.g. fuel, cooling liquid), software (e.g. engine control software, driver's manual), and service (e.g. operating explanations given by the salesman).

NOTE 2   Service is the result of at least one activity necessarily performed at the interface between the supplier and customer and is generally intangible. Provision of a service can involve, for example, the following:

— an activity performed on a customer-supplied tangible product (e.g. automobile to be repaired);

— an activity performed on a customer-supplied intangible product (e.g. the income statement needed to prepare a tax return);

— the delivery of an intangible product (e.g. the delivery of information in the context of knowledge transmission);

— the creation of ambience for the customer (e.g. in hotels and restaurants).

Software consists of information and is generally intangible and can be in the form of approaches, transactions or **procedures** (3.2)

Hardware is generally tangible and its amount is a countable characteristic. Processed materials are generally tangible and their amount is a continuous characteristic. Hardware and processed materials often are referred to as goods.

[ISO 9000:2000, definition 3.4.2]

3.5

project

unique **process** (3.3) consisting of a set of coordinated and controlled activities with start and finish dates, undertaken to achieve an objective conforming to specific requirements, including the constraints of time, cost and resources

NOTE 1   An individual project can form part of a larger project structure.

NOTE 2   In some projects, the objectives are refined and the product characteristics defined progressively as the project proceeds.

NOTE 3   The outcome of a project may be one or several units of **product** (3.4).

[ISO 9000:2000, definition 3.4.3]

3.6

quality management system

management system to direct and control an organization with regard to quality

[ISO 9000:2000, definition 3.2.3]

2

3.7
quality objective
something sought, or aimed for, related to quality

NOTE 1   Quality objectives are generally based on the organization's quality policy.

NOTE 2   Quality objectives are generally specified for relevant functions and levels in the organization.

[ISO 9000:2000, definition 3.2.5]

3.8
quality plan
document specifying which **processes** (3.3), **procedures** (3.2) and associated resources will be applied by whom and when, to meet the requirements of a specific **project** (3.5), **product** (3.4), process or contract

NOTE 1   These procedures generally include those referring to quality management processes and to product realization processes.

NOTE 2   A quality plan often makes reference to parts of the quality manual or to procedure documents.

NOTE 3   A quality plan is generally one of the results of quality planning.

3.9
record
document stating results achieved or providing evidence of activities performed

NOTE   Adapted from ISO 9000:2000, definition 3.7.6 (the Notes have not been included).

3.10
specific case
subject of the **quality plan** (3.8)

NOTE   This term is used to avoid repetition of "process, product, project or contract" within this International Standard.

4   Development of a quality plan

4.1   Identifying the need for the quality plan

The organization should identify what need there may be for quality plans. There are a number of situations where quality plans may be useful or necessary, for example:

a)   to show how the organization's quality management system applies to a specific case;

b)   to meet statutory, regulatory or customer requirements;

c)   in developing and validating new products or processes;

d)   to demonstrate, internally and/or externally, how quality requirements will be met;

e)   to organize and manage activities to meet quality requirements and quality objectives;

f)   to optimize the use of resources in meeting quality objectives;

g)   to minimize the risk of not meeting quality requirements;

h)   to use as a basis for monitoring and assessing compliance with the requirements for quality;

i)   in the absence of a documented quality management system.

NOTE   There may or may not be a need to prepare a quality plan for a specific case. An organization with an established quality management system may be able to fulfil all of its needs for quality plans under its existing system; the organization may then decide that there is no need to prepare separate quality plans.

4.2 Inputs to the quality plan

Once the organization has decided to develop a quality plan, the organization should identify the inputs for preparation of the quality plan, for example:

a) the requirements of the specific case;

b) the requirements for the quality plan, including those in customer, statutory, regulatory and industry specifications;

c) the quality management system requirements of the organization;

d) risk assessments on the specific case;

e) the requirement for and availability of resources;

f) information on the needs of those engaged in carrying out activities covered by the quality plan;

g) information on the needs of other interested parties who will use the quality plan;

h) other relevant quality plans;

i) other relevant plans, such as other project plans, environmental, health and safety, security and information management plans.

4.3 Scope of the quality plan

The organization should determine what is to be covered by the quality plan and what is covered or to be covered by other documents. Unnecessary duplication should be avoided.

The scope of the quality plan will depend on several factors, including the following:

a) the processes and quality characteristics that are particular to the specific case, and will therefore need to be included;

b) the requirements of customers or other interested parties (internal or external) for inclusion of processes not particular to the specific case, but necessary for them to have confidence that their requirements will be met;

c) the extent to which the quality plan is supported by a documented quality management system.

Where quality management procedures have not been established, they may need to be developed to support the quality plan.

There may be benefits from reviewing the scope of the quality plan with the customer or other interested parties, for example in order to facilitate their use of the quality plan for monitoring and measurement.

4.4 Preparation of the quality plan

4.4.1 Initiation

The person responsible for preparing the quality plan should be clearly identified. The quality plan should be prepared with the participation of people who are involved in the specific case, both within the organization and, where appropriate, external parties.

When preparing a quality plan, quality management activities applicable to the specific case should be defined and, where necessary, documented.

4.4.2 Documenting the quality plan

The quality plan should indicate how the required activities will be carried out, either directly or by reference to appropriate documented procedures or other documents (e.g. project plan, work instruction, checklist,

computer application). Where a requirement results in a deviation from the organization's management systems, this deviation should be justified and authorized.

Much of the generic documentation needed may already be contained in the organization's quality management system documentation, including its quality manual and documented procedures. This documentation may need to be selected, adapted and/or supplemented. The quality plan should show how the organization's generic documented procedures are applied, or alternatively modified or overridden by procedures in the quality plan.

A quality plan may be included as part of another document or documents, for example project quality plans are often included in project management plans (see ISO 10006).

4.4.3 Responsibilities

In preparing the quality plan, the organization should agree and define the respective roles, responsibilities and obligations both within the organization and with the customer, regulatory authorities or other interested parties. Those administering the quality plan should ensure that the persons it refers to are aware of the quality objectives and any specific quality issues or controls required by the quality plan.

4.4.4 Consistency and compatibility

The contents and format of the quality plan should be consistent with the scope of the quality plan, the inputs to the plan and the needs of the intended users. The level of detail in the quality plan should be consistent with any agreed customer requirement, the organization's method of operation and the complexity of the activities to be performed. The need for compatibility with other plans should also be considered.

4.4.5 Presentation and structure

The presentation of the quality plan may have any of several forms, for example a simple textual description, a table, a document matrix, a process map, a work flow chart or a manual. Any or all of these may be presented in electronic or hard-copy formats.

NOTE   Examples of quality plans are provided in Annex A.

The quality plan may be broken up into several documents, each of which represents a plan for a distinct aspect. Control of the interfaces between the different documents needs to be clearly defined. Examples of these aspects include design, purchasing, production, process control or particular activities (such as acceptance testing).

An organization may wish to prepare a quality plan that conforms to applicable requirements of ISO 9001. A cross-reference matrix is provided in Annex B for guidance.

5   Content of the quality plan

5.1   General

The examples and lists provided in this clause should not be considered comprehensive or limiting in any way.

The quality plan for a specific case should cover the topics examined below as appropriate. Some topics in this guidance may not be applicable, for example where design and development are not involved.

5.2 Scope

The scope should be clearly stated in the quality plan. This should include:

a) a simple statement of the purpose and expected outcome of the specific case;

b) the aspects of the specific case to which it will be applied, including particular limitations to its applicability;

c) the conditions of its validity (e.g. dimensions, temperature range, market conditions, resource availability or quality management systems certification status).

5.3 Quality plan inputs

It may be necessary to list or describe the inputs to the quality plan (see 4.2), to facilitate, for example,

— reference to input documents by users of the quality plan,

— checking consistency with input documents during maintenance of the quality plan, and

— identification of changes to input documents that may necessitate a review of the quality plan.

5.4 Quality objectives

The quality plan should state the quality objectives for the specific case and how they will be achieved. Quality objectives may be established, for example, in relation to

— quality characteristics for the specific case,

— important issues for satisfaction of the customer or other interested parties, and

— opportunities for improvement of work practices.

These quality objectives should be expressed in measurable terms.

5.5 Management responsibilities

The quality plan should identify individuals within the organization who are responsible, in the specific case, for the following:

a) ensuring that the activities required for the quality management system or contract are planned, implemented and controlled, and their progress monitored;

b) determining the sequence and interaction of the processes applicable to the specific case;

c) communicating requirements to all affected departments and functions, subcontractors and customers, and resolving problems that arise at the interfaces between such groups;

d) reviewing the results of any audits conducted;

e) authorizing requests for exemption from the organization's quality management system requirements;

f) controlling corrective and preventive actions;

g) reviewing and authorizing changes to, or deviations from, the quality plan.

Reporting lines of those involved in implementing the quality plan may be presented in the form of a flow chart.

5.6 Control of documents and data

For documents and data applicable to the specific case, the quality plan should state:

a) how the documents and data will be identified;

b) by whom the documents and data will be reviewed and approved;

c) to whom the documents will be distributed, or their availability notified;

d) how access to the documents and data can be obtained.

5.7 Control of records

The quality plan should state what records should be established and how they will be maintained. Such records might include design review records, inspection and test records, process measurements, work orders, drawings, minutes of meetings. Matters to be considered include the following:

a) how, where and for how long records will be kept;

b) what the contractual, statutory and regulatory requirements are, and how they will be satisfied;

c) on what media the records will be kept (such as hard copy or electronic media);

d) how legibility, storage, retrievability, disposition and confidentiality requirements will be defined and satisfied;

e) what methods will be used to ensure that records are available when required;

f) what records will be supplied to the customer, when and by what means;

g) where applicable, in what language textual records will be provided;

h) the disposal of records.

5.8 Resources

5.8.1 Provision of resources

The quality plan should define the type and amount of resources needed for the successful execution of the plan. These resources may include materials, human resources, infrastructure and work environment.

Where a particular resource has limited availability, the quality plan may need to identify how demand from a number of concurrent products, projects, processes or contracts will be satisfied.

5.8.2 Materials

Where there are specific characteristics for required materials (raw materials and/or components), the specifications or standards to which the materials have to conform should be stated or referred to in the quality plan.

5.8.3 Human resources

The quality plan should specify, where needed, the particular competences required for defined roles or activities within the specific case. The quality plan should define any specific training or other actions required for personnel.

This should include:

a) the need for, and training of, new personnel;

b) the training of existing personnel in new or revised operating methods.

The need or applicability of team development and motivational strategies should also be considered.

NOTE   The qualification of personnel is addressed in 5.13, and training in the use of quality plans is addressed in 6.2.

5.8.4 Infrastructure and work environment

The quality plan should state the particular requirements of the specific case with regard to the manufacturing or service facility, workspace, tools and equipment, information and communication technology, support services and transport facilities necessary for its successful completion.

Where the work environment has a direct effect on product or process quality, the quality plan may need to specify the particular environmental characteristics, for example:

a) the air-borne particle content for a clean room;

b) electrostatic sensitive device protection;

c) biological hazard protection;

d) the temperature profile of an oven;

e) ambient light and ventilation.

5.9 Requirements

The quality plan should include or make reference to the requirements to be met for the specific case. A simple overview of the requirements may be included to help users to understand the context of their work, for example an outline of a project. In other cases, there may be a need for a comprehensive list of requirements, developed from input documents.

The quality plan should state when, how and by whom the requirements specified for the specific case will be reviewed. The quality plan should also state how the results of this review will be recorded and how conflicts or ambiguities in the requirements will be resolved.

5.10 Customer communication

The quality plan should state the following:

a) who is responsible for customer communication in particular cases;

b) the means to be used for customer communication;

c) where applicable, communication pathways and contact points for specific customers or functions;

d) the records to be kept of customer communication;

e) the process to be followed when a customer compliment or complaint is received.

5.11 Design and development

5.11.1 Design and development process

The quality plan should include or make reference to the plan(s) for design and development.

The quality plan should take account of applicable codes, standards, specifications, quality characteristics and regulatory requirements, as appropriate. It should identify the criteria by which the design and development inputs and outputs should be accepted, and how, at what stage(s), and by whom, the outputs should be reviewed, verified and validated.

Design and development is a complex process and guidance should be sought from appropriate sources, including the organization's design and development procedures.

NOTE   ISO 9004 provides general guidance on the design and development process. ISO/IEC 90003 provides specific guidance for the software sector.

5.11.2 Control of design and development changes

The quality plan should state the following:

a) how requests for changes to the design will be controlled;

b) who is authorized to initiate a change request;

c) how changes will be reviewed in terms of their impact;

d) who is authorized to approve or reject changes;

e) how the implementation of changes will be verified.

In some cases there may be no requirement for design and development. However, there may still be a need to manage changes to existing designs.

5.12 Purchasing

The quality plan should define the following:

a) the critical characteristics of purchased products that affect the quality of the organization's product;

b) how those characteristics will be communicated to suppliers, to enable adequate control throughout the product or service life cycle;

c) the methods to be used to evaluate, select and control suppliers;

d) requirements for, and reference to, supplier quality plans or other plans, where appropriate;

e) the methods to be used to satisfy the relevant quality assurance requirements, including statutory and regulatory requirements that apply to purchased products;

f) how the organization intends to verify purchased product conformity to specified requirements;

g) the facilities and services that will be outsourced.

NOTE   See website www.iso.org/tc176/sc2 for guidance on "outsourced".

5.13 Production and service provision

Production and service provision, together with the relevant monitoring and measurement processes, commonly form the main part of the quality plan. The processes involved will vary, depending on the nature of the work. For example, a contract may involve manufacturing, installation and other post-delivery processes. The interrelationship between the various processes involved may be effectively expressed through the preparation of process maps or flow charts.

Production and service processes may need to be checked, to ensure they are capable of delivering the required output; such a check should always be undertaken if the output of a process cannot be verified by subsequent monitoring or measurement.

The quality plan should identify the inputs, realization activities and outputs required for carrying out production and/or service delivery. Where appropriate, the quality plan should include or refer to the following:

a) the process steps;

b) relevant documented procedures and work instructions;

c) the tools, techniques, equipment and methods to be used to achieve the specified requirements, including details of any necessary material, product or process certification;

d) required controlled conditions to meet planned arrangements;

e) mechanisms for determining compliance with such conditions, including any specified statistical or other process controls;

f) details of any necessary qualification and/or certification of personnel;

g) criteria for workmanship or service delivery;

h) applicable statutory and regulatory requirements;

i) industry codes and practices.

Where installation or commissioning is a requirement, the quality plan should state how the product will be installed and which characteristics have to be verified and validated at that time.

Where the specific case includes post-delivery activities (e.g. maintenance, support or training services), the quality plan should state how the organization intends to assure conformance to applicable requirements, such as:

a) statutes and regulations;

b) industry codes and practices;

c) the competence of personnel, including trainees;

d) the availability of initial and on-going technical support during the agreed time period.

NOTE   Guidance on project processes to be managed under this clause is provided in ISO 10006.

5.14   Identification and traceability

Where product identification is appropriate, the quality plan should define the methods to be used. Where traceability is a requirement, the quality plan should define its scope and extent, including how the affected products will be identified.

The quality plan should state:

a) how contractual, statutory and regulatory traceability requirements are identified and incorporated into working documents;

b) what records relating to such traceability requirements will be generated and how they will be controlled and distributed;

c) specific requirements and methods for the identification of the inspection and test status of products.

NOTE   Identification and traceability is part of configuration management. For further guidance on configuration management, see ISO 10007.

5.15   Customer property

The quality plan should state

a) how products provided by the customer (such as material, tooling, test equipment, software, data, information, intellectual property or services) are identified and controlled,

b) the methods to be used to verify that customer-supplied products meet specified requirements,

c) how nonconforming customer-supplied products will be controlled, and

d) how damaged, lost or unsuitable product will be controlled.

NOTE   Guidance on information security is given in ISO/IEC 17799.

5.16   Preservation of product

The quality plan should state:

a) requirements for handling, storage, packaging and delivery, and how these requirements will be met;

b) (if the organization is to be responsible for delivery) how the product will be delivered to the specified site, in a manner that will ensure that its required characteristics are not degraded.

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5.17 Control of nonconforming product

The quality plan should define how nonconforming product will be identified and controlled to prevent misuse, until proper disposal or acceptance by concession is completed. The quality plan may need to define specific limitations, such as the degree or type of rework or repair allowed, and how such rework or repair will be authorized.

5.18 Monitoring and measurement

Monitoring and measurement processes provide the means by which objective evidence of conformity will be obtained. In some instances, customers request submission of monitoring and measurement plans (commonly referred to as "inspection and test plans") alone, without other quality plan information, as a basis for monitoring conformity with specified requirements.

The quality plan should define the following:

a) process and product monitoring and measurements to be applied;

b) the stages at which they should be applied;

c) the quality characteristics to be monitored and measured at each stage;

d) the procedures and acceptance criteria to be used;

e) any statistical process control procedures to be applied;

f) where inspections or tests are required to be witnessed or performed by regulatory authorities and/or customers, for example,

— a test, or series of tests (sometimes referred to as "type tests"), directed towards the approval of a design and conducted to determine if the design is capable of meeting the requirements of the product specification,

— site testing including acceptance,

— product verification, and

— product validation;

g) where, when and how the organization intends, or is required by the customer, statutory or regulatory authorities, to use third parties to perform inspections or tests;

h) the criteria for product release.

The quality plan should identify the controls to be used for monitoring and measuring equipment intended for use for the specific case, including its calibration confirmation status.

NOTE 1   Guidance on the management of measurement systems can be found in ISO 10012.

NOTE 2   Guidance on the selection of statistical methods can be found in ISO/TR 10017.

5.19 Audits

Audits may be used for several purposes, such as:

a) to monitor the implementation and effectiveness of quality plans;

b) to monitor and verify conformity with specified requirements;

c) for surveillance of suppliers to the organization;

d) to provide independent objective assessment, when required, to meet the needs of customers or other interested parties.

The quality plan should identify the audits to be performed for the specific case, the nature and extent of such audits and how the results of the audits should be used.

NOTE   Further guidance for auditing is given in ISO 19011.

6   Review, acceptance, implementation and revision of the quality plan

6.1   Review and acceptance of the quality plan

The quality plan should be reviewed for adequacy and effectiveness, and should be formally approved by an authorized person or a group that includes representatives from relevant functions within the organization.

In contractual situations, a quality plan may need to be submitted to the customer by the organization for review and acceptance, either as part of a pre-contract consultation process or after a contract has been awarded. Once a contract is awarded, the quality plan should be reviewed and, where appropriate, revised to reflect any changes in requirements that may have occurred as a result of the pre-contract consultation.

Where a project or contract is conducted in stages, the organization may be expected to submit a quality plan to the customer for each stage, prior to the start of that stage.

6.2   Implementation of the quality plan

In the implementation of the quality plan, the organization should give consideration to the following issues.

a)   Distribution of the quality plan

The quality plan should be distributed to all relevant people. Care should be taken to distinguish between copies that are distributed under document control provisions (to be updated as appropriate), and those that are supplied for information only.

b)   Training in the use of quality plans

In some organizations, for example those engaged in project management, quality plans may be used as a routine part of the quality management system. However in others, quality plans may be used only occasionally. In this case, special training may be needed to assist users in applying the quality plan correctly.

c)   Monitoring conformity with quality plans

The organization is responsible for monitoring conformity with each quality plan that it operates. This may include

— operational supervision of the planned arrangements,

— milestone reviews, and

— audits.

Where many short-term quality plans are used, audits are generally undertaken on a sampling basis.

Where quality plans are submitted to customers or other external parties, these parties may establish provisions for monitoring conformity with the quality plans.

Whether carried out by internal or external parties, such monitoring can assist in

1)   assessing the commitment of the organization to the effective implementation of the quality plan,

2)   evaluating the practical implementation of the quality plan,

3)   determining where risks may arise in relation to the requirements of the specific case,

4)   taking corrective or preventive action where appropriate, and

5)   identifying opportunities for improvement in the quality plan and associated activities.

6.3 Revision of the quality plan

The organization should revise the quality plan:

a) to reflect any changes to quality plan inputs, including

— the specific case for which the quality plan is established,

— the processes for the realization of the product,

— the organization's quality management system, and

— statutory or regulatory requirements;

b) to incorporate agreed improvements to the quality plan.

An authorized person or persons should review changes to the quality plan for impact, adequacy and effectiveness. Revisions to the quality plan should be made known to all those involved in its use. Any documents that are affected by changes in the quality plan should be revised as necessary.

The organization should consider how and under what circumstances the organization would authorize a deviation from the quality plan, including

— who will have the authority to request such deviations,

— how such a request will be made,

— what information will be provided and in what form, and

— who will be identified as having the responsibility and authority to accept or reject such deviations.

A quality plan should be treated as a configuration item and should be subject to configuration management.

6.4 Feedback and improvement

Where appropriate, experience gained from the application of a quality plan should be reviewed and the information used to improve future plans or the quality management system itself.

Annex A
(informative)

Simplified examples of formats for the presentation of quality plans

A.1 General

This annex provides examples of some of the formats in which quality plans may be presented.

The examples shown should not be taken as being complete as regards the quality plan content defined in Clause 5. Actual quality plans may be more complex. It would normally be expected that all the processes for product realization would be covered, unless they do not apply to the specific case.

Presentation of quality plans may be in any format deemed suitable for meeting the agreed requirements. A textual presentation rather than a diagrammatic one may be more appropriate in certain circumstances. Similarly, a diagrammatic format may be supplemented with text. Other formats better suited to a specific case may be used.

Where the quality plan is available electronically, documents referred to, such as procedures, could be accessible via hyperlinks.

Examples 1 and 2 are different presentations of the same case, in order to illustrate that there is no particular alignment of a given presentation for a specific case. As examples of presentation, the contents of Examples 1 to 4 are illustrative and do not represent recommendations.

The examples include

— Example 1: Table (Processed materials quality plan),

— Example 2: Flow chart (Processed materials quality plan),

— Example 3: Form (Manufacturing quality plan), and

— Example 4: Text (Software development quality plan).

A.2 Examples

A.2.1 Example 1: A "table" type quality plan (for processed materials)

QPL - 005	Product/Product Line: Specification Grade Chemicals	Originated by:	Approved by:	Rev: 01	05/09/03

Activity	Description	Document/ Procedure[a]	Area/ Dept.[b]
Scope	This quality plan is applicable to the processes of production and distribution of specification-grade chemicals.	—	—
Quality objectives	Our quality objectives are yield (93 %); on-time delivery ($+/-$ 1 day).	QSP - 005	various
Management responsibilities	Job descriptions and organization charts of the responsibilities of personnel involved in the planning, executing, controlling and monitoring the progress of the activities covered by this plan are to be found in referenced documents.	QSP - 020 SOP - 800	MGMT/ HRS
Documentation	There are no special document control requirements. Contractual documents will be retained for a minimum of five years.	QSP - 050	TSS
Records	Identifiable and retrievable records will be maintained to furnish evidence of activities affecting quality. Records will be retained for a minimum of five years.	QSP - 055	QA
Resources	The requirements for storage, process and transportation of raw materials and components are specified in //VSB\materials.doc.	QSP - 020	MGMT
	All staff are required to have successfully completed training on the handling of the materials specified in the contract.	SOP - 810	HRS
	No special infrastructure or work environment conditions apply.		
Requirements review/ Customer specifications	All quotations given and all customer specifications and orders received will be reviewed prior to acceptance, to ensure that the requirements are properly defined, all differences satisfactorily resolved, and the company has the capacity to meet the requirements involved.	SOP - 100 SOP - 110 SOP - 120	MKT/ TSS/ MFG/QA
Customer communication	Customer feed back is collected either by visiting the website or using form SOP-190F1 and is discussed at monthly meetings between the customer and the contract management team.	SOP - 150 SOP - 190	MKT
Design and development	All accepted customer specifications that differ significantly from regular company specifications require review and approval (SOP-200). This may require customer prototype approval, and process verification and validation.	SOP - 200 SOP - 220	TSS
Purchasing	All critical products purchased by the company are subject to receiving inspection and testing as required in the current raw material and package specifications. Bulk tank cars will not be unloaded until all required testing is satisfactorily completed. Nonconforming materials may be approved by concession, disposed of, or returned to the supplier.	SOP - 300 SOP - 310 SOP - 400 SOP - 470 SOP - 490	PUR/ MAT
Production	Standard operating procedures apply.	SOP - 500	MFG
Identification and traceability	Standard operating procedures apply.	SOP - 440 SOP - 540	MAT/ MFG
Customer property	Customer specifications and proprietary test methods will be processed and protected through the formal specification system to preserve their integrity and ensure the confidentiality of the information contained therein.	SOP - 110	MKT/ TSS
	Standard operating procedures apply to special packaging materials provided by the customer.	SOP - 410	MAT/ MFG
Storage and handling	Purchased materials, intermediates and finished products will be stored in secure containers, tanks and warehouse facilities. Careful handling methods will be used to prevent damage, deterioration or contamination of the product. Bulk products will be shipped in dedicated tank cars.	SOP - 400 SOP - 700 SOP - 750	MAT

Activity	Description	Document/ Procedure[a]	Area/ Dept.[b]
Nonconforming products	Products failing to pass the Final Lot Acceptance Requirements will be diverted to a special quarantine area or tank. A written concession from the customer will be required before any nonconforming product can be shipped.	**SOP - 570 SOP - 580 SOP - 590**	**MFG/ TSS/QA**
Monitoring and measurement	Sampling and testing plans exist or will be prepared to cover all product realization processes.	**SOP - 600**	**QA**
Inspection and testing equipment	The company maintains a range of measuring and testing equipment to cover the scope of its development, production and control activities. All required calibration is done in-house or by the equipment manufacturer.	**SOP - 610**	**QA**
Audit	The facilities may receive internal, customer and regulatory audits.	**SOP-675**	**QA**
[a] QSP: Quality System Procedure; SOP: Standard Operating Procedure. [b] HRS: Human Resources; MAT: Materials Control; MKT: Marketing and Sales; MFG: Manufacturing; QA: Quality Assurance; PUR: Purchasing; MGMT: Top Management; TSS: Technical Services.			

A.2.2 Example 2: A "flow-chart" type of quality plan (for processed materials)

A full-page example follows.

A.2.3 Example 3: A "form" type of quality plan (for a manufacturing facility)

A full-page example follows.

"Flow chart" type of quality plan

SOP - 100 — Requirements rewiew

Quotation/ Order request

Differences resolved? — Yes → SOP - 110 Define customer specifications or use internal

No

Quote/Order not accepted

SOP - 120 — Take order. Review quality, quantity delivery, price

Order accepted? — Yes / No

Differences resolved? — Yes / No

D & D required? — Yes → SOP - 200 SOP - 220 Carry out D & D, and D & D verification and validation. Establish change control

No

SOP - 500 — Schedule production

Customer-supplied materials required? — Yes → SOP - 410 Control customer-supplied material / No

SOP - 400 SOP - 440 — Receive test & inspect materials

SOP - 310 — Purchase materials

SOP - 500/SOP - 540/SOP - 600 product & process specifications, quality control plans

Materials approved? — Yes → Manufacture, test & inspect

No — SOP - 470 Quarantine & disposition

Concession? — Yes / No — SOP - 490 Dispose of, or return to supplier

In-process & final tests OK? — Yes → SOP - 700 Package & warehouse

No — SOP - 550 Quarantine & disposition

Concession or downgrade? — Yes / No — SOP - 580 Rework → Retest OK? — Yes / No — SOP - 590 Dispose of

SOP - 750 — Ship to customer

SOP - 150 — Service

SOP - 190 — Customer feedback

Support documents
- Quality policy
- Quality objectives
- Quality manual
- Management responsibilities
- Control of documents
- Control of records

QSP - 001
QSP - 005
QSP - 010
QSP - 020
QSP - 050
QSP - 055

Support activities
- Supplier relations
- Monitoring & measurement
- Control of inspection & test equipment
- Internal audit
- Org. charts & job descriptions
- Training

SOP - 300
SOP - 600
SOP - 610
SOP - 675
SOP - 800
SOP - 810

Product Line: Specification-grade chemicals		Originated by:	Approved by:
QPL - 005	Rev. 01	05 - 09 - 03	

"Form" type of quality plan

Line name	Process flow chart	Process name	Work instruction (number)	Quality characteristic to be controlled (process condition to be checked)	Instruction for process control (number)	Process control method				Inspection and test item	Inspection and test method	Remarks
						Chart or sheet for process control	Person responsible for process control	Sampling and measurement method				
Line A		Pre-heating	WI-A1	(Temperature)		Check sheet CS-A-1	Operator A	2 times/day				
		Forming	WI-A2	Length L		Control chart CC-A-1	Foreman A	5 samples/lot with micrometer				
				(Temperature)	IPC-A1	Check sheet CS-A-2	Operator B	1 time/day				
				(Pressure)		Check sheet CS-A-3	Operator B	1/day				
		Testing of product	WI-A3	Fraction defective		Control chart CC-A-2	Foreman B	All products	Length L	All products		
									Electric characteristics	10 samples/lot		

NOTE ○ Manufacturing ◇ Inspection and testing □ Storage

A.2.4   Example 4: A "text" type of quality plan (for the development of software, for a pedestal mounted display unit)

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1   Scope

The purpose of this quality plan is to identify the quality management methods being applied to the contract between the company and its client for a garment distribution system.

a)   **Inclusions**

This quality plan applies to the development and supply of the distribution, concession management and marketing subsystems. The financial management systems are the subject of a subcontract with the subcontractor and so the quality plan is concerned solely with the subcontract management aspects of that part of the project.

b)   **Exclusions**

The development work being undertaken by the subcontractor is covered by the purchase order and is not included in detail in this plan.

2   Quality objectives

The client has made no specific demands in terms of quantified quality objectives. Accordingly, the company standard of releasing software with no known category A defects, no known category B defects, and category C defects only with client agreement shall apply. A defect is defined as system behaviour showing evidence of nonconformity against the agreed requirements.

In addition, the company objective of commissioning systems within a 5 % margin of the contractual date based on the contractual elapsed time for the project shall also apply.

3   Responsibilities

The Project Manager has overall responsibility for the successful execution of the project, including conformity with the company's QMS and meeting the above objectives.

The Quality Manager is responsible for project audits and for following through any corrective actions from them. Any required deviation from the QMS is to be approved by the Quality Manager before the deviation takes place.

4   Documentation

Some documents used in this project have references that do not conform to the latest QMS requirements. The existing references shall be retained. In all other respects, the QMS applies.

5   Records

The project file and associated records are to be retained for a period of not less than three years after the warranty period has expired. Disposition at that time shall be by agreement with the client. In accordance with the company policy, the client may view any contract-related records at any reasonable time. All contract-specific computer files shall be backed up at least weekly.

6   Resources

The client is to supply a sample of OCR forms (at least 2 000) for use in testing the document reader being supplied as part of the system. The subcontractor shall obtain and commission the document reader as part of their supply of the financial management system.

All of the development team shall be employees of the company. Appropriately qualified individuals will be made available by the Human Resources Manager to meet the needs of the project. The Project Manager shall be J. Smith.

7   Project inputs

The primary input is the Requirements Specification KLOB-D-001 prepared by the client's advisors. Sample marketing documents and Annual Reports are to be provided by the company for familiarization purposes.

8   Customer communications

Any queries with the specification are to be raised with the client through the Project Manager at project meetings. Their decision is final. The client does not have a software technical capability so technical queries should be addressed through the Project Manager or his delegate. Minutes of project meetings will be prepared by the Project Manager. Similarly, communications from the customer (queries, complaints, compliments) should be routed through the Project Manager.

9   Design and development

The project schedule will be presented using an approved scheduling tool. The critical dates are customer acceptance tests (by end October) and system roll-out (before April next year).

All of the company standards in the Software Development Manual shall apply. Review and approvals shall be as in the company's Quality Manual.

Change requests that affect the functionality as seen by the users must be approved by the company. Detailed design changes at the subcontractor and the company must be approved by the Project Manager before work in them commences.

The approach to testing shall be as the company's Quality Manual. The document data capture testing will require the document reader. The final tests of the marketing subsystem will need the pedestal mounted display unit, to test customer reaction. The distribution system as a whole is to be tested at the company before shipment and customer acceptance at their premises.

10   Purchasing

All equipment is being purchased by the client (computers through the subcontractor, other items directly). Any other purchases must be handled to the company's procedures.

11   Installation and commissioning

The document reader will be delivered to the client's HQ. The pedestals will be rolled out by the client to their programme after field trials. Support may be needed for the first installations while customer staff are gaining familiarity with the systems.

12   Special processes

There are no special processes in this project.

13   Configuration management

Document identifiers shall conform to the version of the Quality Manual in place at the start of the project, except for those documents already identified beforehand.

Current company approved configuration management tools shall be used.

14   Customer property

Any equipment belonging to the client must be so identified while in the company or its subcontractors' possession. Customer property of any kind must be recorded in the project log.

15   Product handling

Software will be delivered on CD-ROM. All CDs will be virus checked.

16   Nonconformities

No software shall be delivered with known nonconformities other than cosmetic ones without a written concession from the client. The process will be as given in the company QM and SDM.

17 Monitoring and measurement

The project progress will be recorded on time sheets and registered on the Project Schedule on a weekly basis. A report shall be prepared for and presented to the progress meetings with the client. The subcontractor will be invited to selected meetings. Records shall be kept by the programming team leader of any problems identified with the software at second and third level testing. Categorization of problems into problem origin: Requirements Spec. (missing or incorrect), Design (missing or incorrect), coding (missing, incorrect logic, interface error, data handling error) shall be performed.

18 Internal audit

An audit of the implementation and effectiveness of the quality plan shall take place at the end of the design stage.

This quality plan has been prepared by the project manager of the client's Distribution Project and applies to all work carried out under the contract.

Author: Date

Quality Manager: Date

Document No: KLOB-QP-001   Version 1

Annex B

(informative)

Correspondence between ISO 10005:2005 and ISO 9001:2000

Table B.1 — Correspondence between ISO 10005:2005 and ISO 9001:2000

Clause in ISO 10005:2005	Heading	Clause in ISO 9001:2000
4	Development of a quality plan	7.1
5	Content of the quality plan	7.1
5.1	General	7.1
5.2	Scope	7.1
5.3	Quality plan inputs	7.1
5.4	Quality objectives	7.1a
5.5	Management responsibilities	5.1, 5.5.1, 5.5.3, 8.5.2
5.6	Control of documents and data	4.2.3
5.7	Control of records	4.2.4
5.8	Resources	6
5.8.1	Provision of resources	6.1
5.8.2	Materials	6.1
5.8.3	Human resources	6.2
5.8.4	Infrastructure and work environment	6.3, 6.4
5.9	Requirements	7.2.1, 7.2.2
5.10	Customer communication	7.2.3, 8.2.1
5.11	Design and development	7.3
5.11.1	Design and development process	7.3.1 to 7.3.6
5.11.2	Control of design and development changes	7.3.7
5.12	Purchasing	7.4
5.13	Production and service provision	7.5.1 7.5.2
5.14	Identification and traceability	7.5.3
5.15	Customer property	7.5.4
5.16	Preservation of product	7.5.5
5.17	Control of nonconforming product	8.3
5.18	Monitoring and measurement	7.6, 8.2.3, 8.2.4, 8.4
5.19	Audits	8.2.2
6	Review, acceptance, implementation and revision of the quality plan	7.1
6.1	Review and acceptance of the quality plan	7.1
6.2	Implementation of the quality plan	7.1
6.3	Revision of the quality plan	7.1
6.4	Feedback and improvement	8.5
NOTE Correspondence between clauses does not imply conformity.		

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[1]   ISO 9001:2000, *Quality management systems — Requirements*

[2]   ISO 9004:2000, *Quality management systems — Guidelines for performance improvements*

[3]   ISO 10006:2003, *Quality management systems — Guidelines for quality management in projects*

[4]   ISO 10007:2003, *Quality management systems — Guidelines for configuration management*

[5]   ISO 10012:2003, *Measurement management systems — Requirements for measurement processes and measuring equipment*

[6]   ISO/TR 10013:2001, *Guidelines for quality management system documentation*

[7]   ISO 10015:1999, *Quality management — Guidelines for training*

[8]   ISO/TR 10017:2003, *Guidance on statistical techniques for ISO 9001:2000*

[9]   ISO/IEC 17799:—[1], *Information technology — Security techniques — Code of practice for information security management*

[10]   ISO 19011:2002, *Guidelines for quality and/or environmental management systems auditing*

[11]   ISO/IEC 90003:2004, *Software engineering — Guidelines for the application of ISO 9001:2000 to computer software*

[12]   *ISO 9001 for Small Businesses — What to do.* Advice from ISO/TC 176. ISO Handbook, 2nd edition, 2002

[13]   Reference websites: www.iso.org — www.tc176.org — www.iso.org/tc176/sc2

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1)   To be published. (Revision of ISO/IEC 17799:2000)

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10005:2005**

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