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ISO 9000-3

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Quality management and quality assurance standards —

Part 3:
Guidelines for the application of ISO 9001 to the development, supply and maintenance of software

Normes pour la gestion de la qualité et l'assurance de la qualité —
Partie 3: Lignes directrices pour l'application de l'ISO 9001 au développement, à la mise à disposition et à la maintenance du logiciel

Reference number
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Contents

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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.

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 9000-3 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*.

ISO 9000 consists of the following parts, under the general title *Quality management and quality assurance standards*:

— *Part 1: Guidelines for selection and use*

— *Part 2: Generic guidelines for the application of ISO 9001, ISO 9002 and ISO 9003*

— *Part 3: Guidelines for the application of ISO 9001 to the development, supply and maintenance of software*

Part 1 will be a revision of ISO 9000:1987. Part 2 is to be published.

Annexes A and B of this part of ISO 9000 are for information only.

Introduction

With the progress of information technology, the amount of software products has been increasing and the quality management of software products is essential. One of the means of establishing a quality management system is to provide guidance for software quality assurance.

The requirements for a generic quality system for two-party contractual situations have already been published: ISO 9001:1987, *Quality systems — Model for quality assurance in design/development, production, installation and servicing.*

However, the process of development and maintenance of software is different from that of most other types of industrial products. In such a rapidly evolving technology field it is therefore necessary to provide additional guidance for quality systems where software products are involved, taking into account the present status of this technology.

The nature of software development is such that some activities are related to particular phases of the development process, while others may apply throughout the process. These guidelines have therefore been structured to reflect these differences. This document thus does not correspond directly in format with ISO 9001 and cross-reference indexes (annex A and annex B) are provided to give assistance when referring to that standard.

Contracts between two parties for software product development may occur in many variations. In certain cases of two-party contracts, these guidelines might not be applicable even if "tailored". It is therefore important to determine the adequacy of the application of this part of ISO 9000 to the contract.

This part of ISO 9000 deals primarily with situations where specific software is developed as part of a contract according to purchaser's specifications. However, the concepts described may be equally of value in other situations.

NOTES

1 In English, use of the masculine gender in this part of ISO 9000 is not meant to exclude the feminine gender where applied to persons. Similarly, use of the singular does not exclude the plural (and vice versa) when the sense allows.

2 Throughout this part of ISO 9000 where there is no further guidance, the text of the relevant ISO 9001 clause is given and printed in italics.

3 In this part of ISO 9000 there are a number of lists; none of these is presumed to be exhaustive — they are intended as examples.

Quality management and quality assurance standards —

Part 3:
Guidelines for the application of ISO 9001 to the development, supply and maintenance of software

1 Scope

This part of ISO 9000 sets out guidelines to facilitate the application of ISO 9001 to organizations developing, supplying and maintaining software.

It is intended to provide guidance where a contract between two parties requires the demonstration of a supplier's capability to develop, supply and maintain software products.

The guidelines in this part of ISO 9000 are intended to describe the suggested controls and methods for producing software which meet a purchaser's requirements. This is done primarily by preventing nonconformity at all stages from development through to maintenance.

The guidelines in this part of ISO 9000 are applicable in contractual situations for software products when

a) the contract specifically requires design effort and the product requirements are stated principally in performance terms, or they need to be established;

b) confidence in the product can be attained by the adequate demonstration of a certain supplier's capabilities in development, supply and maintenance.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 9000. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 9000 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 2382-1:1984, *Data processing — Vocabulary — Part 01: Fundamental terms.*

ISO 8402:1986, *Quality — Vocabulary.*

ISO 9001:1987, *Quality systems — Model for quality assurance in design/development, production, installation and servicing.*

ISO 10011-1:1990, *Guidelines for auditing quality systems — Part 1: Auditing.*

3 Definitions

For the purposes of this part of ISO 9000, the definitions given in ISO 2382-1 and ISO 8402 apply, together with the following definitions.

3.1 software: Intellectual creation comprising the programs, procedures, rules and any associated documentation pertaining to the operation of a data processing system.

[ISO 2382-1:1984, 01.04.04]

NOTE 4 Software is independent of the medium on which it is recorded.

3.2 software product: Complete set of computer programs, procedures and associated documentation and data designated for delivery to a user.

3.3 software item: Any identifiable part of a software product at an intermediate step or at the final step of development.

3.4 development: All activities to be carried out to create a software product.

3.5 phase: Defined segment of work.

NOTE 5 A phase does not imply the use of any specific life-cycle model, nor does it imply a period of time in the development of a software product.

3.6 verification (for software)**:** The process of evaluating the products of a given phase to ensure correctness and consistency with respect to the products and standards provided as input to that phase.

3.7 validation (for software)**:** The process of evaluating software to ensure compliance with specified requirements.

4 Quality system — Framework

4.1 Management responsibility

4.1.1 Supplier's management responsibility

4.1.1.1 Quality policy

The supplier's management shall define and document its policy and objectives for, and commitment to, quality. The supplier shall ensure that this policy is understood, implemented and maintained at all levels in the organization.

[ISO 9001:1987, 4.1.1]

4.1.1.2 Organization

4.1.1.2.1 Responsibility and authority

The responsibility, authority and the interrelation of all personnel who manage, perform and verify work affecting quality shall be defined; particularly for personnel who need the organizational freedom and authority to

a) *initiate action to prevent the occurrence of product nonconformity;*

b) *identify and record any product quality problems;*

c) *initiate, recommend or provide solutions through designated channels;*

d) *verify the implementation of solutions;*

e) *control further processing, delivery or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected.*

[ISO 9001:1987, 4.1.2.1]

4.1.1.2.2 Verification resources and personnel

The supplier shall identify in-house verification requirements, provide adequate resources and assign trained personnel for verification activities.

Verification activities shall include inspection, test and monitoring of the design, production, installation and servicing processes and/or product; design reviews and audits of the quality system, processes and/or product shall be carried out by personnel independent of those having direct responsibility for the work being performed.

[ISO 9001:1987, 4.1.2.2]

4.1.1.2.3 Management representative

The supplier shall appoint a management representative who, irrespective of other responsibilities, shall have defined authority and responsibility for ensuring that the requirements of [ISO 9001] *are implemented and maintained.*

[ISO 9001:1987, 4.1.2.3]

4.1.1.3 Management review

The quality system adopted to satisfy the requirements of [ISO 9001] *shall be reviewed at appropriate intervals by the supplier's management to ensure its continuing suitability and effectiveness. Records of such reviews shall be maintained.*

NOTE — Management reviews normally include assessment of the results of internal quality system audits, but are carried out by, or on behalf of, the supplier's management viz management personnel having direct responsibility for the system.

[ISO 9001:1987, 4.1.3]

4.1.2 Purchaser's management responsibility

The purchaser should cooperate with the supplier to provide all necessary information in a timely manner and resolve pending items.

The purchaser should assign a representative with the responsibility for dealing with the supplier on contractual matters. This representative should have the authority commensurate with the need to deal with contractual matters which include, but are not limited to, the following:

a) defining the purchaser's requirements to the supplier;

b) answering questions from the supplier;

c) approving the supplier's proposals;

d) concluding agreements with the supplier;

e) ensuring the purchaser's organization observes the agreements made with the supplier;

f) defining acceptance criteria and procedures;

g) dealing with the purchaser-supplied software items that are found unsuitable for use.

4.1.3 Joint reviews

Regular joint reviews involving the supplier and purchaser should be scheduled to cover the following aspects, as appropriate:

a) conformance of the software to the purchaser's agreed requirements specification;

b) verification results;

c) acceptance test results;

The results of such reviews should be agreed and documented.

4.2 Quality system

4.2.1 General

The supplier should establish and maintain a documented quality system. The quality system should be an integrated process throughout the entire life cycle, thus ensuring that quality is being built in as development progresses, rather than being discovered at the end of the process. Problem prevention should be emphasized rather than depending on correction after occurrence.

The supplier should ensure the effective implementation of the documented quality system.

4.2.2 Quality system documentation

All the quality system elements, requirements and provisions should be clearly documented in a systematic and orderly manner.

4.2.3 Quality plan

The supplier should prepare and document a quality plan to implement quality activities for each software development on the basis of the quality system, and ensure that it is understood and observed by the organizations concerned.

4.3 Internal quality system audits

Internal quality audits

The supplier shall carry out a comprehensive system of planned and documented internal quality [system] *audits to verify whether quality activities comply with planned arrangements and to determine the effectiveness of the quality system.*

Audits shall be scheduled on the basis of the status and importance of the activity.

The audits and follow-up actions shall be carried out in accordance with documented procedures.

The results of the audits shall be documented and brought to the attention of the personnel having responsibility in the area audited. The management personnel responsible for the area shall take timely corrective action on the deficiencies found by the audit.

[ISO 9001:1987, 4.17]

See ISO 10011-1.

4.4 Corrective action

The supplier shall establish, document and maintain procedures for

a) *investigating the cause of nonconforming product and the corrective action needed to prevent recurrence;*

b) *analysing all processes, work operations, concessions, quality records, service reports and customer complaints to detect and eliminate potential causes of nonconforming product;*

c) *initiating preventive actions to deal with problems to a level corresponding to the risks encountered;*

d) *applying controls to ensure that corrective actions are taken and that they are effective;*

e) *implementing and recording changes in procedures resulting from corrective action.*

[ISO 9001:1987, 4.14]

5 Quality system — Life-cycle activities

5.1 General

A software development project should be organized according to a life-cycle model. Quality-related activities should be planned and implemented with respect to the nature of the life-cycle model used.

This part of ISO 9000 is intended for application irrespective of the life-cycle model used. Should any description, guidance, requirement or structure be read differently, this is unintended and should not be read as indicating that the requirement or guidance is restricted to a specific life-cycle model only.

5.2 Contract review

5.2.1 General

The supplier should establish and maintain procedures for contract review and for the coordination of these activities.

Each contract should be reviewed by the supplier to ensure that

a) the scope of the contract and requirements are defined and documented;

b) possible contingencies or risks are identified;

c) proprietary information is adequately protected;

d) any requirements differing from those in the tender are resolved;

e) the supplier has the capability to meet contractual requirements;

f) the supplier's responsibility with regard to subcontracted work is defined;

g) the terminology is agreed by both parties;

h) the purchaser has the capability to meet contractual obligations.

Records of such contract reviews should be maintained.

5.2.2 Contract items on quality

Among others, the following items are frequently found to be relevant in the contract:

a) acceptance criteria;

b) handling of the changes in purchaser's requirements during the development;

c) handling of problems detected after acceptance, including quality-related claims and purchaser complaints;

d) activities carried out by the purchaser, especially the purchaser's role in requirements specification, installation and acceptance;

e) facilities, tools and software items to be provided by the purchaser;

f) standards and procedures to be used;

g) replication requirements (see 5.9).

5.3 Purchaser's requirements specification

5.3.1 General

In order to proceed with software development, the supplier should have a complete, unambiguous set of functional requirements. In addition, these requirements should include all aspects necessary to satisfy the purchaser's need. These may include, but are not limited to, the following: performance, safety, reliability, security and privacy. These requirements should be stated precisely enough so as to allow validation during product acceptance.

The purchaser's requirements specification records these requirements. In some cases, this document is provided by the purchaser. If not, the supplier should develop these requirements in close cooperation with the purchaser, and the supplier should obtain the purchaser's approval before entering the development stage. The purchaser's requirements specification should be subject to documentation control and configuration management as part of the development documentation.

All interfaces between the software product and other software or hardware products should be fully specified, either directly or by reference, in the purchaser's requirements specification.

5.3.2 Mutual cooperation

During the development of the purchaser's requirements specification, attention to the following issues is recommended:

a) assignment of persons (on both sides) responsible for establishing the purchaser's requirements specification;

b) methods for agreeing on requirements and approving changes;

c) efforts to prevent misunderstandings such as definition of terms, explanations of background of requirements;

d) recording and reviewing discussion results on both sides.

5.4 Development planning

5.4.1 General

The development plan should cover the following:

a) the definition of the project, including a statement of its objectives and with reference to related purchaser or supplier projects;

b) the organization of the project resources, including the team structure, responsibilities, use of sub-contractors and material resources to be used;

c) development phases (as defined in 5.4.2.1);

d) the project schedule identifying the tasks to be performed, the resources and time required for each and any interrelationships between tasks;

e) identification of related plans, such as

— quality plan,

— configuration management plan,

— integration plan,

— test plan.

The development plan should be updated as development progresses and each phase should be defined as in 5.4.2.1 before activities in that phase are started. It should be reviewed and approved before execution.

5.4.2 Development plan

5.4.2.1 Phases

The development plan should define a disciplined process or methodology for transforming the purchaser's requirements specification into a software product. This may involve dividing the work into phases, and the identification of

a) development phases to be carried out;

b) required inputs for each phase;

c) required outputs from each phase;

d) verification procedures to be carried out at each phase;

e) analysis of the potential problems associated with the development phases and with the achievment of the specified requirements.

5.4.2.2 Management

The development plan should define how the project is to be managed, including the identification of

a) schedule of development, implementation and associated deliveries;

b) progress control;

c) organizational responsibilities, resources and work assignment;

d) organizational and technical interfaces between different groups.

5.4.2.3 Development methods and tools

The development plan should identify methods for ensuring that all activities are carried out correctly. This may include

a) rules, practices and conventions for development;

b) tools and techniques for development;

c) configuration management.

5.4.3 Progress control

Progress reviews should be planned, held and documented to ensure that outstanding resource issues are resolved and to ensure effective execution of development plans.

5.4.4 Input to development phases

The required input to each development phase should be defined and documented. Each requirement should be defined so that its achievement can be verified. Incomplete, ambiguous or conflicting requirements should be resolved with those responsible for drawing up the requirements.

5.4.5 Output from development phases

The required output from each development phase should be defined and documented. The output from each development phase should be verified and should

a) meet the relevant requirements;

b) contain or reference acceptance criteria for forwarding to subsequent phases;

c) conform to appropriate development practices and conventions, whether or not these have been stated in the input information;

d) identify those characteristics of the product that are crucial to its safe and proper functioning;

e) conform to applicable regulatory requirements.

5.4.6 Verification of each phase

The supplier should draw up a plan for verification of all development phase outputs at the end of each phase.

Development verification should establish that development phase outputs meet the corresponding input requirements by means of development control measures such as

a) holding development reviews at appropriate points in the development phases;

b) comparing a new design with a proven similar design, if available;

c) undertaking tests and demonstrations.

The verification results and any further actions required to ensure that the specified requirements are met should be recorded and checked when the actions are completed. Only verified development outputs should be submitted to configuration management and accepted for subsequent use.

5.5 Quality planning

5.5.1 General

As part of the development planning, the supplier should prepare a quality plan.

The quality plan should be updated along with the progress of the development and items concerned with each phase should be completely defined when starting that phase.

The quality plan should be formally reviewed and agreed by all organizations concerned in its implementation.

The document that describes the quality plan (see 5.5.2) may be an independent document (entitled quality plan) or a part of another document, or composed of several documents including the development plan.

5.5.2 Quality plan content

The quality plan should specify or reference the following items:

a) quality objectives, expressed in measurable terms whenever possible;

b) defined input and output criteria for each development phase;

c) identification of types of test, verification and validation activities to be carried out;

d) detailed planning of test, verification and validation activities to be carried out, including schedules, resources and approval authorities;

e) specific responsibilities for quality activities such as

— reviews and tests,

— configuration management and change control,

— defect control and corrective action.

5.6 Design and implementation

5.6.1 General

The design and implementation activities are those which transform the purchaser's requirements specification into a software product. Because of the complexity of software products, it is imperative that these activities be carried out in a disciplined manner, in order to produce a product according to specification rather than depending on the test and validation activities for assurance of quality.

NOTE 6 The level of information disclosure to be provided to the purchaser needs to be mutually agreed to by the parties, as design and implementation processes are frequently proprietary to the supplier.

5.6.2 Design

In addition to the requirements common to all the development phases, the following aspects inherent to the design activities should be taken into account.

a) Identification of design considerations: in addition to the input and output specifications, aspects such as design rules and internal interface definitions should be examined.

b) Design methodology: a systematic design methodology appropriate to the type of software product being developed should be used.

c) Use of past design experiences: utilizing lessons learned from past design experiences, the supplier should avoid recurrences of the same or similar problems.

d) Subsequent processes: the product should be designed to the extent practical to facilitate testing, maintenance and use.

5.6.3 Implementation

In addition to the requirements common to all the development activities, the following aspects should be considered in each implementation activity.

a) Rules: rules such as programming rules, programming languages, consistent naming conventions, coding and adequate commentary rules should be specified and observed.

b) Implementation methodologies: the supplier should use appropriate implementation methods and tools to satisfy purchaser requirements.

5.6.4 Reviews

The supplier should carry out reviews to ensure that the requirements are met and the above methods are correctly carried out. The design or implementation process should not proceed until the consequences of all known deficiencies are satisfactorily resolved or the risk of proceeding otherwise is known.

Records of such reviews should be maintained.

5.7 Testing and validation

5.7.1 General

Testing may be required at several levels from the individual software item to the complete software product. There are several different approaches to testing and integration.

In some instances, validation, field testing and acceptance testing may be one and the same activity.

The document that describes the test plan may be an independent document or a part of another document, or may be composed of several documents.

5.7.2 Test planning

The supplier should establish and review the test plans, specifications and procedures before starting testing activities. Consideration should be given to

a) plans for software item, integration, system test and acceptance test;

b) test cases, test data and expected results;

c) types of tests to be performed, e.g. functional tests, boundary tests, performance tests, usability tests;

d) test environment, tools and test software;

e) the criteria on which the completion of the test will be judged;

f) user documentation;

g) personnel required and associated training requirements.

5.7.3 Testing

Special attention should be paid to the following aspects of testing:

a) the test results should be recorded as defined in the relevant specification;

b) any discovered problems and their possible impacts to any other parts of the software should be noted and those responsible notified so the problems can be tracked until they are solved;

c) areas impacted by any modifications should be identified and retested;

d) test adequacy and relevancy should be evaluated;

e) the hardware and software configuration should be considered and documented.

5.7.4 Validation

Before offering the product for delivery and purchaser acceptance, the supplier should validate its operation as a complete product, when possible under conditions similar to the application environment as specified in the contract.

5.7.5 Field testing

Where testing under field conditions is required, the following concerns should be addressed:

a) the features to be tested in the field environment;

b) the specific responsibilities of the supplier and purchaser for carrying out and evaluating the test;

c) restoration of the user environment (after test).

5.8 Acceptance

5.8.1 General

When the supplier is ready to deliver the validated product, the purchaser should judge whether or not the product is acceptable according to previously agreed criteria and in a manner specified in the contract.

The method of handling problems detected during the acceptance procedure and their disposition should be agreed between the purchaser and supplier and should be documented.

5.8.2 Acceptance test planning

Before carrying out acceptance activities, the supplier should assist the purchaser to identify the following:

a) time schedule;

b) procedures for evaluation;

c) software/hardware environments and resources;

d) acceptance criteria.

5.9 Replication, delivery and installation

5.9.1 Replication

Replication is a step which should be conducted prior to delivery. In providing for replication, consideration should be given to the following:

a) the number of copies of each software item to be delivered;

b) the type of media for each software item, including format and version, in human-readable form;

c) the stipulation of required documentation such as manuals and user guides;

d) copyright and licensing concerns addressed and agreed to;

e) custody of master and back-up copies where applicable, including disaster recovery plans;

f) the period of obligation of the supplier to supply copies.

5.9.2 Delivery

Provisions should be made for verifying the correctness and completeness of copies of the software product delivered.

5.9.3 Installation

The roles, responsibilities and obligations of the supplier and purchaser should be clearly established, taking into account the following:

a) schedule, including out-of-normal working hours and weekends;

b) access to purchaser's facilities (security badges, passwords, escorts);

c) availability of skilled personnel;

d) availability and access to purchaser's systems and equipment;

e) the need for validation as part of each installation should be determined contractually;

f) a formal procedure for approval of each installation upon completion.

5.10 Maintenance

5.10.1 General

When maintenance of the software product is required by the purchaser, after initial delivery and installation, this should be stipulated in the contract. The supplier should establish and maintain procedures for performing maintenance activities and verifying that such activities meet the specified requirements for maintenance.

Maintenance activities for software products are typically classified into the following:

a) problem resolution;

b) interface modification;

c) functional expansion or performance improvement.

The items to be maintained, and the period of time for which they should be maintained, should be specified in the contract. The following are examples of such items:

a) program(s);

b) data and their structures;

c) specifications;

d) documents for purchaser and/or user;

e) documents for supplier's use.

5.10.2 Maintenance plan

All maintenance activities should be carried out and managed in accordance with a maintenance plan defined and agreed beforehand by the supplier and purchaser. The plan should include the following:

a) scope of maintenance;

b) identification of the initial status of the product;

c) support organization(s);

d) maintenance activities;

e) maintenance records and reports.

5.10.3 Identification of the initial status of the product

The initial status of the product to be maintained should be defined, documented and agreed to by both supplier and purchaser.

5.10.4 Support organization

It may be necessary to establish an organization, with representatives from both supplier and purchaser, to support the maintenance activities. Since activities in the maintenance stage cannot always be carried out on a scheduled basis, this organization should be flexible enough to cope with the unexpected occurrence of problems. It may also be necessary to identify facilities and resources to be used for the maintenance activities.

5.10.5 Types of maintenance activities

All changes to the software (for reasons of problem resolution, interface modifications, functional expansion or performance improvement) carried out during maintenance should be made in accordance with the same procedures, as far as possible, used for the development of the software product. All such changes should also be documented in accordance with the procedures for document control and configuration management.

a) Problem resolution: problem resolution involves the detection, analysis and correction of software nonconformities causing operational problems. When resolving problems, temporary fixes may be used to minimize downtime and permanent modifications carried out later.

b) Interface modifications: interface modifications may be required when additions or changes are made to the hardware system, or components, controlled by the software.

c) Functional expansion or performance improvement: functional expansion or performance improvement of existing functions may be required by the purchaser in the maintenance stage.

5.10.6 Maintenance records and reports

All maintenance activities should be recorded in predefined formats and retained. Rules for the submission of maintenance reports should be established and agreed upon by the supplier and purchaser.

The maintenance records should include the following items for each software item being maintained:

a) list of requests for assistance or problem reports that have been received and the current status of each;

b) organization responsible for responding to requests for assistance or implementing the appropriate corrective actions;

c) priorities that have been assigned to the corrective actions;

d) results of the corrective actions;

e) statistical data on failure occurrences and maintenance activities.

The record of the maintenance activities may be utilized for evaluation and enhancement of the software product and for improvement of the quality system itself.

5.10.7 Release procedures

The supplier and purchaser should agree and document procedures for incorporating changes in a software product resulting from the need to maintain performance.

These procedures should include the following:

a) ground rules to determine where localized "patches" may be incorporated or release of a complete updated copy of the software product is necessary;

b) descriptions of the types (or classes) of releases depending on their frequency and/or impact on the purchaser's operations and ability to implement changes at any point in time;

c) methods by which the purchaser will be advised of current or planned future changes;

d) methods to confirm that changes implemented will not introduce other problems;

e) requirements for records indicating which changes have been implemented and at what locations, for multiple products and sites.

6 Quality system — Supporting activities (not phase dependent)

6.1 Configuration management

6.1.1 General

Configuration management provides a mechanism for identifying, controlling and tracking the versions of each software item. In many cases earlier versions still in use must also be maintained and controlled.

The configuration management system should

a) identify uniquely the versions of each software item;

b) identify the versions of each software item which together constitute a specific version of a complete product;

c) identify the build status of software products in development or delivered and installed;

d) control simultaneous updating of a given software item by more than one person;

e) provide coordination for the updating of multiple products in one or more locations as required;

f) identify and track all actions and changes resulting from a change request, from initiation through to release.

6.1.2 Configuration management plan

The supplier should develop and implement a configuration management plan which includes the following:

a) organizations involved in configuration management and responsibilities assigned to each of them;

b) configuration management activities to be carried out;

c) configuration management tools, techniques and methodologies to be used;

d) the stage at which items should be brought under configuration control.

6.1.3 Configuration management activities

6.1.3.1 Configuration identification and traceability

The supplier should establish and maintain procedures for identifying software items during all phases, starting from specification through development, replication and delivery. Where required by contract, these procedures may also apply after delivery of the product. Each individual software item should have a unique identification.

Procedures should be applied to ensure that the following can be identified for each version of a software item:

a) the functional and technical specifications;

b) all development tools which affect the functional and technical specifications;

c) all interfaces to other software items and to hardware;

d) all documents and computer files related to the software item.

The identification of a software item should be handled in such a way that the relationship between the item and the contract requirements can be demonstrated.

For released products, there should be procedures to facilitate traceability of the software item or product.

6.1.3.2 Change control

The supplier should establish and maintain procedures to identify, document, review and authorize any changes to the software items under configuration management. All changes to software items should be carried out in accordance with these procedures.

Before a change is accepted, its validity should be confirmed and the effects on other items should be identified and examined.

Methods to notify the changes to those concerned and to show the traceability between changes and modified parts of software items should be provided.

6.1.3.3 Configuration status report

The supplier should establish and maintain procedures to record, manage and report on the status of software items, of change requests and of the implementation of approved changes.

6.2 Document control

6.2.1 General

The supplier should establish and maintain procedures to control all documents that relate to the contents of this part of ISO 9000. This covers

a) the determination of those documents which should be subject to the document control procedures;

b) the approval and issuing of procedures;

c) the change procedures including withdrawal and, as appropriate, release.

6.2.2 Types of documents

The document control procedures should be applied to relevant documents including the following:

a) procedural documents describing the quality system to be applied in the software life-cycle;

b) planning documents describing the planning and progress of all activities of the supplier and his interactions with the purchaser;

c) product documents describing a particular software product, including

— development phase inputs,

— development phase outputs,

— verification and validation plans and results,

— documentation for purchaser and user,

— maintenance documentation.

6.2.3 Document approval and issue

All documents should be reviewed and approved by authorized personnel prior to issue. Procedures should exist to ensure that

a) the pertinent issues of appropriate documents are available at appropriate locations where operations essential to the effective functioning of the quality system are performed;

b) obsolete documents are promptly removed from appropriate points of issue or use.

Where use is made of computer files, special attention should be paid to appropriate approval, access, distribution and archiving procedures.

6.2.4 Document changes

Changes to documents shall be reviewed and approved by the same functions/organizations that performed the original review and approval unless specifically designated otherwise. The designated organizations shall have access to pertinent background information upon which to base their review and approval.

Where practicable, the nature of the change shall be identified in the document or the appropriate attachments.

A master list or equivalent document control procedure shall be established to identify the current version of documents in order to preclude the use of non-applicable documents.

Documents shall be reissued after a practical number of changes have been made.

[ISO 9001:1987, 4.5.2]

6.3 Quality records

The supplier shall establish and maintain procedures for identification, collection, indexing, filing, storage, maintenance and disposition of quality records.

Quality records shall be maintained to demonstrate achievement of the required quality and the effective operation of the quality system. Pertinent subcontractor quality records shall be an element of these data.

All quality records shall be legible and identifiable to the product involved. Quality records shall be stored and maintained in such a way that they are readily retrievable in facilities that provide a suitable environment to minimize deterioration or damage and prevent loss. Retention times of quality records shall be established and recorded. When agreed contractually, quality records shall be made available for evaluation by the purchaser or his representative for an agreed period.

[ISO 9001:1987, 4.16]

6.4 Measurement

6.4.1 Product measurement

Metrics should be reported and used to manage the development and delivery process and should be relevant to the particular software product.

There are currently no universally accepted measures of software quality. However, at a minimum, some metrics should be used which represent reported field failures and/or defects from the customer's viewpoint. Selected metrics should be described such that results are comparable.

The supplier of software products should collect and act on quantitative measures of the quality of these software products. These measures should be used for the following purposes:

a) to collect data and report metric values on a regular basis;

b) to identify the current level of performance on each metric;

c) to take remedial action if metric levels grow worse or exceed established target levels;

d) to establish specific improvement goals in terms of the metrics.

6.4.2 Process measurement

The supplier should have quantitative measures of the quality of the development and delivery process. These metrics should reflect

a) how well the development process is being carried out in terms of milestones and in-process quality objectives being met on schedule;

b) how effective the development process is at reducing the probability that faults are introduced or that any faults introduced go undetected.

Here, as for product metrics, the important thing is that levels are known and used for process control and improvement and not what specific metrics are used. The choice of metrics should fit the process being used and, if possible, have a direct impact on the quality of the delivered software. Different metrics may be appropriate for different software products produced by the same supplier.

6.5 Rules, practices and conventions

The supplier should provide rules, practices and conventions in order to make the quality system specified in this part of ISO 9000 effective. The supplier should review these rules, practices and conventions and revise them as required.

6.6 Tools and techniques

The supplier should use tools, facilities and techniques in order to make the quality system guidelines in this part of ISO 9000 effective. These tools, facilities and techniques can be effective for management purposes as well as for product development. The supplier should improve these tools and techniques as required.

6.7 Purchasing

6.7.1 General

The supplier should ensure that a purchased product or service conforms to specified requirements.

Purchasing documents should contain data clearly describing the product or service ordered. The supplier should review and approve purchasing documents for adequacy of specified requirements prior to release.

NOTE 7 A purchased product may be a software and/or hardware item intended for inclusion in the required end product or a tool intended to assist in the development of the required product.

6.7.2 Assessment of sub-contractors

The supplier shall select sub-contractors on the basis of their ability to meet sub-contract requirements, including quality requirements. The supplier shall establish and maintain records of acceptable sub-contractors.

The selection of sub-contractors and the type and extent of control exercised by the supplier shall be dependent upon the type of product and, where appropriate, on records of sub-contractors' previously demonstrated capability and performance.

The supplier shall ensure that quality system controls are effective.

[ISO 9001:1987, 4.6.2]

6.7.3 Validation of purchased product

The supplier is responsible for the validation of sub-contracted work. This may require the supplier to conduct design and other reviews in line with the supplier's own quality system and, if so, such requirements should be included in the sub-contract. Any requirements for acceptance testing of the sub-contracted work by the supplier should be similarly included.

Where specified in the contract, the purchaser or his representative should be afforded the right to determine at source, or upon receipt, that purchased product conforms to specified requirements. Validation by the purchaser may not absolve the supplier of the responsibility to provide acceptable product nor may it preclude subsequent rejection.

When the purchaser or his representative elects to carry out validation at the sub-contractor's premises, such validation should not be used by the supplier as evidence of effective control of quality by the sub-contractor.

6.8 Included software product

The supplier may be required to include or use software product supplied by the purchaser or by a third party. The supplier should establish and maintain procedures for validation, storage, protection and maintenance of such product. Consideration should be given to the support of such software product in any maintenance agreement related to the product to be delivered.

Purchaser-supplied product that is found to be unsuitable for use should be recorded and reported to the purchaser. Validation by the supplier does not absolve the purchaser of the responsibility to provide acceptable product.

6.9 Training

The supplier should establish and maintain procedures for identifying the training needs and provide for the training of all personnel performing activities affecting

quality. Personnel performing specific assigned tasks should be qualified on the basis of appropriate education, training and/or experience, as required.

The subjects to be addressed should be determined considering the specific tools, techniques, methodologies and computer resources to be used in the development and management of the software product. It might also be required to include the training of skills and knowledge of the specific field with which the software is to deal.

Appropriate records of training/experience should be maintained.