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QUALITY MANAGEMENT IN THE DEVELOPMENT, SUPPLY AND MAINTENANCE OF SOFTWARE: ISO 9000 PART 3*

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* The views expressed in this document are those of the author and do not necessarily reflect the views of the Secretariat of the United Nations Industrial Development Organization (UNIDO). Mention of company names and commercial products does not imply the endorsement of UNIDO. This document has not been edited.

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1. Executive Summary

In 1987, the International Organization for Standardization (ISO) approved a series of standards that since then has become well-known as ISO 9000.

In this ISO 9000 series the International Organization for Standardization for the first time specifies requirements to achieve quality, not for products themselves but for the processes involved when producing a product.

The acceptance of this new series of standards is overwhelming. Within a few years, ISO 9000 has become a major topic for industries all over Europe and many companies now either decided or feel the pressure of the market to adapt their internal quality system in accordance with ISO 9000. Earlier attempts to define requirements of quality systems on national levels in Europe have been replaced by the approval of ISO 9000 on a national level and - with some time delay - similar activities are now taking place in Japan and the United States of America.

Although the ISO 9000 series states that its requirements apply basically to every type of company and thus to software companies as well, a specific standard for producing software was approved in 1991 by the International Organization for Standardization called ISO 9000 Part 3. This new standard - called *Guidelines for the application of ISO 9001 to the development, supply and maintenance of software* - is a major step forward in defining requirements of software quality systems on an international level.

Although it is still at a very early stage, it seems not too difficult to predict that ISO 9000 Part 3 will have a major impact on software companies and the software market. Not only is there increasing pressure on the software companies to have their internal quality system certified according to ISO 9000 Part 3, but this pressure will also lead to major changes in the internal structure and organization of software companies and to changes in the international software market as a whole.

The major threat of this development to software companies, especially in the developing countries, is that without ISO 9000 certification sooner or later they will be cut off from markets where this standard is becoming a prerequisite for being in business. At this point of time it can be expected that especially the EC market will be developing in this direction.

Less clear is the development in this respect of the software markets in the United States and Japan. The major concern is, therefore, how to create possibilities for software companies in the developing countries to obtain ISO 9000 certificates that are accepted by their major export markets.

At present nearly all certification bodies operating quality system certification are accredited on a national level in one of the European countries. No procedure seems to be in place at present for international accreditation of certification bodies operating quality system certification and, even worse, no certification body seems to be operating in developing countries yet. So if the software companies outside Europe, Japan and the United States want to and have to apply for ISO 9000 certificates on time, immediate action has to be considered to establish certification bodies with internationally accepted accreditation, accessible to those companies.

2. What is ISO 9000 Part 3?

ISO 9000 Part 3 is Part of the ISO 9000 series. Therefore, it is necessary to understand what the ISO 9000 series is about and how ISO 9000 Part 3 relates to the rest of the ISO 9000 series.

2.1 History

Although it was not until 1991 that the International Organization for Standardization approved ISO 9000 Part 3: *Quality management and quality assurance standards; guidelines for the applications of ISO 9001 to the development, supply and maintenance of software*, the history of quality management and quality assurance in the development of software starts much earlier.

In Figure 1 we present an overview of the most important standards outside the International Organization for Standardization concerning software quality, which goes back to the year 1981, when IEEE approved its standard for software quality assurance plans. However IEEE was primarily and only concerned with software quality.

The International Organization for Standardization took quite a different approach. It was primarily concerned with the creation of standards for quality systems independent of the type of product and the type of company. So in 1986 the predecessor of ISO 9000 was approved, namely ISO 8402 *Quality Management and Quality Assurance; Vocabulary*. Finally, in 1987, the International Organization for Standardization

approved the first edition of the four main parts of the ISO 9000 series as presented in Figure 2. Very soon afterwards, still in 1987, the European Standards Institution approved ISO 9000 - ISO 9004 as European standards EN 29000 - EN 29004.

Although it was quite clear from the beginning of the ISO 9000 history that these standards are not only for manufacturing, it was in fact the manufacturing companies that were the first to accept these standards and to act accordingly.

However, already in ISO 8402 it was stated that a product is the result of activities or processes and that products include service, hardware, processed materials, software, or a combination thereof.

Figure 1 History of Software Quality related Standards

IEEE Std. 730	1981	Standard for Software Quality Assurance Plans
IEEE Std. 729	1983	Glossary of Software Engineering, Terminology
IEEE Std. 828	1983	Standard for Software Configuration Management Plans
IEEE Std. 829	1983	Standard for Software Test Documentation
IEEE Std. 730/84	1984	Standard for Software Quality Assurance Plans
IEEE Std. 830	1984	Guide to Software Requirements Specification
IEC TC 45, 880	1986	Software for Computers in the Safety Systems of Nuclear Power Stations
IEEE Std. 983	1986	Guide for Software Quality Assurance Planning
IEEE Std. 990	1987	Ada As a Program Design Language
IEEE Std. 1002	1987	Taxonomy for Software Engineering Standards
IEEE Std. 1008	1987	Standard for Software Unit Testing

IEEE Std. 1012	1986	Standard for Software Verification and Validation Plans
IEEE Std. 1016	1987	Recommended Practice for Software Design Descriptions
IEEE Std. 1042	1987	Guide to Software Configuration Management
IEEE Std. 1058.1	1987	Standard for Software Project Management Plans
IEEE Std. 1063	1987	Standard for Software User Documentation
IEC SC 65A	1988	Architecture of Safety Related Software Systems
IEEE Std. 982.1	1988	Standard Dictionary of Measures to Produce Reliable Software
IEEE Std. 982.2	1988	Guide for the Use of IEEE Standard Dictionary of Measures to Produce Reliable Software
IEEE Std. 1028	1988	Standard for Software Reviews and Audits

The situation for software companies changed drastically when the International Organization for Standardization approved ISO 9000 Part 3 - *Quality management and assurance standards; guidelines for the application of ISO 9001 to the development, supply and maintenance of software.*

Figure 2 Important "Historical" Dates

1986	ISO 8402: *Quality management and quality assurance - Vocabulary*
15. 03. 1987	1. edition of ISO 9000: *Quality management and quality assurance standards; Guidelines for selection and use* ISO 9001: *Quality systems; Model for quality assurance in design, development, production, installation and servicing* ISO 9002: *Quality systems; Model for quality assurance in production and installation* ISO 9003: *Quality systems; Model for quality assurance in final inspection and test* ISO 9004: *Quality management and quality system elements; Guidelines;*

	is approved by ISO (International Organization for Standardization, Geneva)
10. 12. 1987	ISO 9000 - ISO 9004 are approved by CEN (European Standards Institution, Brussels) as European standards EN 29 000 - EN 29 004
1991	ISO 9000-3: *Quality management and quality assurance standards; Guidelines for the application of ISO 9001 to the development, supply and maintenance of software*

Because of this special standard and for some other reasons explained later in this report, software companies, at least in Europe, are now taking the ISO 9000 series very seriously and have start applying for the certificate.

2.2 What is Quality?

Many ordinary words in every day use are used in the quality field in a specific or restricted manner compared with the full range of the dictionary definitions. It is therefore important to clarify and standardize the quality terms as they apply to the field of quality management.

The word *quality*, in popular usage, often means different things to different people:

In ISO 9000, quality is defined as the totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs.

There are many other usages of this term such as

- *Conformance to requirements;* or
- *Degree of excellence.*

This gives rise to considerable confusion and misunderstanding. *Conformance to requirements* leads people to argue that quality costs less. The implication is that satisfying needs correctly the first time should be very cost effective. On the other hand, the *degree of excellence* usage implies the opposite - that quality costs more. An example of this usage is that it costs more to provide and run a five star hotel than a boarding house.

Although the definition of quality as it is used in ISO 9000 is very important, it should become clear that ISO 9000 is not about quality but about quality system, as it is defined in Figure 3.

Figure 3 Vocabulary according to ISO 8402

Quality - Q	The totality of characteristics of a product or a service that bear on its ability to satisfy stated and implied needs
Quality management - QM	All activities of the overall management function that determine the quality policy, objectives and responsibilities and implement them by means such as quality planning, quality control, quality assurance and quality improvement, within the quality system
Quality system - Q-System	The organizational structure, responsibilities, procedures, processes and resources needed to implement quality management
Development	All activities to be carried out to create a software product
Verification	The process of evaluating the products of a defined segment of work to ensure correctness and consistency with respect to the products and standards provided as input to that defined segment of work
Validation	The process of evaluating software to ensure compliance with specified requirements

To state it in simple words, ISO 9000 is not a standard about how to achieve a certain degree of excellence. Rather, as defined in **Figure 3**, ISO 9000 defines requirements that a quality system has to fulfill in order to be in conformity with ISO 9000. The quality system itself consists of the organizational structure, responsibilities, procedures, processes and resources needed for all activities of an organization with regard to quality.

2.3 The ISO 9000 Series

Since its first edition in 1987, the ISO 9000 series has grown substantially in size and volume. It presently consists of a total of 14 parts grouped into three main subgroups as can be seen in **Figure 4**.

Figure 4 Overview of the 14 Parts of ISO 9000	ISO	Pa ges	
		1987	1993
Quality management and quality assurance standards;	*9000*	*22*	*192*
Guidelines for selection and use	9000 - 1	22	74
General guidelines for application of ISO 9001, ISO 9002 and ISO 9003	9000 - 2	-	73
Guidelines for the application of ISO 9001 to the development, supply and maintenance of software	9000 - 3	-	34
Application to dependability management	9000 - 4	-	11
Quality systems; Model for quality assurance ...		*71*	*110*
... in design, development, production, installation and servicing	9001	31	42
... in production and installation	9002	27	38
... in final inspection and test	9003	13	30
Quality management and quality system elements;	*9004*	*73*	*416*
Guidelines	9004 - 1	73	90
Guidelines for services	9004 - 2	-	43
Guidelines for processed materials	9004 - 3	-	80
Guidelines for management of quality improvement	9004 - 4	-	92
Guidelines for quality plans	9004 - 5	-	41
Guidelines for project management	9004 - 6	-	30
Guidelines for configuration management	9004 - 7	-	40
Total		166	718

The first group - ISO 9000 itself - consists at present of Parts 1-4 and gives guidelines for the selection and use of the three quality system models presented in ISO 9001, ISO 9002 and ISO 9003.

Of the three quality system models only the ISO 9001 model for quality assurance in design, development, production, installation and servicing is of relevance to software companies because the ISO 9000 Part 3 explicitly refers to ISO 9001. The reason for this is that:

- ISO 9002 and ISO 9003 basically apply to manufacturing industries only;

while

- ISO 9001 has included design, development and servicing and applies to a much broader field.

Finally, ISO 9004 consists at present of parts 1-7 and states guidelines of quality management and quality system elements for different types of products and/or activities.

Although it is helpful to know the 14 parts of ISO 9000 series, it is important to note that all the information concerning software is stated in ISO 9000 Part 3, and although it refers to ISO 9001, the ISO 9000 Part 3 is self-explanatory. It is for this reason that the latter part of this report refers to ISO 9000-3 only.

2.4 Requirements of the Quality System

According to ISO 9000 Part 3, there are some quality system elements the supplier *must have*, while others the supplier *should have*. The latter are therefore less binding.

Figure 5 lists all

- Organizational structures;
- Responsibilities;
- Procedures;
- Processes; and
- Resources

which the supplier must have as elements of his quality system.

By supplier, the ISO 9000 series always refers to the organization whose quality system is defined.

Figure 5 Requirements of the Quality System according to ISO 9000 Part 3

The supplier *must* ...

- Define its policy and objectives for quality;
- Ensure that this policy is understood, implemented and maintained;
- Define the responsibility and authority of all personnel;
- Identify in-house verification requirements, provide adequate resources and assign trained personnel for verification activities;
- Appoint a management representative who shall have defined authority and responsibility for ensuring that the requirements of ISO 9001 are implemented and maintained;
- Carry out a comprehensive system of planned and documented internal quality system audits;
- Establish, document and maintain procedures for corrective actions;
- Establish and maintain procedures for identification, collection, indexing, filing, storage, maintenance and disposition of quality records;
- Select subcontractors on the basis of their ability to meet subcontract requirements;
- Establish and maintain records of acceptable sub-contractors.

3. ISO 9000 Part 3 and Inspection of Conformity

Inspection of conformity is an activity such as examining or testing a software product in order to establish whether the fulfillment of specified requirements is achieved.

Inspection of conformity is by no means obsolete if a software company performs according to ISO 9000 Part 3.

As is stated in ISO 9001: *It is emphasized that the quality system requirements specified in this international standard are complementary (not alternative) to the technical (product) specified requirements. They specify requirements which determine what elements quality systems have to encompass but it is not the purpose of this international standard to enforce uniformity of quality systems.*

Clearly for a supplier who produces a software product for which technical requirements exist, it is sufficient to have a certificate that his software product conforms to these technical requirements. However, there are only a few

software products for which such technical requirements as an international standard exist (see Figure 6).

Figure 6 Software Products with Existing Technical Specified Requirements	
. COBOL - ISO 1989	. ALGOL 60 - ISO 1538
. FORTRAN - ISO 1539	. POSIX - ISO 9945
. PASCAL - ISO 8652	. GKS - ISO 7942, ISO 8651, ISO 8805
. C - ISO 9899	. CGI (Computer Graphics Interface) - ISO 9636
. BASIC - ISO 6373	
. ADA - ISO 8652	. X/OPEN - XPG3

In all other cases, ISO 9000 Part 3 represents the only international standard to support the fulfillment of specified requirements by the purchased software product. In other words, the importance of ISO 9000 Part 3 is not so much in areas where an international standardization of the product itself exists - especially for compilers - but rather for customer specific or any other kind of non-standardized software products.

4. Motivation for ISO 9000 Part 3

International standards are rarely enforced by national or international law. It is much more common that companies themselves have for some reason a strong interest in the application of specific international standards. This is very much the case with ISO 9000 in general and ISO 9000 Part 3 in particular.

The reasons and motivations for both parties, namely purchasers and suppliers, to implement ISO 9000 Part 3 are now discussed. It is for these reasons that ISO 9000 Part 3 is becoming a major topic in the software industry.

4.1 Purchaser's View

The most obvious objective of any purchaser is to purchase software products that fulfil specified requirements. Clearly a company that has a quality system according to ISO 9000 Part 3 in place is trustworthy with respect to their software product fulfilling specified requirements and thus reduces the purchaser's risk.

The purchaser's objective of simplifying and thus reducing the costs for the process of selecting and evaluating suppliers is along the same lines. Purchasers who have experienced costs resulting from purchased software products that did not fulfill specified requirements tend to prefer suppliers having a certificate for ISO 9000 Part 3. This is a much less expensive way of decision-making than having to extensively test the purchased product.

These two motivations do not depend on the purchaser's situation with respect to ISO 9000. However, if the purchaser himself has a quality system in place that fulfills ISO 9000 Part 3 or if the purchaser of a software product is a company meeting the ISO 9001 or ISO 9002 requirements, it follows that the purchaser must:

a. Insure that a purchased product or service conforms to specified requirements;

b. Select suppliers on the basis of their ability to meet contract requirements, including quality requirements.

This means that any purchaser having a certified quality system will have a very strong tendency to buy software only from companies who have the same.

This is, of course, not mandatory but the two above-mentioned requirements for the purchaser would otherwise imply that he would have to test the supplier as well as the purchased software product and usually these tests are much more expensive than the selection of software suppliers on the basis of their ISO 9000 conforming quality system.

It is for this reason that, as with a 'snowball' effect, more and more suppliers are forced to implement an ISO 9000 conforming quality system. When customers themselves have an ISO 9000 conforming quality system they tend to require the same from their suppliers because of the requirements of ISO 9001 and ISO 9000 Part 3 as explained above.

4.2 Supplier's View

In Figure 7 the main objectives for the suppliers are listed, divided into external objectives and internal objectives.

Although fulfilling requirement of customers is really the main reason for suppliers to consider implementing ISO 9000 Part 3, there are also other motivations listed.

Figure 7 Motivation for ISO 9000 Part 3 - Supplier's View

External Objectives	Internal Objectives
. Fulfilling requirement of customers	. Reduction of costs of non-conformity
. Fulfilling national/international requirements, e.g. Radio Technical Commission for Aeronautics for software in airborne systems, International Electrotechnical Commission and IAEA for software related to the safety of nuclear power plants, National Computer Security Center, U.S.A., for software related to computer security.	. Transfer of costs of non-conformity and of liability risk to the subcontractor
. Improving the image	. Improving the internal organization
. Improving/ensuring the market position	. Motivation of personnel
. Improving the international competitiveness	
. Support of marketing	. Reduction and/or avoiding costs of audits of the quality systems by the customers
. Reduction of liability risk (in some countries - e.g. Germany, the supplier must prove that he is not guilty with respect to the non-conforming product; having a certified quality system can be such a proof)	
. Reduction of liability insurance premium	

In specific areas where especially high risks are involved, that is:

- Airborne systems; and
- Safety of nuclear power plants

the Radio Technical Commission for Aeronautics as well as the International Electrotechnical Commission have created their own standards with regard to software (see also [1], [8], [9] and [13]).

Although it has not yet taken place, judging by the experience with ISO 9000 in other industries it can be expected that ISO 9000 Part 3 will become a prerequisite for suppliers of software in airborne systems and for software related to the safety of nuclear power plants.

While the external objectives for suppliers are mostly market oriented except for cost reduction of:

- Liability risks; and
- Liability insurance premium

the internal objectives are clearly to reduce costs resulting from non-conformity of the software products. This also includes the motivation of personnel by implementing a quality system, and - last but not least - avoiding costly audits of the supplier's quality system by the customer.

5. The Quality System Elements

Although this paper does not intend to describe the contents of ISO 9000 Part 3 completely (this is much better done by reading ISO 9000 Part 3 itself), it gives a brief outline of what ISO 9000 Part 3 requires.

There are three main parts in ISO 9000 Part 3 which will be covered in the following three chapters.

The scope of ISO 9000 Part 3 is described as follows:

> The guidelines of ISO 9000 Part 3 are intended to describe the suggested controls and methods for producing software which meet a purchaser's requirements. This is done primarily by preventing non-conformity at all stages from development through to maintenance.

5.1 Framework

Quality policy:

The supplier's management shall define and document its policy and objectives for quality.

Responsibility and authority:

The responsibility and authority and the interrelation of all personnel who manage, perform and verify work affecting quality shall be defined.

Verification resources and personnel:

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

Management representative:

The supplier shall appoint a management representative who shall have defined authority and responsibility for ensuring that the requirements of ISO 9001 are implemented and maintained.

Management review:

The quality system adopted to satisfy the requirements of ISO 9001 shall be reviewed at appropriate intervals by the supplier's management.

Purchaser's management responsibility:

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

Joint reviews:

Regular joint reviews involving the supplier and purchaser should be scheduled.

Quality system documentation:

All the quality system elements, requirements and provisions should be clearly documented.

Quality plan:

The supplier should prepare and document a quality plan to implement quality activities for each software development.

Internal quality systems audits:

The suppliers shall carry out a comprehensive system of planned and documented internal quality system audits.

Corrective action:

The supplier shall establish, document and maintain procedures for corrective action.

5.2 Life-cycle Activities

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. ISO 9000 Part 3 is intended for application irrespective of the life-cycle model used.

Contract review:

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

Purchaser's requirements specification:

In order to proceed with software development the supplier should have a complete, unambiguous set of functional requirements.

Development planning:

The development plan should cover:

- The definition of the project;
- The organization of the project resources, including the team structure, responsibilities and use of sub-contractors;
- Development phases;
- The project schedule identifying the tasks to be performed, the resources and time required for each and any interrelationships between tasks;
- 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 before activities

in that phase are started. It should be reviewed and approved before execution.

Quality planning:

As part of the development planning the supplier should prepare a quality plan. This plan should specify the following items:

- Quality objectives, expressed in measurable terms, whenever possible;
- Defined input and output criteria for each development phase;
- Identification of types of test, verification and validation activities to be carried out;
- Detailed planning of test activities;
- Specific responsibilities for quality activities.

Design:

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

- Design methodology;
- Use of past design experiences;
- Subsequent processes (the products should be designed to the extent practically possible to facilitate the testing, maintenance and use).

Implementation:

The following aspects should be considered in each implementation activity:

- Rules such as programming rules, programming languages, consistent naming conventions, coding and adequate commentary rules;
- Implementation methodologies.

Reviews:

The supplier should carry out reviews to ensure that the requirements are met and the methods are correctly carried out.

Test planning:

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

Testing:

The test results should be recorded. Any problems discovered and their possible impacts should be noted and test adequacy should be evaluated.

Validation:

Before offering the product for delivery, the supplier should validate its operation as a complete product.

Delivery:

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

Installation:

The roles, responsibilities and obligations of the supplier and purchaser should be clearly established.

Maintenance plan:

All maintenance activities should be carried out and managed in accordance with a maintenance plan.

Maintenance records and reports:

All maintenance activities should be recorded in pre-defined formats and retained.

Release procedures:

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

5.3 Activities not Dependent on Phases

Configuration management:

Configuration management provides a mechanism for identifying, controlling and tracking the versions of each software item.

Configuration management plan:

The supplier should develop and implement a configuration management plan.

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.

Change control:

The supplier should establish and maintain procedures to identify, document, review and authorize any changes to the software items under configuration management.

Configuration status report:

The supplier should establish and maintain procedures to record, manage and report on the status of software items.

Document control:

The supplier should establish and maintain procedures to control all documents that relate to the contents of ISO 9000 Part 3. The document control procedures should be applied to relevant documents including the following:

- Procedural documents describing the quality system;
- Planning documents describing the planning and progress of all activities of the supplier and his interactions with the purchaser;
- Product documents describing a particular software product.

Document approval and issue:

All documents should be reviewed and approved by authorized personnel prior to issue.

Document changes:

Changes to documents shall be reviewed and approved by the same functions that performed the original review and approval.

Quality records:

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

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 the minimum, some metrics should be used which represent reported field failures and/or defects from the customer's viewpoint. Selected metrics should be described so that results are comparable.

Process measurement:

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

Tools and techniques:

The supplier should use tools, facilities and techniques in order to make the quality system guidelines in ISO 9000 Part 3 effective.

Purchasing:

The supplier should insure that a purchased product or service conforms to specified requirements. The supplier shall select subcontractors on the basis of their ability to meet subcontract requirements, including quality requirements.

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.

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.

6. Certification

In Figure 8 all the international standards concerning certification are listed.

The idea of ISO 9000 series is, of course, not only to define requirements for a quality system but also to establish ways

so that a quality system can be assessed independently and objectively.

Figure 8 Overview of the International Standards concerning Certification	ISO
Guidelines for developing quality manuals	10 013
Guidelines for auditing quality systems;	*10 011*
Auditing	10 011 - 1
Qualification criteria for quality systems auditors	10 011 - 2
Management of audit programs	10 011 - 3

The vocabulary used concerning certification is given in **Figure 9.**

Figure 9 Vocabulary concerning Certification according to ISO 8402

Quality audit:	A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives
Certification of quality systems:	The formal acknowledgement of the fulfillment of the International Standard ISO 9001, ISO 9002 or ISO 9003 by a specific quality system

The process of implementing a quality system according to ISO 9000 Part 3 is itself a major project that should be carried out in a well planned and careful manner.

In the following we describe the phases of such a project. By no means however is this a requirement of the International Organization for Standardization. Rather it has proven to be a practical way of implementing a quality system.

6.1 Analysis and Planning

The analysis and planning phase is concerned with the analysis of the existing quality system and the planning and documentation of the improved or new quality system.

In **Figure 10** the phases of the process of implementing the quality system are presented.

The project has to start with a project planning phase consisting of the definition of the objectives of the project, of the persons responsible for the project and of a project plan in terms of time schedule and resources.

The first step then is the analysis of the existing quality system to find out what already exists either documented in a formal way or otherwise not documented at all.

The new quality system then has to be designed and compared with the existing quality system so that it becomes clear what changes to the existing quality system have to be made and what is required to bring these changes about.

When the new quality system has been design and approved by management, it can then be documented. The main piece of documentation is the quality manual, which is also the document that is examined by the certification body and usually also requested by the customers. The contents of the quality manual are given in **Figure 11** and the new ISO 10013 *Guidelines for developing quality manuals* gives detailed information.

The final phase of planning the quality system consists of the development of all the detailed procedural documents describing the quality system.

6.2 Implementation

Again as shown in **Figure 10**, steps have to be undertaken in order to guarantee that the quality system is not only well documented but, even more important, implemented and applied.

Therefore, all personnel has to be trained and motivated to really live up to the quality system. The quality system then has to be tested, compared to the quality manual, and all the other documents describing the quality system and the results of the test have to be evaluated.

The final step before applying for certification is the internal audit in which the conformity of the quality system to the documented quality system has to be assessed, and in

case of nonconformity corrective actions have to be undertaken.

Figure 10 Process of Certification

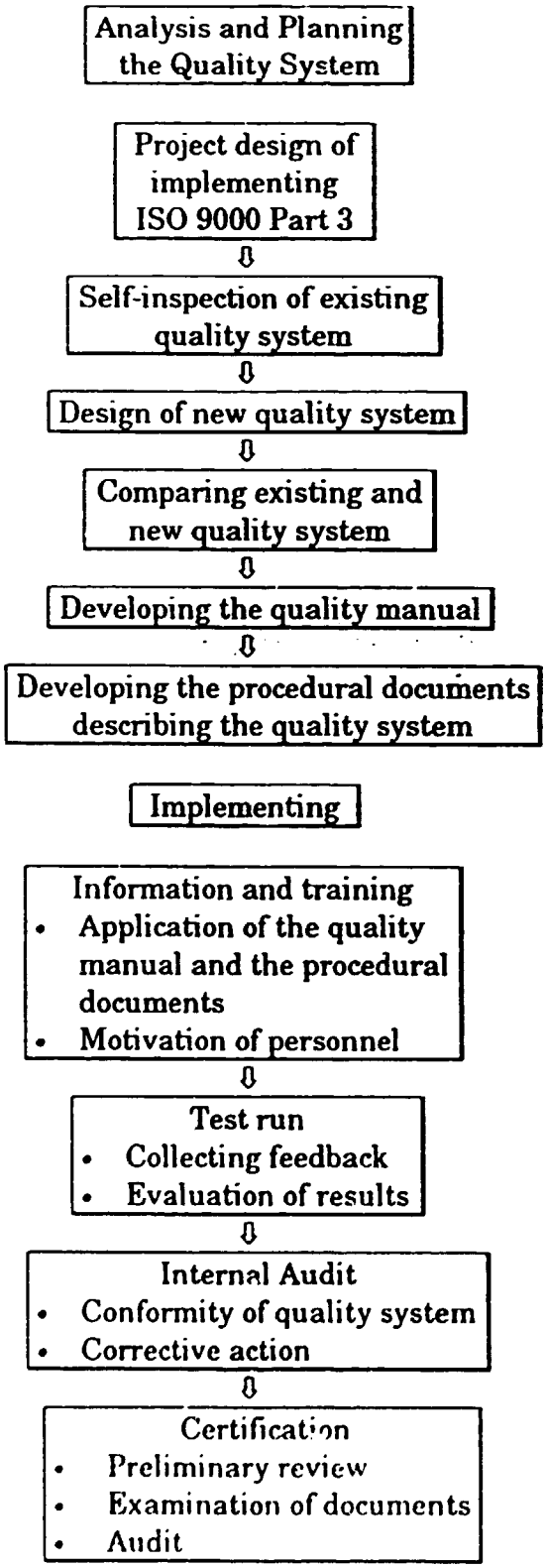


Figure 11 Quality Manual according to ISO 9000 Part 3

Shall contain:

- Quality policy
- The responsibilities, authorities and interrelationships of personnel who manage, perform, verify or review work affecting quality
- A statement of reviewing, updating and controlling the manual

6.3 Audit

Auditing the quality system for certification has to follow the rules laid out in ISO 10011 (see also **Figure 8**).

The auditing is done by an independent certification body which should be accredited (though accreditation is not mandatory) (for more details about accreditation see **Chapter 7**).

The auditing basically consists of three parts:

1. The preliminary review whose purpose is:

   - To introduce the members of the audit team to the auditees' senior management;
   - Review the scope and the objectives of the audit;
   - Confirm that the resources and facilities needed by the audit team are available;
   - Confirm the time and date for the closing meeting and any interim meetings of the audit team and the auditee's senior management;
   - Clarify any unclear details of the audit plan.

2. Examination of documents:

   This includes the examination of the quality manual and the procedural documents describing the quality system and any other document the audit team may require.

3. Collecting evidence:

   Evidence shall be collected through interviews and observation of activities and conditions in the areas of concern. Clues suggesting non-conformities of the quality system shall be noted if they seem significant. Information gathered through interviews shall be tested by acquiring the same information from other independent sources such as physical observation, measurements and records.

All audit observations shall be documented. After all activities have been audited, the audit team shall review all of their observations to determine which are to be reported as non-conformities.

The audit team shall then ensure that these are documented in a clear concise manner and are supported by evidence. All observations of non-conformities shall be acknowledged by the auditee's management.

The auditee is responsible for determining and initiating corrective action needed to correct a non-conformity or to correct the cause of a non-conformity. The auditor is only responsible for identifying the non-conformity.

Corrective action and subsequent follow-up audits should be completed within a time period agreed to by the client and the auditee in consultation with the auditing organization.

6.4 Expenditure

Although there is not yet much empirical evidence about the amount of work involved to implement a quality system according to ISO 9000 Part 3, one can draw upon similar experiences with implementing ISO 9001 in manufacturing companies. These experiences are listed in Figure 12.

Figure 12 Expenditure for Process of Certification

Phase	Length in months	Expenditure of man-months
Analysis and Planning	9 - 12	> 10
Implementing	9 - 12	> 10
Certification	3 - 6	~ 4
Monitoring audit	annual	~ 1
Re-audit for renewal of certificate	every 3 years	~ 1

Because in manufacturing companies quality systems are implemented to a higher degree than in software companies, prior to implementing a quality system according to ISO 9000 one could expect that the amount of work involved in implementing a quality system in a software company might even be substantially higher and take more time.

It is also important to notice that in order to maintain the certificate a regular re-audit has to take place at least every three years and, depending on the certification body, a monitoring audit has to take place within even shorter intervals.

All these audits have to be undertaken by an independent certification body.

7. Accreditation

Accreditation is the formal recognition at a national or international level that a certification body is competent and reliable in the operation of quality system certification irrespective of the sector involved.

It is interesting to note that although the accreditation is an important part of the whole system of ISO 9000, only certification within the EC standards have been established to specify the criteria for accreditation (see Figure 13).

Figure 13 Overview of the European Standards related to Accreditation	EN
General criteria for the operation of testing laboratories	45 001
General criteria for the assessment of testing laboratories	45 002
General criteria for laboratory accreditation bodies	45 003
General criteria for certification bodies operating product certification	45 011
General criteria for certification bodies operating Quality System certification	45 012
General criteria for certification bodies operating certification of personnel	45 013
General criteria for suppliers' declaration of conformity	45 014

The basic idea behind the general criteria for certification bodies operating quality system certification is that such a certification body itself must have a quality system in place that conforms to ISO 9001.

It is also important to notice that at this point in time accreditation is a national activity and not an international one. It is also important to mention that accredited certification bodies are not limited to a specific sector but operate quality system certifications in all areas.

Although some of the accredited certification bodies are operating internationally, most of them are really concentrating on their national market as can be seen in **Figure 14.**

At the moment the whole development is still a mostly European affair. Some accredited certification bodies have established a European network of quality system assessment and certification bodies.

Figure 14 Accredited Certification Bodies operating Quality System Certification

E-Q-Net European Network for Quality System Assessment and Certification

Austria - ÖQS	Greece - ELOT	Portugal - IPQ
Belgium - AIB Vincote	Iceland - STRI	Spain - AENOR
	Ireland - NSAI	Sweden - SIS
Denmark - DS	Italy - CISQ	Switzerland - SQS
Finland - SFS	Netherlands - KEMA	United Kingdom - BSI
France - AFAQ		
Germany - DQS		

Other countries

Canada - QMI	Russia - GOST	South Africa - SABS
Israel - SII	Singapore - SISIR	
Japan - JMI	Slovenia - IKM	Turkey - TSE
		USA - AGA

Accredited certification bodies operating internationally

Det Norske Veritas, Kema Netherlands	Lloyd's Register United Kingdom	TÜV Rheinland Germany

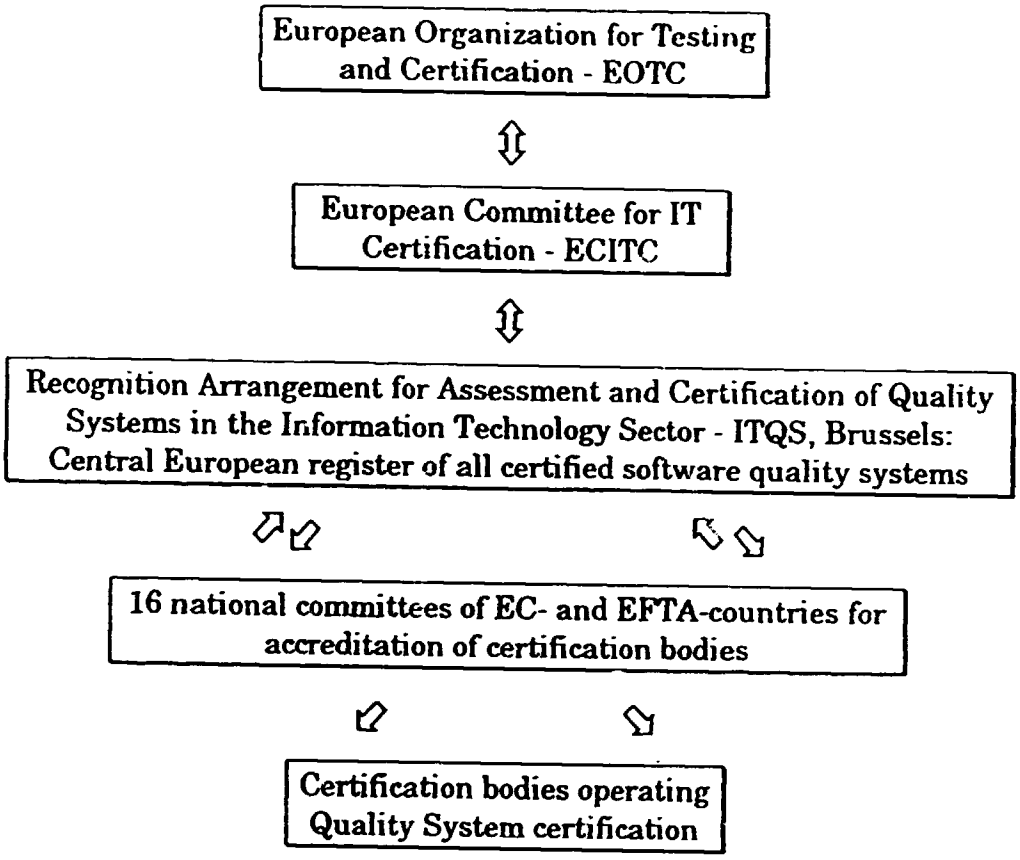
This European network guarantees that each certificate by any member of this European network is accepted and considered equivalent by any other certification body which is a member of this European network.

The acceptance of certificates across borders is actually the weakest point of the whole certification scheme of ISO 9000 because no international rules have been laid out how to guarantee that certificates by different certification bodies are equivalent.

In Figure 15 the total structure of accreditation in Europe is presented.

It is important to notice that a specific organization called ITQS has been established with its secretariat in Brussels which not only tries to coordinate the activities with regard to certification of software quality systems, but which also represents the central European register of all certified software quality systems (see also [10]).

Figure 15 Accreditation in Europe



What has not been established yet, but for which the *European network for quality system assessment and certification* might be a nucleus, is the establishment of a truly international network for quality system assessment and certification, thus guaranteeing that certificates by any member of this international network will be accepted by most nations and most customers.

8. Possible Side-effects of ISO 9000 Part 3

Although there are many advantages in implementing ISO 9000 Part 3, one must be aware that certain side-effects may occur as listed in **Figure 16.**

In manufacturing industry it has sometimes been found that quality systems are rather seen as a way of documenting processes than as a method of improving quality.

Figure 16 Possible Side-effects of ISO 9000 Part 3

INTERNAL	EXTERNAL	ECONOMIC
Bureaucratic Loss of flexibility and creativity Rise of costs if the savings of non-conformity costs is less than the additional costs for prevention of non-conformity and for testing	Competitive advantage is only temporary - until all competitors have certified quality systems	**How does the economy change if nearly all companies in U.S.A., EC and Japan have certified quality systems?** . Increase of the barriers for entering the market . Increase of the barriers for exporting products and services from developing countries to U.S.A., EC and Japan

Such a quality system tends to be mostly a bureaucratic system rather than one that increases the organizational performance as a whole. In this case a substantial increase of costs can be observed due to the fact that the costs of the quality system are substantial while no savings in terms of savings of non-conformity costs take place.

For companies in the developing countries the most severe side effect is economic. Exporting products and services to countries where most of the purchasing companies require an ISO 9000 certificate from their suppliers will be severely restricted. This side-effect shall be discussed in more detail in Chapter 10.

9. ISO 9000, TQM and Kaizen

At present differences in the way quality incentive systems have been established can be observed. They differ substantially between:

- Japan
- U.S.A. and
- EC.

As shown in Figure 17 Total Quality Management, which is the dominant topic in terms of quality in the U.S.A., is primarily evaluated and awarded by a competition called Malcolm Baldrige National Quality Award.

Figure 17 ISO 9000, TQM and Kaizen

ISO 9000 Part 3	Total Quality Management	Kaizen
Dominant in EC Certification oriented: ISO 9000 Part 3 - certificate is the criterion for quality	Dominant in U.S.A. Competition oriented: The annual Malcolm Baldrige National Quality Award (since 1987) is the criterion for quality	Dominant in Japan Process oriented: Continuous, gradual improvements through company and Competition oriented: The annual Deming Application Prize (since 1951) is the criterion for quality

This award is similar to the Deming Application Prize which is the dominant quality award in Japan, while clearly Europe is going the path of ISO 9000.

The advantage of the concept of ISO 9000 is that it is open on an international basis, while for companies outside the U.S.A. or Japan it is much harder to compete for the national quality awards within those countries.

The disadvantage of ISO 9000 in terms of quality is that the general view at the moment is that the requirements for the Malcolm Baldrige National Quality Award and also for the Deming Application Prize are substantially higher than the requirements for ISO 9000. Maybe it is for this reason that the ISO 9000 movement in the U.S.A. and in Japan is taking on momentum much more slowly than in Europe.

10. The Developing Countries and ISO 9000 Part 3

Certain conclusions, as to the effects ISO 9000 Part 3 will have on companies in the developing countries especially in the software business, can be drawn. As is the case with many inventions, one can identify problems as well as opportunities for software companies in the developing countries.

10.1 Problems

The main problem for software companies implementing ISO 9000 Part 3 is that it requires a highly sophisticated internal organization with regard to the quality system. This is new for many software companies. Software companies still have a tendency to view the development of software more as an art that requires creativity rather than an engineering process that requires self-discipline and order.

Therefore, many software companies find it hard to change according to the needs of ISO 9000 Part 3.

But nevertheless - and this is the second big problem - these changes take place right now and the number of software companies with a certified quality system increases steadily. This results in those companies who do not have a certificate for their software quality system finding it harder and harder to market their products.

Even more severe is the situation that as the number of companies in general who have a certified quality system increases rapidly, all these potential customers are more or less required to give preference to suppliers who themselves have established a certified quality system. This trend is particularly obvious in Europe and probably will take place with some time delay in the U.S.A. and Japan as well.

But - and this is another problem for software companies in the developing countries right now - it is very difficult to find an accredited and internationally accepted certification body operating quality systems certification in countries outside Europe.

Given the costs involved and also the problems of distance and language, it seems rather unlikely that all software companies applying for certification of their quality system could do this with a certification body situated in some country in Europe.

So the big question at the moment remains: *How can software companies in developing countries willing to implement a quality system according to ISO 9000 Part 3 have this quality system certified?*

10.2 Opportunities

As is well known within the software community, software development is a risky business. It is for this reason that management of many software companies have been considering for some time how to implement a quality system so that their risks in terms of not fulfilling purchaser's requirements are reduced substantially.

Now ISO 9000 Part 3 can give them an answer - not an easy answer but one management can rely on due to its status as an international standard. Thus, it is exactly this international standardization that gives software companies in developing countries the chance to cope with a negative quality image that might occur otherwise and which is difficult to repute.

No matter what a purchaser may think of quality produced in a specific country in general, the documentation of a quality system certified according to ISO 9000 Part 3 is a very strong argument to convince the potential customer that the delivered software products will meet the requirements of the purchaser. In fact, if some software companies in developing countries are taking on quality systems more rapidly than their competitors in Europe, U.S.A. or Japan, they might even experience substantial advantages on those markets.

11. What Has to be Done?

As has already been stated in Chapter 10.1, to give software companies in developing countries a chance to establish a quality system according to ISO 9000 Part 3, it is crucial to establish certification bodies near them that are accredited on an international level.

It is doubtful whether the establishment of certification bodies on a national level in each developing country is a feasible solution because there is some doubt if those certificates will be accepted by customers in Europe, Japan and U.S.A. as being equivalent to certificates from accredited certification bodies in European countries.

UNIDO could play an important role in establishing such internationally accepted certification bodies operating quality system certification in developing countries.

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