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Wrocław University of Technology

Production Management

Barbara Sujak-Cyrul

QUALITY MANAGEMENT SYSTEMS

An Introduction to the Project of Documenting and Audit of Quality Management Systems

Wrocław 2011

Projekt współfinansowany ze środków Unii Europejskiej w ramach
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1. Introduction

The ISO 9000 family standards are a widely applied, universal basis for design, implementation, certification, maintenance and improvement of Quality Management Systems (QMS) in organizations of any type and size. Systems consistent with ISO 9001 standard (or with specific sector standards containing ISO 9001 requirements, which is applicable to e.g. automotive, aerial, telecommunication and medical device industry) require both documentation in a necessary scope, as well as conducting internal audits in a planned time frame, to determine if a given quality management system is consistent with requirements and if it is effectively implemented and sustained. Therefore, it may be presumed that **every engineer, sooner or later, will work in an organization covered by this type of quality management system and should be adequately prepared for this**.

For the above-mentioned reasons, I have had the pleasure to develop a program of the course titled "Documenting and Audit of Quality Management Systems", to be conducted in the form of project at the Faculty of Mechanical Engineering, Wroclaw University of Technology, in the frame of masters programmes focused on management and engineering of production. The aim of the course is mastering by students the basic practical skills in the scope of:

- analysis, design and preparation of elements of a quality management system's documentation according to universal ISO series 9000 standards,
- interpretation of ISO 9001 standard's requirements as well as planning, conducting and documenting internal quality management systems' audits according to ISO 9001 and ISO 19011.

Within the project titled "The development of potential and academic programmes of Wroclaw University of Technology", co-financed from the EU European Social Found, this textbook and certain teaching materials 'ready for use' have been separately prepared for the needs of the course "Documenting and Audit of Quality Management Systems", providing complementary components supporting the learning process in this course.

This textbook contains, in addition to a brief concept description of the project expected to be realized by students and a few relevant comments to avoid possible misunderstanding and misconceptions relevant to this project, two main parts: a theoretical section and a practical one. The theoretical section introduces students to the subject of quality management systems compliant with the standards of ISO 9000, showing such aspects as: the origin of standardized QMSs, basic principles and concepts for QMSs as well as the range of requirements for a QMS set in the 9001:2008 standard. The practical section contains some introductory exercises related to particular aspects of QMS documentation as well as the steps to be taken within the students' group work, to realize the project involving the development of basic quality management system documentation for a chosen micro-enterprise.

The form and content of the developed textbook have been shaped by my previous experiences gained from many years of work on establishing, implementing and maintaining quality management systems, both at the international company ABB and in

some small organizations from different sectors of activities, from past experience of conducting lectures, seminars, projects and master's dissertations on the Quality Management speciality, as well as from participation in several European projects (e.g. VETMAN, EEFQM) related to educational aspects of broadly defined quality management.

Finally let me express my hope that this textbook will effectively support students in gaining the first experience in documenting and auditing a quality management system in practice. At the same time I would like to invite readers of this book to send any comments on it, which I hope to use for the improvement of its next edition.

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2. The concept of the project

The course consists of two clearly separated parts: the first part focused on QMS documenting and the second focused on conducting an internal audit of QMS.

The aim of the first part of the course is stated as mastering by students the essential practical skills in the scope of analysis, design and preparation of elements of a quality management system's documentation according to universal ISO series 9000 standards, on the base of proper understanding and interpretation of ISO 9001 standard's requirements regarding documents and records. Because such skills are necessary both for preparing QMS documentation and auditing QMS, a special emphasis on practice was placed in this part.

It was presumed that the primary role in the successful mastery of these skills will be played by the project, mentioned in the title of the chapter and in the title of the textbook. For the mentioned reason it is assumed that the project must cover virtually the whole of a quality management system for a chosen organization to draw attention to the need of maintaining the integrity of its system. Since the time for this project is strictly limited, the only reasonable solution is to plan its development within the group-work of students for any 'established' micro-enterprise, employing less than 10 employees and leading very, very simple production. Therefore, these conditions were imposed on the project realized by students.

The micro-enterprise documents, developed as the project by one group of students during the first part of the course, will play the role of the original QMS documentation for other group of students in the second part of the course (based on generally accepted models of training for QMS auditors), where in the conditions of simulated organizational situations students are familiarised in a necessary scope with practical aspects of planning, conducting and documenting internal quality management systems' audits according to ISO 9001 and ISO 19011.

While developing the project students spend most of the time working directly with the text of ISO 9001:2008 standard, therefore they have to own an original copy of it.

3. Avoiding misunderstandings and misconceptions

To carry out any project related to a quality management system of an organization, it is important to identify and clarify such word definitions and concepts, which used by people involved in this system may lead to misunderstandings and misconceptions, hindering communication in the project and badly affecting the results achieved in it. At the beginning let's discuss briefly what we mean by the concepts of 'quality management', 'continual' and 'ISO'.

3.1. Quality management – what does it mean?

It seems that the concept of 'quality management' as well as the very concept of quality can be variously understood. What's more, standardized definition of quality management directly formulated in the international standard ISO 9000 as 'coordinated actions to direct and control the organization with regards to the quality' seems to be hardly understandable for people (especially those for whom English is not their native language) as too condensed. In this situation a good solution is to promote an expanded definition of quality management in its much clearer and more useful interpretation shown in Fig.1. That is how quality management should be understood throughout this publication.

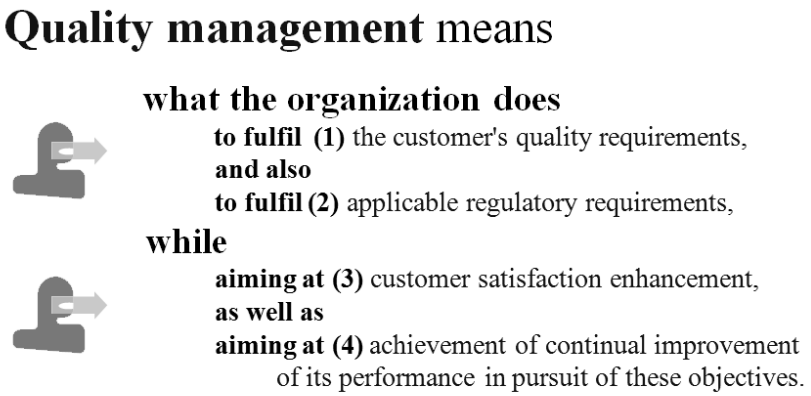


Fig. 1 Useful interpretation of the 'quality management' term.
Source: Adapted from [Frost R., 2009; ISO, 2010a; ISO 9001:2008]

3.2. Continual - what does it mean?

An important aspect of quality management is called continual improvement (see Fig 1) However, as it was observed for example in Poland, the term 'continual' may be wrongly identified with the notion of ‘continuous’ by some people (especially those for whom English is not their native language). Fig. 2 presents an existing difference in meanings of these two mentioned terms and helps to understand that ‘continual improvement’ is an improvement realized on the way of different but repeated activities, which need not be uninterrupted at all.

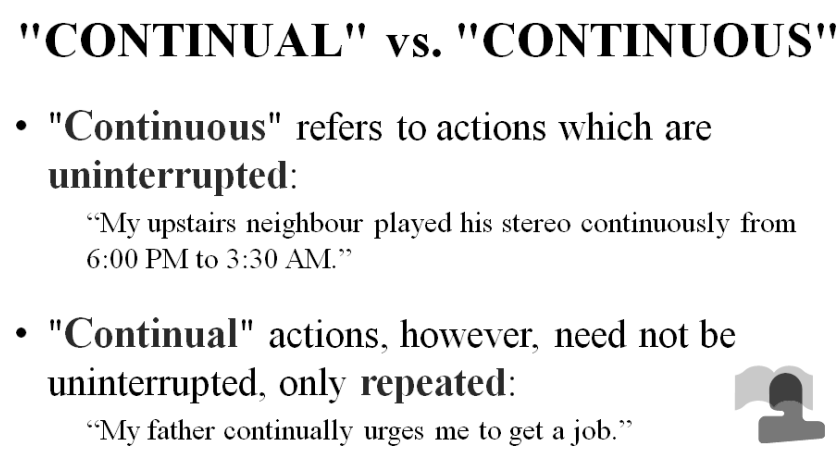


Fig. 2 ‘Continual’ and ‘continuous’ - difference in meaning.
Source: Adapted from [Brians P., 2008]

3.3. ISO – what does it mean?

When working with people performing different functions at different levels of the organization, it is important to clarify what people think when they say ‘ISO’. In my opinion, you can meet the following meanings of ‘ISO’, used in practice by people:

- ISO as the short form of the name of „International Organization for Standardization”, the world’s largest developer and publisher of standards,
- ISO as a prefix, starting an individual „reference number” for every of over 18 000 international standards developed and published by International Organization for Standardization (e.g. ISO 68-1:1998, ISO 1501:2009, ISO 19011:2002),
- ISO as an abbreviation, commonly and incorrectly used to denote standards concerning a quality management system - such as ISO 9000, ISO 9001, ISO 9004 and ISO 19011 from the ISO 9000 family - issued by the International Organization for Standardization (e.g.: “Do you use ISO ?”),

– ISO as an abbreviation, commonly and incorrectly used to denote an existence of the organization's quality management system consistent with ISO 9001 standard (e.g.: "Does your organization have ISO ?").

The first two meanings of properly used 'ISO' are presented on the website of the International Organization for Standardization, the next two meanings of incorrectly used 'ISO' have been shown on the example of Poland [Sujak-Cyrul B., 2005b]. In the remainder of this textbook you will meet only the two correct usages of 'ISO'.

4. Quality management systems according to the standards of ISO 9000 family

4.1. The origins of standardized quality management systems

The operational quality management has roots in the principles and rules presented in the works of authors such as: K. Adamiecki, F. W. Taylor, H. Fayol, M. Weber, A. Shewhart, and after the Second World War in achievements and philosophy of such quality gurus as: E. W. Deming, A. V. Feigenbaum, J. M. Juran, K. Ishikawa, G. Taguchi [Skrzypek E., 2000, p. 95-96; Lisiecka K., 2002, p. 153].

Having place in the 20th century, the dissemination of notion that many interrelated and interacting factors, both technical and managerial (organizational), present at all stages of product creation (from determining requirements for product and its design phase, through purchases of raw materials/components used in the production, to the proper manufacture and supply of the product as well as its maintenance after delivery) have a significant influence on the quality of the final product, in the end has resulted in attempts to create, in this regard, uniform standards for suppliers primarily intended for use in a contractual situation.

Among the first standards that reflect a system approach to manufacturing to ensure product quality (see e.g. [Nixon F., 1971; Drummond H., 1992; Zymonik J., 1995; Dahlgaard J., Kristensen K., Kanji G., 1998; Łańcucki J., 2003; Konarzewska-Gubała E., 2003; Urbaniak M., 2004; Hoyle D., 2006]) there are the following ones developed and published in the twentieth century:

- in the fifties in the U.S. - for suppliers of NATO defense industry (the first versions of AQAP standards, which have been subsequently improved and are applied to the present day),
- in the early seventies in the U.S. – for nuclear energy providers,
- in the seventies in the U.K - for companies introducing quality assurance systems (these were subsequently BS 4891, BS 5179 and BS5750),
- in 1986 and 1987 by the International Organization for Standardization (ISO) – the first international standards focused on organizational issues in general and addressed to companies of any type, implementing quality assurance systems; the draft standards were developed on the basis of the above-mentioned BS5750 standard by the Technical Committee ISO/TC 176 and adopted as international standards on the basis of general consensus among national standard bodies belonging to the ISO, what initiated the ISO 9000 family of standards.

Contemporary quality management systems can be based on different normative and/or legal regulations, with different coverage (national, regional or international) and different purpose (for suppliers to the specific customer, for businesses/ organizations within the specific sector of industry/activity or for universal application by any organization).

However, the ISO 9000 family, especially the ISO 9001 standard, is the most widely spread in the world as the universal basis for design, implementation, certification, maintenance and improvement of quality management systems (QMS) in organizations of any type and size, operating in any sector of activity, and that is why we focus attention on it in our study.

4.2. The ISO 9000 family of standards

Since 1986, or rather 1987, International Standards of the ISO 9000 family have been developed, published (after approval on the basis of general consensus among national standard bodies belonging to the ISO), periodically reviewed and, when necessary, updated or withdrawn by International Organization for Standardization in accordance with general principles of normalization (see e.g. [Ashton T., 1994; Urbaniak M., 2004; ISO, 2011]).

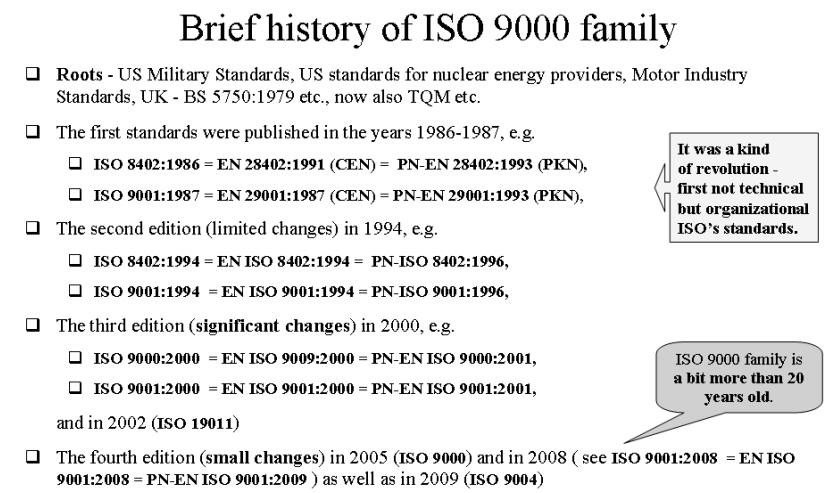


Fig. 3 A brief history of the ISO 9000 family of standards, presented for exemplary standards and their international, European as well as Polish editions.
Source: Own study based on [ISO, 2010; PKN, 2010; Bureau Veritas, 2008; Hoyle D., 2006, etc.]

The most important - from the European point of view - standards of the broadly defined ISO 9000 family are approved and published without any changes by the European Committee for Standardization (CEN, fr. Comité Européen de Normalisation) as European Standards. Therefore, standards of the ISO 9000 family released in Europe as national standards, can be seen as transposition of European Standards (with a prefix containing '-EN ISO') or transposition of International Standards (with a prefix containing 'ISO'). But when released in the form of national standards by national standardization organizations, such as for example:

- AENOR, Asociación Española de Normalización y Certificación – Spanish Association for Standardization and Certification, operating in Spain,
- AFNOR, Association française de Normalisation – The French standards association, operating in France,

- ASI, Österreichisches Normungsinstitut – Austrian Standards Institute, operating in Austria,
- BSI, British Standards Institute Group, operating in the UK,
- DIN, Deutsches Institut für Normung e.V. – the German Institute for Standardization, operating in Germany,
- PKN, Polski Komitet Normalizacyjny – Polish Standardization Committee, operating in Poland,
- SIS, Swedish Standards Institute, operating in Sweden,
- UNI, Ente Nazionale Italiano di Unificazione – Italian Organization for Standardization, operating in Italy,

the standards are supposed to be introduced into the everyday business and non-business practices in individual countries. It should be emphasized that applying these standards in organizations is voluntary.

A brief history of the ISO 9000 family of standards, presented for exemplary standards and their international, European as well as Polish editions, is shown in Fig. 3. It should be emphasized that one of the changes introduced to the standards of ISO 9000 family in the year 2000 was the change of the name "quality assurance system" to "quality management system" to make strong point that the purpose of this system is providing good quality of product as well as ensuring growth of customer satisfaction.

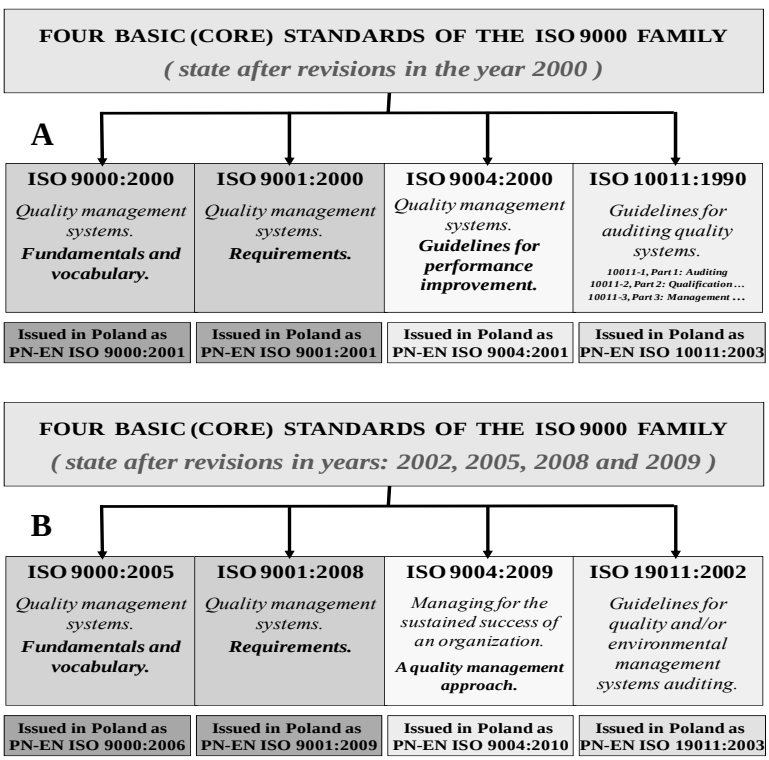


Fig. 4 Four basic (core) standards of the ISO 9000 family – comparison of states (A) after revisions in the year 2000 and (B) after revisions in years: 2002, 2005, 2008 and 2009.
Source: Own study based on [PKN, 2001; ISO, 2002; ISO 9000:2005; PKN, 2006; ISO, 2006; ISO, 2010; PKN, 2010] and the standards referred in the figure

After significant changes in 2000, partial changes in 2002, slight changes in 2005 and 2008 as well as additional partial changes in 2009, **the broadly defined ISO 9000 family of standards consists of four basic (core) standards and also additional standards, technical specifications and technical reports** which are to support the basic standards and to provide guidance on specific matters related to the issues of quality management system [PKN, 2001; ISO, 2002; PKN, 2006; ISO 2006; ISO, 2009].

As shown in Fig. 4 and described below (based on the information contained in [ISO 9000:2000; PKN, 2001; ISO, 2002; ISO 9000:2005; PKN, 2006; ISO, 2006; ISO, 2009; Hoyle D., 2009; Robitaille D., 2010] and the standards referred below)**, the set of four basic (core) standards of ISO 9000 family includes**:

- **ISO 9000:2005 Quality management system – Fundamentals and vocabulary**
  It is the third edition of ISO 9000 standard,
  adopted as the European Standard EN ISO 9000:2005,
  also transposed to the Polish Standard:
  PN-EN ISO 9000:2006 *Systemy zarządzania jakością – Podstawy i terminologia*.

  Serving as **an introduction to the rest of the ISO 9000 family standards** (applicable to both the broad and narrow definition of the family), the ISO 9000:2005 standard defines and describes fundamentals of quality management systems and sets basic terminology related to these systems. Without knowledge about the quality management system fundamentals and associated vocabulary, proper understanding of the content of other standards of the ISO 9000 family is very difficult and at times impossible.

  In comparison to the superseded ISO 9000:2000, this standard introduces only minor changes in terminology, which are caused mainly by the need to unify the terminology and include terms relating to auditing and quality assurance for measurement processes, as defined in the published ISO 19011:2002 and ISO 10012:2003 standards.

- **ISO 9001:2008 Quality management systems – Requirements**,
  It is the fourth edition of ISO 9001 standard,
  adopted as the European standard EN ISO 9001:2008,
  also transposed to the Polish Standard:
  PN-EN ISO 9001:2009 *Systemy zarządzania jakością – Wymagania.*

  The ISO 9001:2008 standard specifies and describes **the basic requirements for quality management system in a way allowing their implementation in any organization** (regardless of its type, size, products and sector of activities), which wants to demonstrate its ability to provide products (also: services) that meet customer and applicable legal requirements, and which is interested in increasing customer satisfaction. What's more, implemented **quality management systems can be certified against requirements of this standard by an independent certification body.** Generally speaking, this standard is intended to be used for contractual and assessment purpose.

In comparison to the superseded ISO 9001:2000, this standard defines no new requirements but only introduces clarifications to the existing requirements and some changes improving consistency with ISO 14001:2004 (requirements for environmental management systems).

- **ISO 9004:2009 Managing for the sustained success of an organization – A quality management approach,**
  It is the second edition of ISO 9004 standard,
  adopted as the European standard EN ISO 9004:2000,
  also transposed to the Polish Standard:
  PN-EN ISO 9004:2010 *Zarządzanie ukierunkowane na trwały sukces organizacji – Podejście wykorzystujące zarządzanie jakością*

  The ISO 9004:2009 standard specifies and describes **guidelines on supporting the achievement of sustained success by a quality management approach, giving an extended model of a process-based quality management system** and emphasizing a particular role of performance improvement in the long-term purpose of any organization, understood as economic survival on the base of sustained success. But, generally speaking, this standard is not intended to be used for certification, contractual and regulatory purpose and also it is not a guide for ISO 9001 implementation.

  In comparison to the superseded ISO 9004:2000, the ISO 9004:2009 standard has demonstrably changed structure, contents, scope as well as its title: from "Quality management systems – Requirements " (ISO 9004:2000) to "Managing for the sustained success of an organization – A quality management approach" (ISO 9004:2009). **New editions of ISO 9001 and ISO 9004 are no longer the consistent pair understood as having the same structure and partly the same text as it was in the earlier edition** (in ISO 9004:2000 the entire text of ISO 9001:2000 was embedded into the standard)**.**

- **ISO 19011:2002 Guidelines on Quality and/or Environmental Management Systems Auditing**,
  It is the first edition of ISO 19011 standard,
  adopted as the European standard EN ISO 19011:2002,
  also transposed to the Polish Standard:
  PN-EN ISO 19011:2003 *Wytyczne dotyczące auditowania systemów zarzadzania jakością i/lub zarządzania środowiskowego*.

  The ISO 19011:2002 standard, as stated at the beginning of its text, introduces basic principles for auditing and determines guidelines on managing the audit programmes, conducting **internal or external audits of quality management systems and/or environmental management systems** as well as competence and evaluation of auditors. It is allowed to use the guidelines also for other types of audits as well as to adapt or extend the guidelines for this purpose.

  The ISO 19011:2002 standard supersedes all previous standards concerning quality systems auditing (ISO 10011-1, ISO 10011-2 and ISO 10011-3 released

in 1994) and environmental auditing (ISO 14010, ISO 14011 and ISO 14012 standards released in 1998), consolidating their core elements in one document.

To conclude reflections on the set of basic (core) standards of ISO 9000 family, it should be noted that

- often **the concept of ISO 9000 family can be understood in two different ways**:
  - **narrowly**, as the 4 core standards [ISO 9000:2000; ISO 9000:2008]; or even only 3 of them – ISO 900X:200X [Hoyle D., 2006],
  - **or, conversely, much more broadly**, as all standards of the group 03.120.10: Quality management and quality assurance [ISO, 2010c];
- **ISO calls ISO 9001 a generic standard** [Frost R., 2009], because it can be applied to any organization:
  - large, medium, small or even micro,
  - whatever its products (goods or services) are,
  - operating in any sector of activity, private or public, and
  - whether it is a business enterprise, a non-profit organization, a public administration, or a government department,
- **ISO 9000, ISO 9004 and ISO 19011 are generic standards too**.

Now let's return to the matter of additional standards, technical specifications and technical reports which are to support the basic (core) standards of ISO 9000 family.

The Technical Committee ISO/TC 176 – as the subdivision of the International Organization for Standardization (ISO) responsible for standardizing works in the area of quality management and quality assurance – has considered supporting the basic standards of ISO 9000 family with additional standards and specifications and technical reports considering such aspects of quality management system as: reacting to customer complaints, quality plans, quality management in projects, configuration management, management of measurement process and measuring equipment, preparing documentation of quality management system, management of economical quality-related issues, training, different statistical methods related to ISO 9001, choosing consultants of quality management systems and using their services, detailed requirements concerning using ISO 9001:2008 in automotive industry, and so on, and so on.

These documents have a different history of subsequent releases. Some – e.g. such as these related to the system documenting or measurement management – in one or other version have already existed since 1990s. Others were issued for the first time in 2004, 2005 or 2007 – this applies for example to dealing with customer complaints or selecting the quality management system consultants and using their services. **The history of editions of these documents reflects the successive stages of development and improvement of quality management** as well as attaching increasing importance to the impact of the various organizational areas and specificity of the requirements related to these areas, to ensure product/service quality and increase in customer satisfaction.

A list of standards, technical specifications and technical reports supporting the basic standards of ISO 9000 family (state for the end of 2010) is presented in Table 1. More

current information about standards, technical specifications and technical reports supporting the basic standards can be found on the websites of ISO (www.iso.org),CEN (www.cen.eu) and national standard bodies e.g. PKN (www.pkn.pl).

To ensure clarity and generality of reflections in the next part of the chapter, since now **we will use the term 'ISO 9000 family' only to describe the set of current editions of four basic (core) standards: ISO 9000, ISO 9001, ISO 9004 and ISO 19011** (Fig.4). This approach is consistent with the recognition of the concept of the ISO 9000 family, contained in ISO 9000:2005 and its earlier edition from 2000, as well as with the practice observed in many companies.

Table 1 Examples of ISO 9000 family guidelines/supporting standards

Reference number	Guidelines/supporting standard title
ISO 10001:2007	Quality management -- **Customer satisfaction** -- Guidelines for codes of conduct for organizations
ISO 10002:2004	Quality management -- **Customer satisfaction** -- Guidelines for complaints handling in organizations
ISO 10003:2007	Quality management -- **Customer satisfaction** -- Guidelines for dispute resolution external to organizations
ISO/TS 10004:2010	Quality management -- **Customer satisfaction** -- Guidelines for monitoring and measuring
ISO 10005:2005	Quality management systems -- Guidelines for **quality plans**
ISO 10006:2003	Quality management systems -- Guidelines for **quality management in projects**
ISO 10007:2003	Quality management systems -- Guidelines for **configuration management**
ISO 10012:2003	Measurement management systems -- Requirements for **measurement processes and measuring equipment**
ISO/TR 10013:2001	Guidelines for **quality management system documentation**
ISO 10014:2006	Quality management -- Guidelines for realizing **financial and economic benefits**
ISO 10015:1999	Quality management -- Guidelines for **training**
ISO/TR 10017:2003	Guidance on **statistical techniques** for ISO 9001:2000
ISO 10019:2005	Guidelines for the selection of **quality management system consultants** and use of their services

Legend: TR – Technical Report, TS – Technical Specification
Sources of data: [ISO, 2009; ISO, 2010b]

4.3. Standardized quality management systems and quality culture

Building on the basic definition of culture ("culture is everything that people do, think and have as members of the community" [Biersted R., 1963, p.129]) and the ISO 9000 terminology, we can assume that "**the culture of quality** is everything what people do,

think and have as members of the community - at various levels of its organization and in different social roles – in order for the products, processes and systems to meet the customer's needs and expectations, which have been established by custom or are obligatory" (def. quoted by [Bugdol M., 2003, p.104,109] in the modified version given in [Sujak-Cyrul B., 2005a, p.209]).

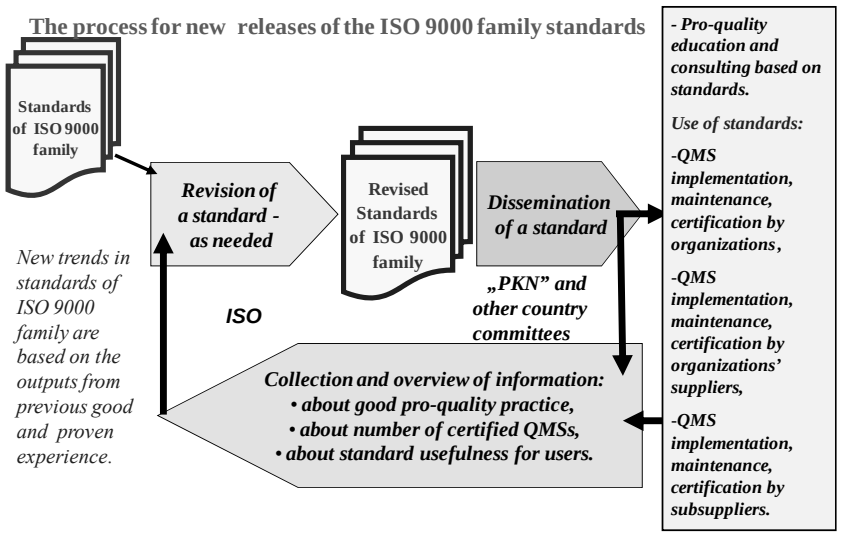


Fig. 5 Standardized quality management systems should be treated as an output and as a source of quality culture.
Source: [Sujak-Cyrul B., 2005a]

Standardized quality management systems, as described in the standards of ISO 9000 family, should certainly be treated as an output of quality culture and as a source of it on a global scale (Fig. 5). In accordance with generally accepted rules of international standardization, treatment of the issues of quality management in the standards and changes subsequently introduced into them is always based on the previously worked out and proven achievements in the form of good business practices (good organizational practices), as well as reflects the growing knowledge in this field. 'New trends' in quality management, before they are reflected in the standards of ISO 9000 family, for a longer time must be used and recognized by many business/quality practitioners as recommendable practices. Like all ISO standards, **every one of the ISO 9000 family is subject to periodic review** performed every 5-6 years **to determine the suitability, adequacy and effectiveness of this standard** in achieving the stated quality management goals. Standards of the ISO 9000 family can be under periodic review process either all together at the same time (as in the case of the year 2000 revision) or each of them separately, at different times. Each periodic review of the ISO 9000 family standards begins with collecting and reviewing information about good quality management practices (good business practices), number of systems certified for compliance with ISO 9001 in the world (which is unique to ISO management standards) and about the suitability of those standards to their direct users (mainly organizations implementing, maintaining and improving systems compatible with ISO 9001 as well as their institutional customers and providers).

On this basis, conclusions are drawn in the form of preliminary findings, stating whether and to what extent, the ISO 9000 family standards should be changed. The final wording of the revised standard comes up through team work and multilateral international **consensus**, i.e. the overall agreement - which is characterized by the absence of sustained opposition to substantial parts of interest in relation to important issues - made in the process of examining the views of all concerned and to reconcile opposing views (consensus definition from [ISO/IEC, 2009]). **Simply saying the same thing – the final shape of the revision of standards is an effect of group work and multilateral international consensus about all crucial elements of those standards**. [Ashton T., 1994; Urbaniak M., 2004; Sujak-Cyrul B., 2005a; Sujak-Cyrul B., 2005b, ISO/IEC, 2009; ISO, 2011; etc.]

Final publication in the form of the international standard of ISO 9000 family requires approval of at least 75% of ISO members taking part in the voting [ISO 9000:2000; ISO 9001:2000; ISO 9004:2000]. Knowing that the ISO is a worldwide federation of 157 national standard bodies (ISO member organizations), representing in total 157 different countries [ISO, 2006b] of about 220 existing in the world, we can say that consensus gained about the contents of the ISO 9000 family standards has indeed **a global dimension.**

Each edition of the ISO 9000 family standards - mainly through the implementation, maintenance and improvement of the quality management systems acc. ISO 9001 in miscellaneous organizations (not only in typical manufacturing and service enterprises) and through the training system relevant to it - has become the source of dissemination and perpetuation of good solutions in practice, in the field of organizational requirements being important for quality of manufactured products and provided services.

A reliable confirmation of a quality management system implementation in an organization is a certificate of its system's compliance with the requirements specified in the ISO 9001 standard, obtained from an independent and competent certification body on the base of positive results of carried out examination of the system (third-part audit, also called a certification audit). Data of the International Organization for Standardization [ISO, 2005] show **a sharp increase in the number of certified quality management systems in 2001-2005 - from 44 388 certificates in 97 countries to 776 608 in 161 countries in the world, from 22 867 to 379 937 certificates in Europe and from 232 to 9718 certificates in Poland.**

The role of stimulators of quality management systems diffusion is played by customer requirements, including the largest corporations in the world [Karaszewski R., 2001] and placed in different parts of the world's legal and normative solutions – e.g. according to the Directives of New Approach to technical harmonization and national legislation implementing them, each manufacturer is obligated to affix the **CE conformity marking** on specified new products (introduced to European Union market) and coming for CE conformity mark through so called modules E or D or H, must operate under the certified quality management system compliance with the ISO 9001.

Some production or service sectors (e.g. automotive, aircraft, telecommunications, medical devices, food production) in order to reflect their specificity need to expand requirements for quality management system, resulting in the publishing of **sector standards** including detailed requirements for the application of ISO 9001 in those sectors – and these standards

are included for sectoral thematic areas more frequently than for the broadly understood ISO 9000 family of standards (see Table 2).

Table 2 Examples of ISO's standards and CEN's standards adapting the generic management system approach or even all ISO 9001 requirements to specific sectors or aspects

Sector/ aspect	Standard
Automotive	**ISO/TS 16949:2009** Quality management systems -- Particular requirements for the application of **ISO 9001:2008** for automotive production and relevant service part organizations
Education	**IWA 2:2007** Quality management systems -- Guidelines for the application of **ISO 9001:2000** in education
Food safety	**ISO 22000:2005** Food safety management systems -- Requirements for any organization in the food chain
Information security	**ISO/IEC 27001:2010** Information technology -- Security techniques -- Information security management system implementation guidance
Health care	**IWA 1:2005** Quality management systems -- Guidelines for process improvements in health service organizations
Local government	**IWA 4:2009** Quality management systems -- Guidelines for the application of **ISO 9001:2008** in local government
Medical devices	**ISO 13485:2003** Medical devices -- Quality management systems -- Requirements for regulatory purposes
Petroleum and gas	**ISO/TS 29001:2007** Petroleum, petrochemical and natural gas industries -- Sector-specific quality management systems -- Requirements for product and service supply organizations
Risk	**ISO 31000:2009** Risk management – Principles and guidelines
Ship recycling	**ISO 30000:2009** Ships and marine technology -- Ship recycling management systems – Specifications for management systems for safe and environmentally sound ship recycling facilities
Supply chain security	**ISO 28000:2007** Specification for security management systems for the supply chain
Aerospace	**EN 9111:2005** Aerospace series - Quality management systems - Assessment applicable to maintenance organizations (based on ISO 9001:2000)
	EN 9101:2008 Aerospace series - Quality management systems - Assessment (based on ISO 9001:2000)
	EN 9121:2009 Aerospace series - Quality management systems - Assessment applicable to stockist distributors (based on ISO 9001:2000)
Transport	**EN 12507:2005** Transportation services - Guidance notes on the application of EN ISO 9001:2000 to the road transportation, storage, distribution and railway goods industries
	EN 12798:2007 Transport Quality Management System - Road, Rail and Inland navigation transport - Quality management system requirements to supplement EN ISO 9001 for the transport of dangerous goods with regard to safety

Legend: TS – Technical Specification, IWA – International Workshop Agreement, EN – European Standard
Sources of data: [ISO, 2010b; ISO, 2010d; CEN, 2010]

At the same time terminology and organizational requirements established in the ISO 9000 family have turn out to be so useful and universal that many of these items were directly used in the creation of related standards compatible with ISO 9001 and defining **other important management systems**, e.g. an environmental management system (see details in ISO 14001:2004 or PN-EN ISO 14001:2005) or an occupational health and safety management system (see details in Polish Standard PN-N-18001:2004, also consistent with the document ILO-OSH 2001 developed by International Labour Organization).

After the year 2000 the universality of application of ISO 9001 as well as industrial sector standards compliant with ISO 9001 and related standards compatible with ISO 9001 allows to recognize ISO 9001 as a **global standard** [Corbett C., Luca A., Pan J., 2003]. The ISO 9001 standard has positive meaning in globalization process and plays an important role:

- in facilitation of global trade,
- in development of global supply chains compliant with the unified organizational requirements to provide quality assurance of the quality of products and services,
- in the dissemination of good quality management practices in developing countries, as well as
- in establishing good normative basis for legislation/ regulations.

The ISO 9001 standard has also a significant **impact on the labour market**. Basing on the example of Polish labor market, it can be said [Sujak-Cyrul B., 2005b; Sujak-Cyrul B., 2006] that ISO 9001 is a generator of new professions (e.g. management representative for quality system, quality engineer, auditor, quality management consultant) as well as a factor modifying requirements for traditional professions (e.g. knowledge of ISO 9001, ability to conduct an internal audit, ability to conduct corrective actions, knowledge of quality improvement tools such as: SPC, FMEA, QFD, DoE, 8D), which - among other things - finds reflection in job advertisements. At the same time it is noticed, that number of organizations maintaining certified quality management systems conformed to ISO 9001 is visibly diverse in individual regions of Poland [Rogala P., Brzozowski T., Skowron P., 2005].

4.4. Basic principles and concepts used in quality management systems according to ISO 9000 family of standards

4.4.1. Eight quality management principles

Since the revision of the ISO 9000 family standards in 2000, the eight principles of quality management have become their foundation. The quality management principles – (1) customer focus, (2) leadership, (3) involvement of people, (4) process approach, (5) system approach to management, (6) continual improvement, (7) factual approach to decision making, (8) mutually beneficial supplier relationships – have been cited in the introduction to ISO 9000 and repeated in ISO 9004 in the version presented on Fig. 6.

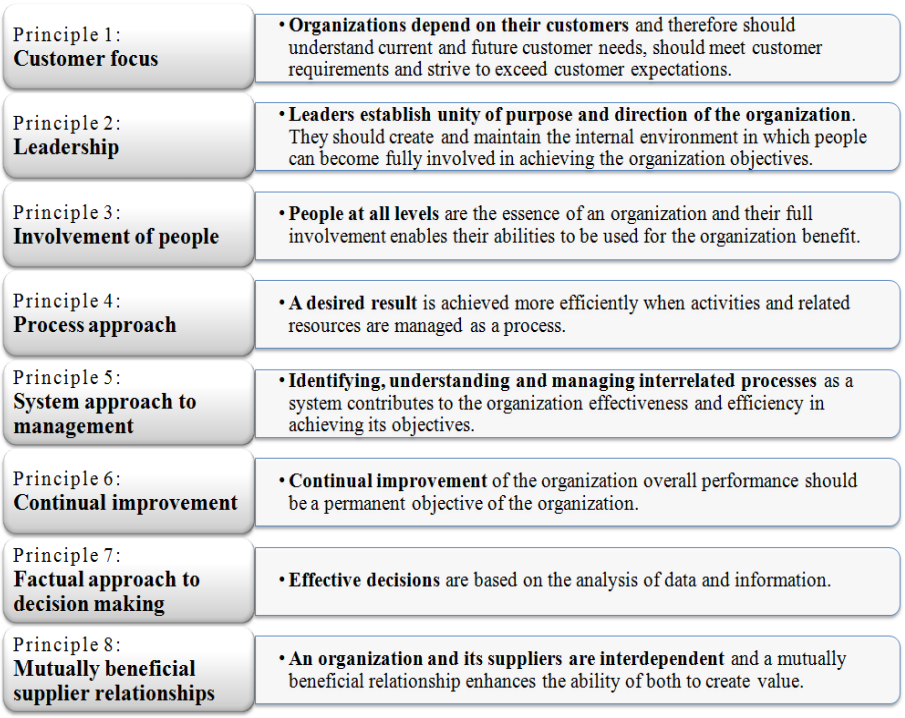


Fig. 6 Eight principles of quality management – overview.
Source: Adapted from [ISO 9000:2000; PN EN IS0 9000:2001; ISO 9004:2000; PN EN ISO 9004:2001; ISO 9000:2005; PN EN IS0 9000:2006; ISO 9004:2009; PN EN ISO 9004:2010]

The above-mentioned quality management principles are a transposition of TQM (Total Quality Management) philosophy to the ISO 9000 family of standards. As explicitly stated in ISO 9000 and ISO 9004, the application of these principles in managing the organization allows managers to manage it in a systematic and clear way as well as make the organization successful. The possible benefits, resulting from the successful application of eight quality management principles, include e.g. visible improvements in the functioning of the organization, focus on value creation, profit growth and increased financial stability of the organization (you can find more about such benefits in [ISO, 2001; PKN, 2001]). Therefore, the base, requirements and guidelines for improvement of the quality management system, described respectively in ISO 9000, ISO 9001 and ISO 9004 as well as ISO 19011, are grounded on these principles.

Table 3 shows the eight quality management principles' reflection in ISO 9001:2008 requirements, observed in clauses and sub-clauses of the standard. As you can see, the spirit of two principles – 'customer orientation' and 'systemic approach to management' - may be found in all major areas of requirements. The 'process approach' principle is clearly reflected in all key areas of requirements with the exception of the management and the 'continual improvement' and 'factual approach to decision making' principles - in appropriate areas of three of the five requirements. The concepts of the 'leadership' and 'commitment to the people' principles can be found in the areas of management

responsibility and resource management. The ‘mutually beneficial supplier relationships’ principle is clearly noticeable only in one area - the area of the product at the stage of purchasing.

The development of ISO 9001 on the ‘eight quality management’ ground brought the standard very close to the idea of TQM [Wawak S., 2002; Grudowski P., 2004] and ended a long lasting wave of criticism of the weakness of systems based on its earlier editions versus TQM.

Table 3 The 8 quality management principles’ reflection in ISO 9001:2000 requirements, observed in clauses and sub-clauses of the standard

QUALITY MANAGEMENT PRINCIPLES (QMPs)		THE 8 QMPs REFLECTION IN ISO 9001:2008 REQUIREMENTS, OBSERVED IN THE SELECTED CLAUSE *:				
		Clause 4 Quality management system	**Clause 5** Management responsibility	**Clause 6** Resource management	**Clause 7** Product realization	**Clause 8** Measurement, analysis and improvement
1.	**Customer focus**	4.1; 4.2	5.1; 5.2; 5.3; 5.5.2; 5.6.1;	6.1	7.2; 7.5.4	8.2.1
2.	**Leadership**		5.1; 5.3; 5.4; 5.6.1;	6.1		
3.	**Involvement of people**		5.5.1; 5.5.3;	6.2		
4.	**Process approach**	4.1; 4.2	5.4.2		7.1; 7.3; 7.5.1; 7.5.2; 7.5.3; 7.5.5; 7.6	8.1; 8.2.3; 8.5.2; 8.5.3
5.	**System approach to management**	4.1; 4.2	5.3; 5.4.2; 5.5.1; 5.5.2;	6.1; 6.3; 6.4	7.4.2	8.1; 8.2.2
6.	**Continual improvement**	4.1; 4.2	5.3; 5.4; 5.6.1;			8.5.1
7.	**Factual approach to decision making**		5.4; 5.5.2; 5.6;		7.3.2; 7.3.4; 7.3.5; 7.3.6; 7.3.7; 7.4.1; 7.4.3; 7.5.2; 7.6	8.1; 8.2; 8.3; 8.4; 8.5.2; 8.5.3
8.	**Mutually beneficial supplier relationships**				7.4.1; 7.4.2	

* Note: The same relations have been observed for ISO 9001:2000 requirements
Source: Own study on content of standard ISO 9001:2000 and ISO:2008, compared with [Wiśniewska M., 2002]

4.4.2. PDCA cycle

The PDCA cycle is not explicitly mentioned by the ISO as the foundation of ISO 9000 standards, but it certainly should be regarded as such an element. Although the ISO 9001 standard in only one added note recalls that the PDCA cycle can be applied to all processes, a clear reflection of this cycle can be found in the wording of many requirements of the

standard. Therefore, the PDCA cycle and its role in continual improvement is reminded by Fig. 7.

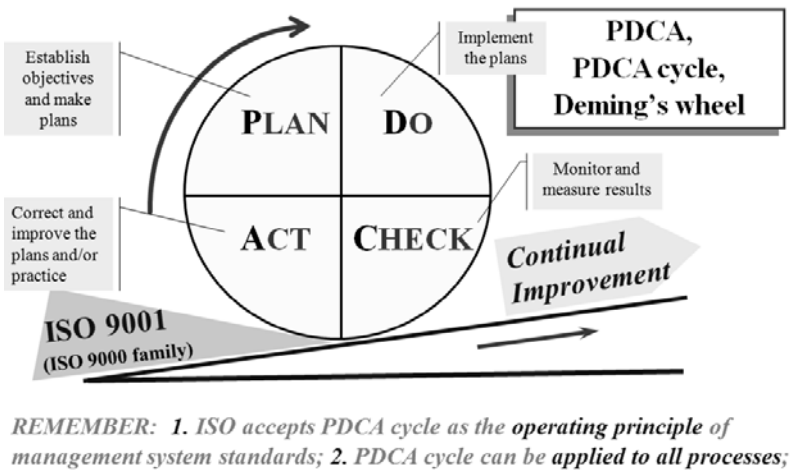


Fig. 7 PDCA cycle often show in literature.
Source: Adapted from literature on quality management

4.4.3. Model of a process-based quality management system

Basing on the assumption that every action which uses resources to enable transformation of inputs into outputs can be considered as a process (Fig. 8), the ISO 9000 family standards use phrase "process approach" to define a situation when there is the application of a system of processes within an organization, beginning from their identification and establishment of their interactions and finishing with managing them as systems of related processes.

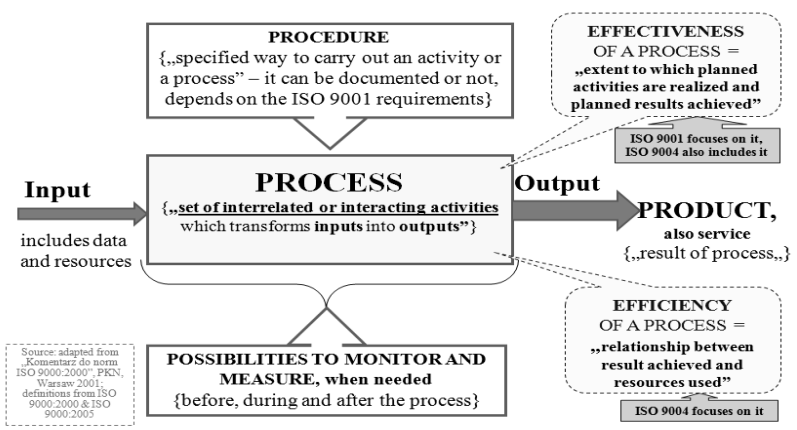


Fig. 8 Schematic presentation of the process concept
Source: Adapted from [PKN, 2001; ISO 9000:2000; ISO 9000:2005]

Fig. 9 shows the model of a quality management system based on processes, which is mentioned in ISO 9000 and described in detail in the ISO 9001. Graphical presentation of the model of a process-based quality management system, characterized in ISO 9000 and ISO 9001 in the process approach:

- universally and generally illustrates interrelations of four groups of processes occurring in an organization, which are called respectively: "Management responsibility", "Resource management", "Product realization", and "Measurement, analysis and improvement" (basic requirements concerning these processes have been specified in clauses 5, 6, 7 and 8 of ISO 9001 standard), and their importance for manufacturing a product which conforms requirements as well as their reflection in a group of processes called "Continual improvement of the quality management system" (general requirements and documentation requirements concerning the aforementioned system have been specified in clause 4 of ISO 9001 standard);
- and also shows that the customers and other interested parties are the main sources of: requirements concerning a product as well as the assessment of the degree of product compliance with these requirements.

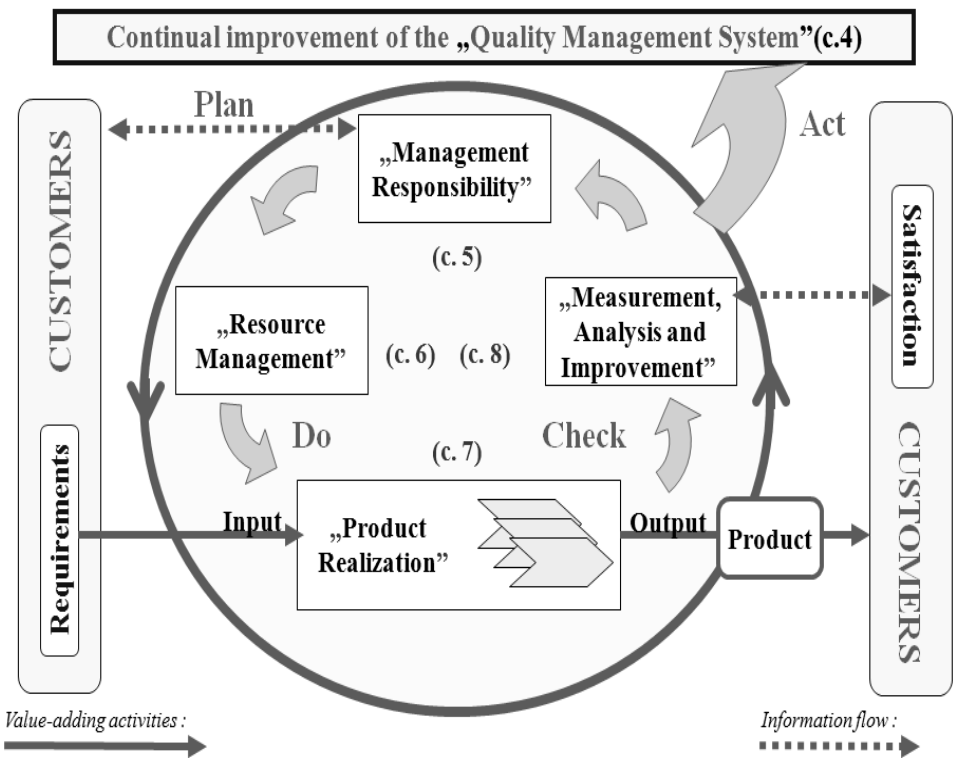


Fig. 9 Model of a process-based quality management system presented in ISO 9001:2000 and ISO 9001:2008 with notes referring to 5 major clauses of ISO 9001 and PDCA cycle.
Source: Adapted from [ISO 9001:2000; PN-EN ISO 9001:2001; ISO 9001:2008; PN-EN ISO 9001:2009; ISO, 2009]

It is said that the introduction of the process approach into ISO 9000 standards was one of the most important aspects of the revision carried out in 2000, that allows you to adjust the structure of quality management system to the actual processes taking place in the organization and is a departure from the frequent previous (for earlier editions of ISO 9001) practice - artificially adjusting the system to the structure of the standard's points [Campbell, I., 2001, PKN, 2001]

Using the model of quality management system based on processes, an organization can improve its system using also other additional standards, which support the ISO 9001 standard and provide guidance on specific matters related to the issues of a quality management system (Fig. 10).

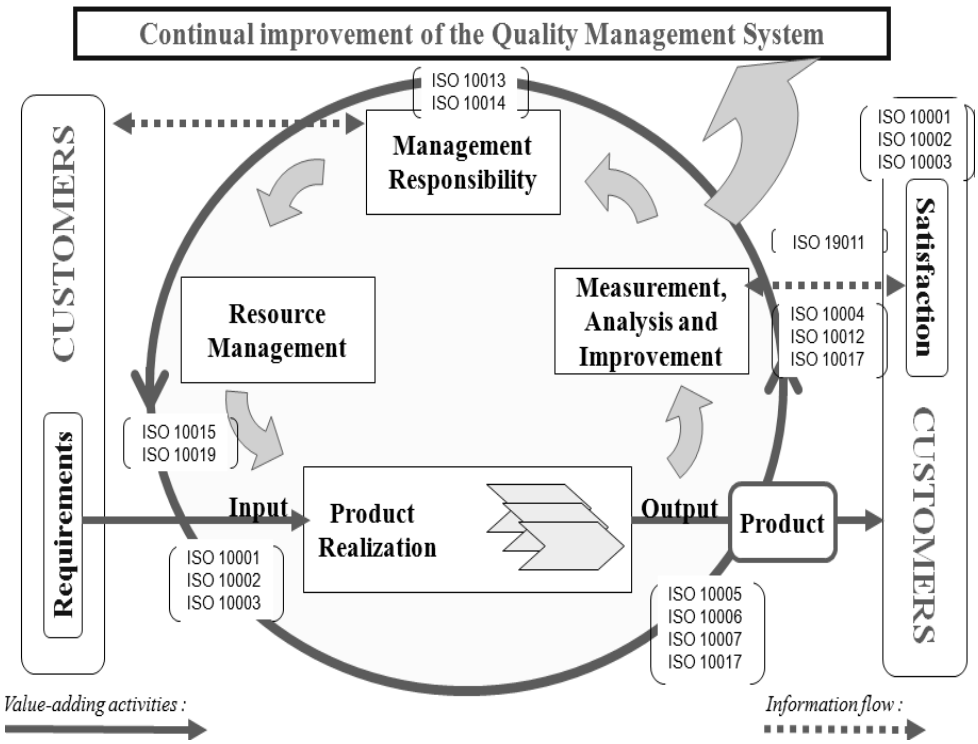


Fig. 10 Model of a process-based quality management system presented in ISO 9001:2000 and ISO 9001:2008 with ISO's suggestions referring to application of other guidelines/supporting standards.
Source: Adapted from [ISO 9001:2008; PN-EN ISO 9001:2009; ISO, 2009]

4.4.4. Basic terminological concepts

The ISO 9000:2005 standard defines about 80 terms, knowledge of which is needed to understand the requirements for quality management system and guidelines for its improvement. In Table 4 a few of them are quoted and discussed. They represent the minimum of terminological concepts essential for such systems.

Table 4 Chosen terminological concepts concerning quality management systems according to ISO 9000:2000 and ISO 9000:2005

Term	Term definition (acc. ISO 9000:2005)	Remarks
Quality	Degree to which a set of inherent characteristics fulfils requirements	Such a definition allows you to talk about the poor, good or excellent quality.
Requirement	Need or expectation that is stated, generally implied, or obligatory	Sources of requirements are primarily customer needs and expectations expressed in the agreement or contract, laws and regulations in force in the industry, as well as certain other conditions affecting the increase in customer satisfaction.
Characteristic	Distinguishing feature	There are different classes of characteristics: physical, sensory, behavioral, temporal, ergonomic, functional. Characteristic may be qualitative or quantitative.
Customer satisfaction	Customer's perception of the degree to which the customer's requirements have been fulfilled	The complaint lodged by the client clearly indicates a lack of satisfaction. However, lack of complaints does not necessarily mean a high level of satisfaction.
Process	Set of interrelated or interacting activities which transforms inputs into outputs	Please note that the entries to the processes are generally outputs of other processes.
Product	Result of a process	As outlined in the standard, the product may be a service, an intellectual product, material object, processed material , or their combination.
Procedure	Specified way to carry out an activity or a process	Remember that procedures can be documented (written) or undocumented.
Nonconformity	Non-fulfillment of a requirement	Non-compliance is a condition opposite to compliance, understood as the 'fulfillment of a requirement/ requirements'.
Defect	Non-fulfillment of a requirement related to an intended or specified use	Every defect is a nonconformity, but not every nonconformity is a defect.
Quality management system	Management system to direct and control an organization with regard to quality	A set of interrelated or interacting elements for establishing quality policy and quality objectives as well as for archiving these objectives, used to direct the organization and control it with regard to quality (this developed definition is taken from [Wawak S., 2002, p. 15])
Quality assurances	Part of quality management focused on providing confidence that quality requirements will be fulfilled	Element of the quality management system that helps create confidence that the requirements will be met (this developed definition is taken from [Wawak S., 2002, p. 15]).

Source: Adapted from [ISO 9000:2000; PN-EN ISO 9000:2001; ISO 9000:2005; PN-EN ISO 9000:2006, Wawak S., 2002]

4.5. Requirements for a quality management system set in ISO 9001:2008

In the sub-clause 1.1 of ISO 9001:2008 standard it has been declared that the standard specifies general requirements for a quality management system which are applicable to any type of organization which:

- wants to demonstrate its ability to provide a product compliant (also: a service compliant) with customer requirements and with applicable regulatory requirements (!), and
- aims to enhance customer satisfaction through effective application of the system, including processes for continual improvement of the system and assurance of conformity to requirements (of a customer as well as resulting from the applicable regulations).

These requirements have been contained in five clauses of the standard (Fig. 11) and concern respectively: Quality management system, Management responsibility, Resource management, Product realization, and Measurement, analysis and improvement. However, it should be noticed that requirements of ISO 9001 do not include (and never have) specified requirements concerning specific product but only requirements concerning organizational actions to ensure proper establishment of these requirements and their fulfillment by an organization.

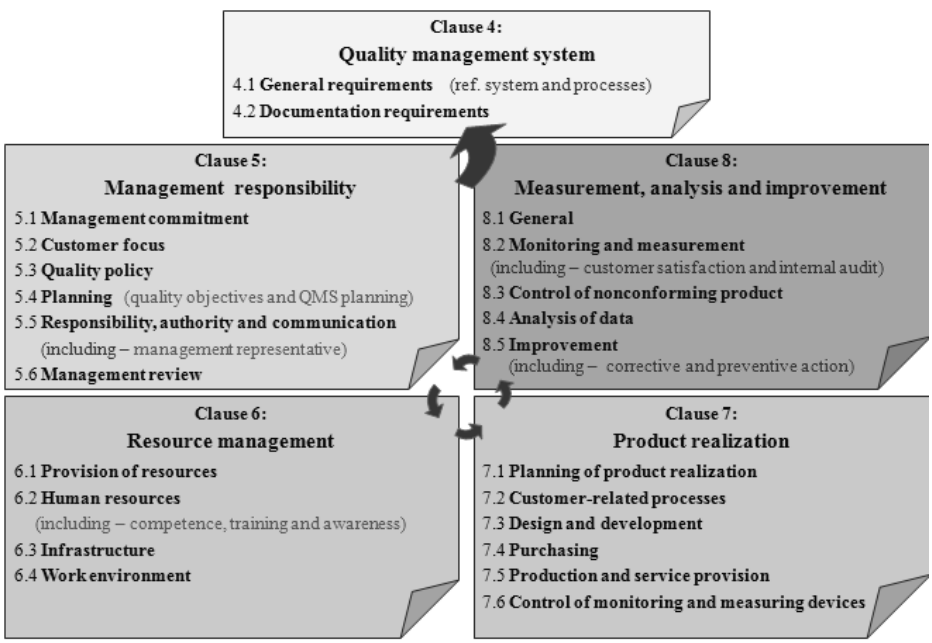


Fig. 11 The set of ISO 9001:2000/ ISO 9001:2008 requirements
Source: Adapted from [ISO 9001:2000; ISO 9001:2008; Wiśniewska M., 2002]

In the case where the nature of organization or its product prevents application of any requirements of ISO 9001:2008, the standard allows possibility of considering an exclusion of such requirement.

Nevertheless every situation such as:

- lack of justification of executed exclusions with a real situation, or
- exclusion of requirements from clauses other than clause 7 (Product realization), or
- influence of the exclusion on organization's ability to provide product compliant with customer requirements and with applicable regulatory requirements, or
- influence of the exclusion on organization's responsibility to provide such product,

prevents claims of quality management system conformity to ISO 9001 standard because of lack of the standard requirements fulfillment.

The following synthetic discussion of the basic requirements contained in individual main clauses of the standard is provided to allow readers to gain a general idea about the scope and structure of the requirements to be met by an organization wishing to have a quality management system compliant with ISO 9001:2008.

Those who wish to deepen their knowledge of these requirements, are referred by the author in particular to the ISO 9001 standard as the most original source (international or equivalent national version - see e.g. [PN-EN ISO 9001:2009]) and to interpretations of the ISO / TC 176 (its originals or national equivalents - see e.g. [ISO , 2002]) or interpretations of national standard bodies (see e.g. [PKN, 2001]), as well as to many discussions in literature referring to the practice of implementation of such systems (in Poland, see e.g. [Wawak S., 2002; Wiśniewska M., 2002; Łańcucki J., 2003; Grudowski P., 2004; Sokołowicz W., Srzednicki A., 2004; Urbaniak M., 2004], in the UK see e.g. [Hoyle, D., 2006]).

Anyone who directly establishes, implements, documents and maintains a quality management system complying with ISO 9001, should not confine oneself to this study and ought to work with the original ISO 9001 standard.

4.5.1. Requirements in clause 4 titled "Quality management system"

Clause 4 of ISO 9001:2008, titled "Quality Management System", includes two groups of requirements: the first, called **general requirements,** is referring to **a system and processes** while the second group, called **documentation requirements,** is referring to **general as well as more detailed requirements for various documents** needed in the system.

Specification of the requirements in clause 4 of the standard starts with a general statement that "**the organization shall establish, document and maintain a quality management**

system and **continually improve its effectiveness** in accordance with the requirements of this International Standard" (i.e. ISO 9001:2008).

According to the **process approach** assumed in the standard (see Chapter 4.4.3), **identified and properly managed organization processes** are the basis of the system of quality management**.** Therefore, the organization must first determine the processes necessary in the quality management system and their application throughout the organization (according to organization's specificity, its purpose, mission, goals etc.) as well as their sequence and interactions – taking into consideration processes for (1) management activities, (2) provision of resources, (3) product realization and (4) measurement. Once the relationship between processes is known, the organization must clearly define criteria and methods necessary to ensure effective operation of the processes and their effective control. The availability of resources (personnel and means) and information (documents/records when required), needed to operate and control these processes, also must be ensured by the organization. The standard requires the organization to implement actions necessary to achieve planned results of the processes and the actions aiming at their continual improvement. Additionally, the organization shall identify, define and ensure control over any process outsourced to operation, if the process affects conformity of the organization's product to requirements. Finally, management of all the processes, identified as necessary in quality management system, must be carried out by the organization in accordance with all the requirements contained in all clauses of ISO 9001 – the above-mentioned general requirements for processes, in some instances duplicated in other clauses of the standard, are only part of them.

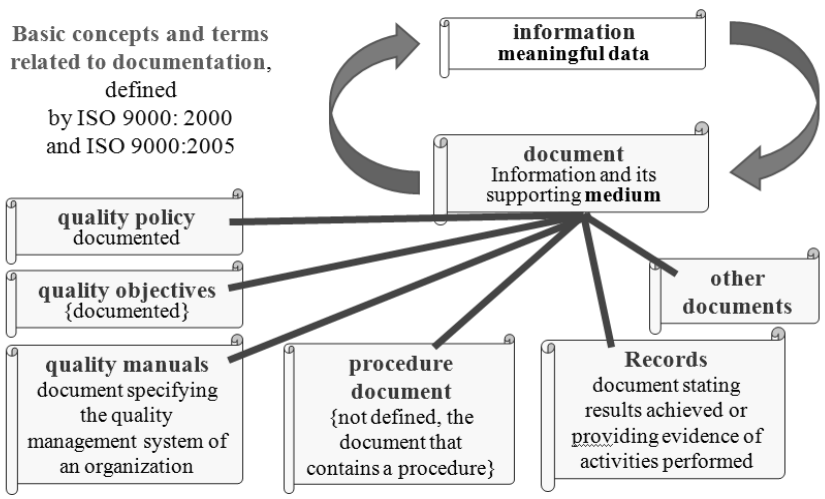


Fig. 12 Basic concepts and terms related to documentation.
Source: Adapted from [ISO 9001:2000; PN-EN ISO 9001:2001; ISO 9000:2005; PN-EN ISO 9000:2006]

According to ISO 9001 the organization shall document its system of quality management in a degree indispensable "to prove efficient planning, operation, control, and continual improvement of the quality management system and its process" (see guidelines concerning system documentation [ISO/TR 10013:2001]). **The indispensable system documentation shall include four required groups of documents:** (1) documented statements of **quality policy** and **quality objectives,** (2) **a quality manual,** (3) **documented procedures and records required directly** by ISO 9001 standard, as well as (4) **documents, including records, necessary for the organization** to ensure effective planning, operation and control of its **processes**.

To better understand the above-mentioned overall documentation requirement you are referred to study basic concepts and terms related to documentation included in ISO 9000 and, to begin with, see Fig. 12.

Scope, form and media of the quality management system documentation may be diverse in particular organizations, depending on the organization size, type of activities, complexity of realized processes as well as competence of personnel. This shall ensure the organization an unconstrained choice of the way the system is documented and enable adjusting the scope, form and documentation media to the particular requirements of the organization.

In the comment defining the term of "**documented procedure**" mentioned in the standard, the concept is considered as "the procedure which is established, documented, implemented and maintained". According to the provisions included in six different sub-clauses of ISO 9001 – "documented procedure" is required only for (1) control of documents, (2) control of records, (3) control of nonconforming product, (4) internal audit, (5) corrective action and (6) preventive action. Of course it does not mean that each of the required documented procedures must be written only in the form of an individual document or that an individual document must cover only the content of one required documented procedure.

Additional requirements concern **establishing and maintaining** by the organization **a quality manual,** which shall obligatorily include the following items:

- information about the scope of the quality management system including the details about any exclusions (with regard to clause 7 of the standard, when applicable due to the range of organization's activity) with their justification,
- documented procedures of the quality management system or appropriate references,
- a description of interactions and relations between the processes of quality management system (in practice often illustrated by a map of processes, which actually is not mentioned in the standard directly).

The organization has to **control the system documentation** whereby the **scope** of required **control** is **partly different for the documents and records** which are a special kind of documents (Fig. 13) made and stored in order to provide evidence of conformity to requirements as well as evidence of effective operation of the systems (detailed requirements concerning the range of records appear in many sub-clauses of ISO 9001 standard).

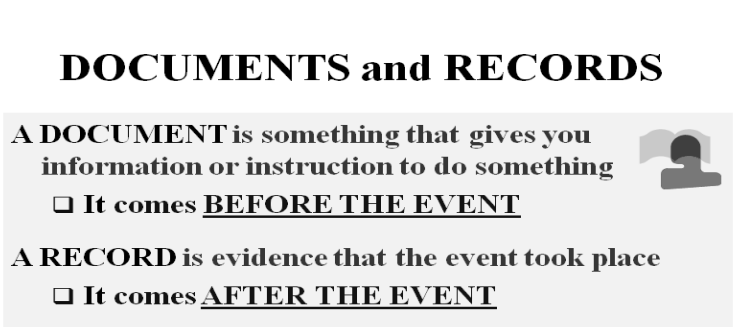


Fig. 13 'Document' and 'record' – difference in meaning.
Source: Adapted from [CQ ITI, 2009]

Generally, all documents and records have to be legible and readily identifiable. In order to ensure appropriate control of documentation, the organization shall establish:

- **Documented procedure of documents control** which shall regulate: (1) approving of documents for their adequacy (before forwarding to use), (2) review of documents and – where necessary – updating and re-approval, (3) ensuring that the changes and the current revision status of the document are easy to identify, (4) ensuring availability of current versions of the documents at points of their use, (5) ensuring that the documents stay legible and readily identifiable, (6) ensuring that the documents of external origin – determined as necessary for the organization – are identified and their distribution is controlled, (7) preventing an accidental use of obsolete documents or documents invalid for any reasons and applying suitable identification to them if they are retained for any purpose.
- **Documented procedure of records control** which shall regulate: unambiguous identification, secure storage, easy and fast lookup, appropriate protection, retention of records for a particular period of time, availability of records.

4.5.2. Requirements in clause 5 titled "Management responsibility"

Effective and profitable quality management system can be established, operated and developed only **under the condition of top management commitment,** in the way evident for the personnel. For this reason, the top management shall **provide evidence** of their personal **involvement in establishing, implementation** and further **continual improvement of the quality management system** of the organization.

The scope of evidence required from the top management includes:

- **communicating** within the organization the information on **the importance of meeting customer and legal requirements** to enhance the customer growing satisfaction,
- establishing personally a documented **quality policy** (Fig. 14), i.e. formally expressed set of intentions and arrangements of the organization, concerning quality (according to ISO 9000) in compliance with the purposes of the

organization's existence, including commitment of the organization to the activities supporting conformity to the requirements and continual improvement of effectiveness of the quality management system,

- establishing documented **objectives concerning quality** (Fig. 14), i.e. subjects of efforts and arrangements relating to quality (according to ISO 9000), measurable and consistent with the quality policy, related to the system of quality management as well as conformity to products/services requirements ascertained at relevant functions and levels within the organization,
- personal and documented (by records) **reviews of management system** at planned intervals in order to ensure continual suitability, adequacy and effectiveness of the quality management system applied in the organization i.e.:
    - to determine if the system of quality management used in the entire organization is still useful, suitable for the organization and effective at achieving planned purposes (as a minimum, on the basis of the information coming from: ▪ audits conducted in the organization, ▪ customers' opinions, ▪ analysis of the organization's processes' functioning, ▪ analysis of achievement of products' and services' conformity and the cases when such conformity is not achieved, evidenced as the result of control, complaints, service activities, ▪ extent and status of conducted preventive and corrective actions, ▪ status of realization of the follow-up actions from previous management reviews, ▪ analysis of possible effect of changes in organization and its surroundings on the quality management system and recommendations concerning improvement)
    - to evaluate the need of changes and opportunities for improvement in order to make relevant decisions and take actions concerning the system (including quality policy and quality related purposes) and its processes as well as the products, taking into account both customer requirements and required resources.

In addition, the top management shall ensure that the quality policy is communicated and understood by the personnel and cause that **the planning of quality management system** is consistent with relevant requirements concerning processes and products in order to achieve the goals relating to quality. Integrity of the quality management system shall be maintained also in the case of changes planned and implemented to the system.

The top management shall also make efforts ensuring that:

- **responsibilities and authorities** are defined and communicated within the organization (it means that every employee is informed what he/she is expected to do, what he/she is allowed to do and that he/she understands the relations between responsibilities and authorities of different persons),
- appoint a management member who, irrespective of other responsibilities, as **the management representative,** shall watch over the quality management system. The representative shall be responsible for, and authorized to ensure that relevant processes are established, implemented and maintained within the system and that the awareness of customer requirements is recognized within the organization. His/her responsibility is also to report to the top

management on the system functioning and any needs connected with its improvement,

– develop and implement an effective **internal communication system** within the entire organization, including communication concerning efficiency of the quality management system (the methods of communication shall be selected according to the needs and abilities of the organization so the information necessary for realization of the processes is available at appropriate point and time).

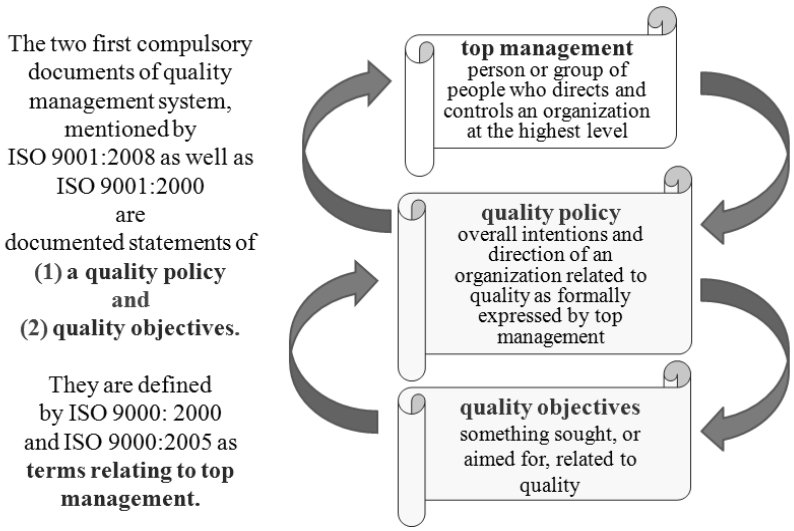


Fig. 14 'Quality policy' and 'quality objectives' as terms relating to top management.
Source: Adapted from [ISO 9001:2000; PN-EN ISO 9001:2001; ISO 9000:2005; PN-EN ISO 9000:2006]

4.5.3. Requirements in clause 6 titled "Resource management"

Resources are needed to implement, maintain and continually improve the quality management system and to enhance customer satisfaction by meeting customer requirements.

Therefore, the organization shall define and provide the assets including **human resources** (personnel competent on the basis of education, training, skills and experience – documented with records; personnel aware of the relevance of their activities and how the activities contribute to the achievement of the quality objectives; provide trainings or other actions to satisfy the requirements concerning competence and evaluate effectiveness of the actions taken) as well as **infrastructure, work environment and other resources according to the needs** to obtain conformity to product requirements.

4.5.4. Requirements in clause 7 titled "Product realization"

In the cycle of product realization there are usually typical elements (processes) – like: planning, customer related processes, design and development, purchasing, production and product delivery, control of the equipment for monitoring and measurements – which shall be realized in the organization according to the detailed requirements in clause 7 of ISO 9001:2008 standard. Exclusion of any of the requirements included in clause 7 from the scope of the quality management system of an organization is possible only in the case when it cannot be applied in practice due to specificity of the organization and its product.

The processes required for product **realization** shall be properly **planned and developed** by the organization after defining and considering important inputs like: quality objectives, product requirements, methods of production and service provision, required human and material resources with relevant documentation, methods of product control (verification, validation, monitoring, controlling and testing), including product acceptance criteria, records necessary to evidence conformity of processes and the product being their result.

Customer-related processes shall be conducted effectively by the organization to establish requirements concerning the product (customer requirements, statutory requirements, requirements related to the product's intended use) and to undertake – prior to the commitment to supply a product – a review of the requirements taking into account completeness, unambiguousness and ability to fulfil them as well as to ensure appropriate communication with the customer on matters relating to the product, including complaints and customer feedback information.

In the processes of product design and development, the organization shall effectively ensure a relevant design quality of the product and design **"good products" –** at this stage it is decided whether the organization will be able to produce goods and deliver services characterized by good quality. It is especially important to define and ensure adequate **inputs** relevant to such process (i.e. complete, unambiguous and compatible requirements and appropriate information from realization of similar projects) in the extent specified by the standard and to obtain as the result **the outputs,** consistent with the requirements (defined previously in the inputs) which shall ensure relevant information for purchases realization, production, service provision, product control and its save and proper use. When planning the process, the organization shall ensure appropriate **review, verification and validation** procedures for particular stages of design and development. During realization of the process, the organization shall provide control, verification and validation in accordance with planned arrangements and document results of these activities by appropriate records as well as ensure **control of implemented changes (**including: identification, documentation with records, review with evaluation of the effect of changes on constituent parts of the product and final product, approved prior to the implementation).

A purchasing process shall provide the organization with **goods** of appropriate quality, which shall enable the organization to realize products (including the final products) and provide services meeting customer requirements as well as other obligatory requirements identified by the organization. For this purpose, the organization shall ensure **adequacy of specified requirements relating to the purchases** (specified and approved by

communicating them to the supplier; precisely defining the product to be purchased and – if applicable – defining the product approval and realization process conducted by the supplier, qualifications of supplier's personnel, requirements related to the supplier's quality management system), to make an **assessment and choice of suppliers in terms of their ability to deliver products conforming to** defined requirements of the organization, to perform **control of the suppliers** in relation to the effect of supplier's delivery on the products and services of the organization and to ensure appropriate **verification of purchased product** (by control or other activities) in terms of conformity to specified requirements referring to the purchase.

In the processes of production and providing service, at the execution stage of product realization cycle, ISO 9001 standard points out five important aspects of control such as: control of production and service provision, validation of the processes of production and service provision, identification and traceability of product, customer property, product protection. To ensure required quality of realization, the organization shall, in a planned way, **conduct production and provide services in controlled conditions** – which comprises, to some degree, the access of personnel and their use of necessary information (documentation characterizing the product, operation manuals) and appropriate equipment (in production, measurements and monitoring), implementation of control activities (monitoring, measurements and product release) as well as the activities related to the product provision and service after selling.

Every **process of production and service provision, results of which cannot be controlled by monitoring and measurement** (i.e. some defects may be evidenced after providing a product or service to the customer) shall be **validated** in order to show "capability of the process to achieve planned results" and the control over the process shall be enhanced (including extended criteria of review and acceptation related to the process, equipment, personnel qualification, special methods and procedures and making records). Where applicable, the organization shall **identify products and their status** (while informing about performed investigations and controls – for instance prior to control/after control with positive result, after control with negative result) with the help of accepted product identification system, which enables product identification during the entire process of realization and evaluation of its status due to required investigations and controls. In the conditions of exigibility, the organization shall also ensure **traceability of product** (in the form of unambiguous product identification and related records) to enable tracing the history of application or localization of the product. The organization's special care is required towards **customer property** (material or not material) provided for use or incorporation into product – besides widely understood protection, requirements regarding control over such property also include informing the customer and documenting with records all cases when the property is damaged or lost or otherwise found to be unsuitable for use. The ISO 9001 standard also underlines the need to ensure **conformity of product and its parts to product requirements** while processing it in the organization and during delivery of the product to destination place – to preserve the product conformity, for instance during transportation, storage, or preparing to delivery, the organization shall ensure appropriate handling of the product, including its identification, packaging, storage and protection.

Control of monitoring and measuring equipment and measurements is the last process mentioned in clause 7 of the standard. Although the above mentioned processes are usually considered as **the main processes** of the organization, the control of monitoring and

measuring equipment is classified as an **auxiliary process** (but in essence everything depends on what is produced and how the organization is organized). To provide evidence of conformity of product to determined requirements, the organization shall establish indispensable monitoring and measurements as well as the equipment necessary to undertake the activities (for instance, measuring instruments, tools, standards, computer software) and ensure that the monitoring and measurements can be carried out in a manner conforming to the monitoring and measurements requirements. Where necessary, ensuring valid results requires the measuring equipment to be **calibrated or verified** (at specified intervals, against reliable basis of calibration or verification taking into account valid legal rules). The measuring equipment shall be adjusted, identified and shall possess established calibration status, shall be safeguarded from accidental adjustments, protected against damage and deterioration of metrological properties (for instance during storage and moving). The standard also points out the obligation to assess and document by records the reliability of preceding measurements in the case when **the equipment does not conform to the requirements.** In such case, the organization shall undertake relevant actions with respect to the equipment and all products which could be affected by the nonconformity, including also possible aspect of legal responsibility for providing a customer with the product non-conforming to requirements as well as the consequences resulting from using such product. All calibrations and verifications concerning the case shall be documented by records. More guidelines relating to measuring processes and measuring equipment are included in **ISO 10012:2003** (see Table 1)

4.5.5. Requirements in clause 8 titled "Measurement, analysis and improvement"

In general provisions of clause 8 the ISO 9001 standard requires the organization to plan and implement **"the monitoring, measurement, analysis and improvement processes needed: to demonstrate conformity of the product, to ensure conformity of the quality management system, and to continually improve the effectiveness of the quality management system**" [ISO9001:2008, PN-EN ISO 9001:2009] including specification of applicable methods (also statistical methods) and range of their use. In order to enable factual approach to decision making as the base for further analysis and improvement the organization's performance – **products/services** of the organization, its identified **processes**, **customer satisfaction** and **functioning of its quality management system** must be covered by the planned and implemented processes of monitoring and measurement.

Customer satisfaction (acc. ISO 9000 defined as customer's perception of it, if his/her/its {when it is an organization} requirements have been fulfilled) is particularly strongly exhibited by the standard as one of the most important measures of the quality management system's performance. To monitor the information relating to customer satisfaction the organization needs to determine methods of obtaining customer feedback information and using this information.

Internal audits are independent and effective tools of monitoring and measurement of the quality management system – providing that they are conducted by competent auditors, in accordance with requirements and guidelines of ISO 9001 and ISO 19011 standards as well

as under the stipulation of active auditee participation. Internal audits, within self-recognition of the organization, disclose needs and abilities of improvement of the system. The organization must conduct internal audits regularly – according to an internal audit programme (Fig. 15) and within a **documented procedure** implemented by itself – to determine a state of the maintained quality management system, taking into account conformity with requirements (i.e. with the planned arrangements related to product realization, with requirements of the ISO 9001 standard and with requirements established by the organization for its quality management system) as well as effectiveness of implementation and maintenance of the system. There are detailed guidelines concerning principles of auditing, managing an audit programme, audit activities as well as competence and evaluation of auditors [ISO 19011:2002, PN-EN ISO 19011:2003].

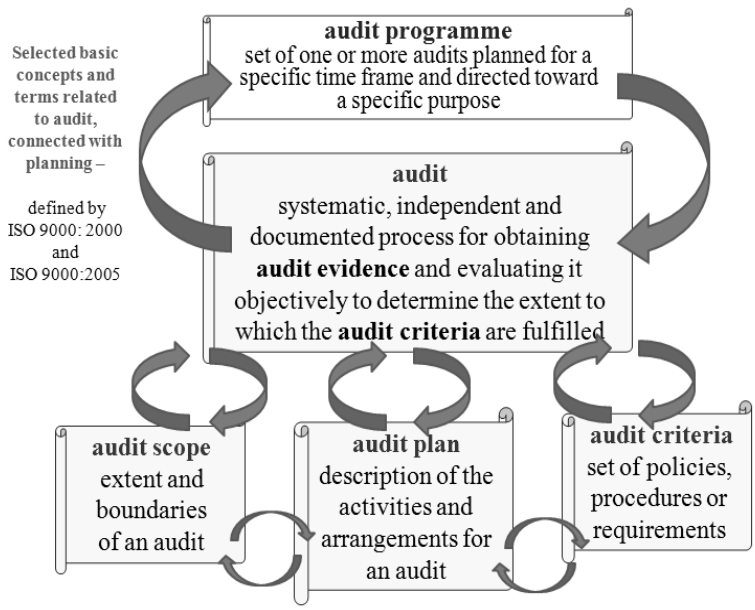


Fig. 15 Selected basic concepts and terms related to audit and connected with planning. Source: Adapted from [ISO 9000:2000; PN-EN ISO 9000:2001; ISO 9000:2005; PN-EN ISO 9000:20006]

When planning frequency of audits and their scope, the organization representatives must take into account the status and importance of the individual processes/areas to be audited, the results of previous audits as well as selection of auditors assuring impartiality and objectivity of the audit process according to established criteria and its proper documented evidence in the form of records. When investigating the quality management system, auditors look for **objective evidences** of its conformity with requirements – as a part of the audit process, subprocess 'to obtain information to formulate a proposal for the audit' is conducted in accordance with the agreed scheme (Fig. 16). If any nonconformities become exposed as a result of an internal audit, the management of the area being audited must ensure undertaking (without undue delay!!) of suitable operations tending towards either

elimination of these nonconformities or exclusion of their causes, by conducting corrective actions.

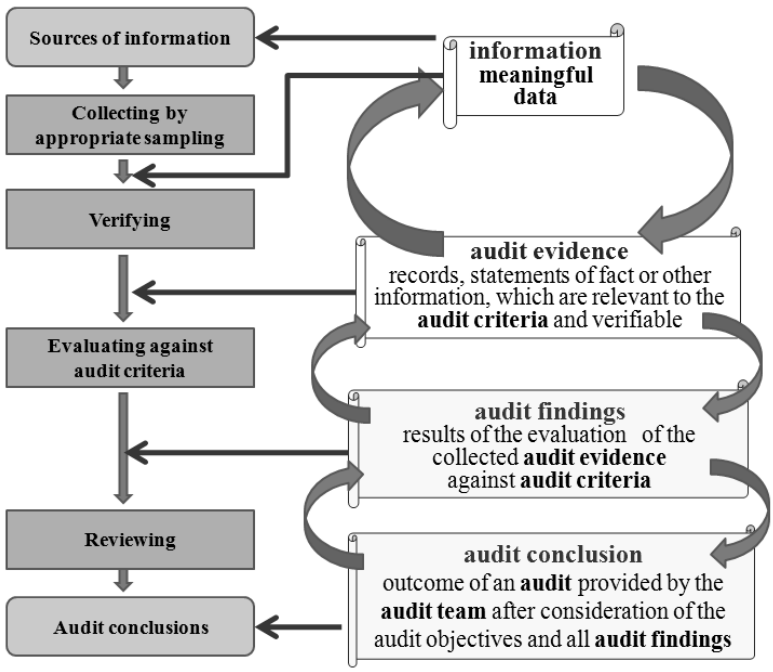


Fig. 16 From collecting information to reaching conclusion in an audit process.
Source: Adapted from [ISO 19011:2002; PN-EN ISO 19011:2003; ISO 9000:2005; PN-EN ISO 9000:20006]

To **demonstrate capability of** the quality management system **processes** to achieve planned results, the organization shall apply suitable methods for monitoring and, where applicable, methods of process measurements, and every process unable to achieve the planned results shall be corrected and subjected to corrective actions as appropriate.

To **verify conformity to product requirements** the organization shall monitor and/or measure characteristics of the product at appropriate stages of the product realization process and document by records the evidence of conformity with acceptance criteria and product release up to the next stage of realization (or delivery to the customer after completion of all required actions with positive result) by authorized person.

The organization shall establish in a documented **procedure** and effectively implement a course of **proceeding with nonconforming product/service** (including responsibilities and authorizing in this area) to ensure that the nonconforming product/service (Fig. 17) is identified and controlled to prevent its unintended use or delivery. The actions taken with respect to the product/services nonconforming to the requirements (Fig. 18) shall be appropriate to the type of detected nonconformity – the actions shall comprise **correction** (elimination of nonconformity of product/service by its alteration, repair, re-classifying), permission to approve the nonconformity or other use. The actions precluding the original use/application of the product (like elimination) shall be documented by records.

Fig. 17 Meaning of the term 'nonconforming product'.
Source: Adapted from [ISO 9001:2000; PN-EN ISO 9001:2001; ISO 9000:2005; PN-EN ISO 9000:2006]

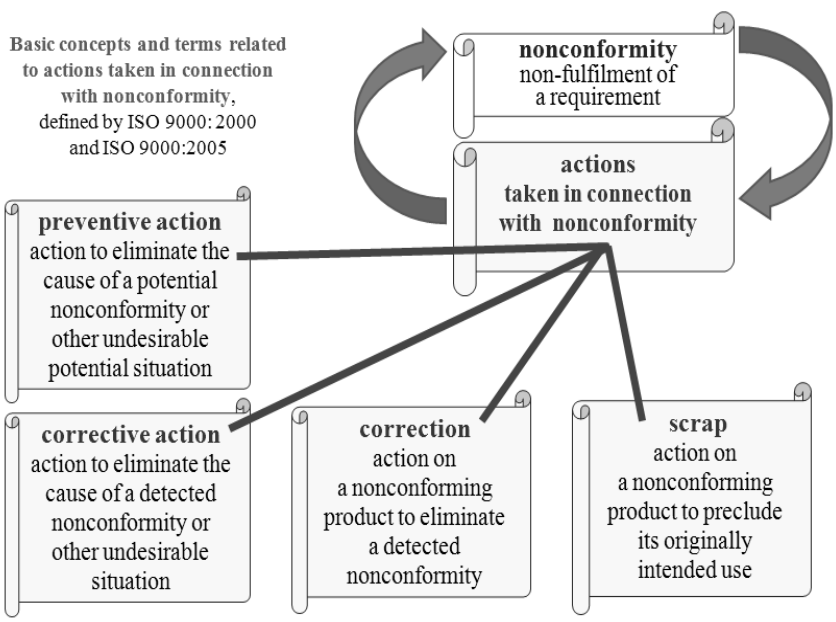


Fig. 18 Basic concepts and terms related to actions taken in connection with nonconformity.
Source: Adapted from [ISO 9001:2000; PN-EN ISO 9001:2001; ISO 9000:2005; PN-EN ISO 9000:2006]

The products after correction shall be subjected to **re-verification** to demonstrate conformity to the requirements. Detection of a nonconforming product after delivery or its application compels the organization to consider the factual and potential effects of this nonconformity and undertake relevant actions. Although the ISO 9001 standard does not define this directly it is worth to keep in mind that immediate detection and appropriate control of products/services nonconforming with the requirements prevents additional costs caused by poor quality and indicates the needs and abilities to improve products/services, processes and the complete system of quality management.

Evaluation of suitability and effectiveness of the quality management system and its capability to improve causes the organization to be compelled to collect and analyse data in the previously defined range – taking into account the data generated as a result of monitoring and measurement as well as other sources important for the organization. The ISO 9001 standard declares that the main objective of the **data analysis** is to provide the organization with the information about customer satisfaction/ non-satisfaction, conformity to product requirements, characteristics and trends of processes and products (including potential corrective actions) and suppliers.

Quality improvement within the organization consists in taking actions directed to enhance the organization's capability to meet the requirements concerning quality. The ISO 9001 standard states that the organization shall **continually improve** the effectiveness of its quality management system through the use of the mechanisms embedded in the system: quality policy, quality objectives, audit results, improvement as well as corrective and preventive actions.

The organization shall conduct corrective and preventive actions, adjusting the actions to the results of **detected nonconformities and potential nonconformities -** see (Fig. 18).

The corrective actions, defined [ISO 9000:2005; PN-EN ISO 9000:2006] as actions aiming at elimination of the cause of already detected nonconformity or other already evidenced undesired situation, are undertaken to prevent recurrent occurrence of such nonconformity or situation in the organization. In contrast, **the preventive actions** defined [ISO 9000:2005; PN-EN ISO 9000:2006] as actions intended to eliminate potential nonconformity or other potential situation, are undertaken prior to occurrence of the nonconformity/ situation (based on presumption that it is possible to happen) in order to prevent it from occurring in the organization.

The organization shall establish and implement **documented procedures** for corrective and preventive actions, by defining the requirements (analogous for the both types of actions) concerning: review of nonconformities/ undesired situation (for instance customer complaint), determination of the causes of nonconformities, evaluation of the need for action, determination and implementation of necessary actions and review of the actions already undertaken in order to evaluate their effectiveness.

Competently conducted corrective and preventive actions are effective means to improve the organization – the actions ensure opportunity to learn from own or somebody else's mistakes and other identified undesired situations both factual and potential.

4.6. Some technical aspects of quality management systems' documentation

Now we know that every quality management system consistent with the ISO 9001 standard (or with any sector specific standard containing ISO 9001 requirements, which is applicable to e.g. automotive, medical device production, telecommunication, aerial industry) requires documentation in a necessary scope and, remember, only in this scope. Every quality management system's documentation should be as simple as possible and can be in any form or medium.

As it is underlined in ISO 9000:2005, the system documentation enables communication of intent and consistency of action. It is useful for:

- achieving the required quality (conformity to requirements),
- evaluating the quality management system,
- quality management system's improvement,
- maintaining improvements,
- demonstrating the quality system to customers and potential customers,

It is good to remember all the time, that the scope of QMS documentation, required by ISO 9001, includes:

- a quality policy and objectives – documented,
- a quality manual,
- documented procedures and records - directly called by this standard (ISO 9001:2008) as required,
- other documents, including records, to ensure effective planning, operation and control of processes – determined by the organization.

When forming a quality policy text, take into account:

- 'links' with 8 quality management principles,
- top management's vision and strategy for the organization's future,
- promoting a commitment to quality throughout the organization,
- using clear and understandable wording.

When formulating your quality objectives, think about information affecting it. The following are very frequently mentioned examples of such type of information:

- organization's strategy,
- results of internal and external audits,
- status of corrective and preventive actions,
- customer complaints,
- customer needs,
- product's data from measurement and monitoring,
- processes' data from monitoring and measurement,
- results of organization's self-assessment,
- results of benchmarking,
- other identified opportunities for improvement,

– lesson from previous experiences and so on.

Two of the eight quality management principles directly use the word ‘process’: the 4th principle ‘Process approach’ and the 5th principle ‘System approach to management’. So it’s no wonder, that you can find requirements for processes in different clauses of ISO 9001:2008 standard:

– general requirements for determining and managing QMS’s processes (see sub-clause 4.1 of ISO 9001:2008),
– requirements for planning and development of processes needed for product realization in the organization (see sub-clause 7.1 of ISO 9001:2008),
– requirements for monitoring and measurement of processes (see sub-clause 8.2.3 of ISO 9001:2008),
– various requirements relating to the specific processes (see ISO 9001 sub-clauses other than those already mentioned above).

Remember, that there are many different ways of describing and presenting graphically the organization’s processes needed for the quality management system, but mapping processes is very useful (Fig. 19). Processes’ documentation ”can be in any form or type of medium”. There is no one best way for all organizations. The extent of QMS’s processes and their documentation can differ (and in practice it really differs!!!) from one organization to another.

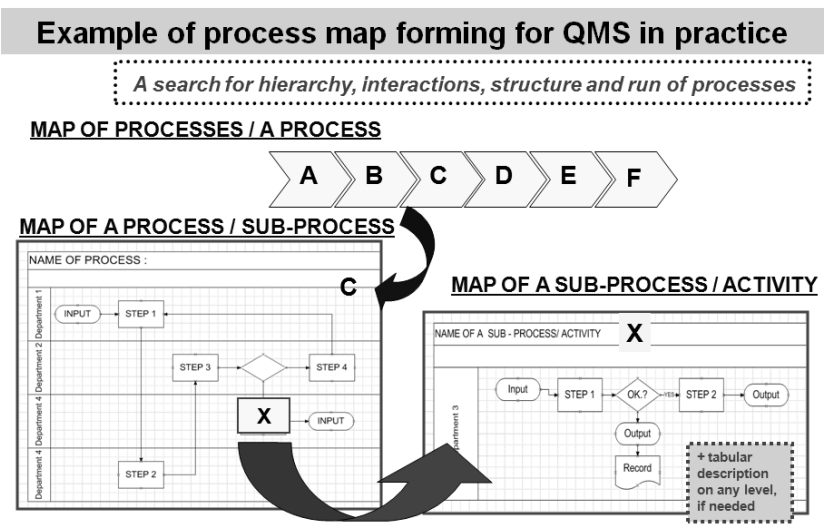


Fig. 19 Example of process map forming for QMS in practice.
Source: Adapted on the basis of data from [Hammer M., Champy J., 1995; Rummler G.H., Brache A.P., 1990]

A good way to distinguish between documents and records is remembering that a document is something that gives you information or instruction to do something and it comes before the event whereas a record is evidence that the event took place and it comes after the event.

Records as required by the standard (its sub-clauses) are relevant to:

- management reviews (5.6.1),
- education and training (6.2.2 e),
- evidence of requirements fulfilled (7.1 d),
- design and development input (7.3.2),
- design reviews (7.3.4),
- design verification (7.3.5),
- design change review (7.3.7),
- results of supplier evaluations (7.4.1),
- process validation (7.5.2 d),
- unique identification (7.5.3),
- nonconforming customer property (7.5.4),
- local standards for calibration (7.6),
- validity of previous results (7.6),
- results of calibration and verification (7.6),
- internal audit records and results (8.2.2),
- record of product conformity (8.2.4),
- product nonconformity (8.3),
- corrective action results (8.5.2),
- preventive action results (8.5.3)

Remember, that there are many different ways of documenting these required records. As all quality system documentation, these records ”can be in any form or type of medium”. There is no one best way for all organizations and records can differ (and in practice they really differ!!!) from one organization to another.

Documented procedures are required only by six different sub-clauses of the standard (ISO 9001:2008), mentioned below: control of documents (sub-clause 4.2.3), control of records (sub-clause 4.2.4), internal audit (sub-clause 8.2.2), control of non-conformity (sub-clause 8.3), corrective action (sub-clause 8.5.2), preventive action (sub-clause 8.5.3). Remember, it does not mean that each of the required documented procedures must be written only in the form of an individual document or that an individual document must cover only the content of one required documented procedure.

When developing a written procedure be in accordance with good practice and do the following actions ‘step by step’:

- review current practice,
- analyse current practice and find gaps,
- develop a draft procedure,
- release draft for comments,
- review comments,
- revise and issue procedure for acceptance,
- obtain approval,
- issue for use,

- implement,
- monitor and review,
- update (when needed) and improve (when possible!).

A frequently suggested format of a documented procedure includes:

- title,
- purpose,
- scope/application,
- revision history (or other way of identification of changes),
- reference/ related documents,
- definitions,
- authority and responsibility,
- procedure/ description of activities (usually – with the process flow chart),
- records, attachments (if any).

Remember, that there are many different ways of documenting procedures. As all quality system documentation, documented procedures ”can be in any form or type of medium”. There is no one best way for all organizations and documented procedures can differ (and in practice they really differ!!!) from one organization to another.

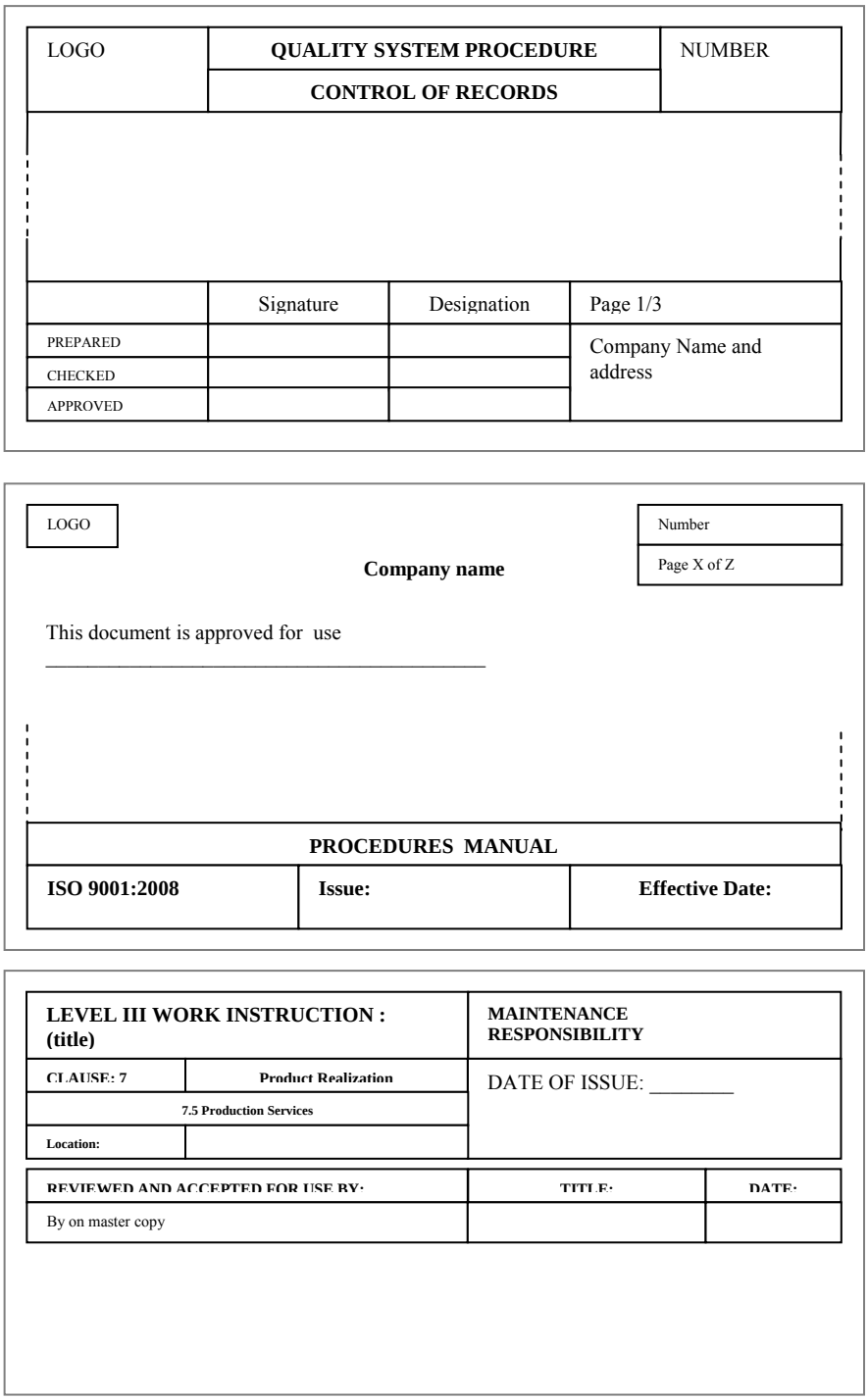
Some examples of ‘header’ and ‘footer’ for documented quality management system procedures are presented in Fig. 20. An example of real written procedure is shown in Fig. 21, Fig. 22 and Fig. 23.

Often suggested format of a quality manual includes:

- title and scope/ application,
- table of contents,
- revision history (or other way of identifying changes),
- definitions,
- quality policy and quality objectives,
- organization, authority and responsibility,
- description of organization’s quality management system (usually – with the map of processes),
- references/ related documents, attachments (if any),

but remember that there are many different ways of documenting an organization’s quality manual.

Take into account that also in the future ISO 9001, ISO 9000 and other standards from the ISO 9000 family will be periodically reviewed and, when necessary, will be changed (updated or removed), to maintain their effectiveness and benefits ”from new developments in the quality management fields and also from user feedback”. If you keep your system documentation as simple as possible, you will have less work in the future.



LOGO	QUALITY SYSTEM PROCEDURE CONTROL OF RECORDS	NUMBER

	Signature	Designation	Page 1/3
PREPARED			Company Name and address
CHECKED			
APPROVED			

LOGO	Number
Company name	Page X of Z

This document is approved for use

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PROCEDURES MANUAL		
ISO 9001:2008	**Issue:**	**Effective Date:**

LEVEL III WORK INSTRUCTION : (title)		**MAINTENANCE RESPONSIBILITY**
CLAUSE: 7	**Product Realization**	DATE OF ISSUE: _____
7.5 Production Services		
Location:		

REVIEWED AND ACCEPTED FOR USE BY:	**TITLE:**	**DATE:**
By on master copy		

Fig. 20 Examples of 'header' and 'footer' for documented quality system management procedures. Source: Adapted from [ITI, 2009; Stoops L., 2009; Wilgosz J., 2010]

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INTERNAL AUDIT (ISO 9001:2008 Clause 8.2.2)

1.0 Introduction

The Organisation's quality management system needs to be audited on a systematic basis to ensure that the planned arrangements are being met in practice.

2.0 Scope

This procedure details the method of planning and carrying out the internal audit to check that the Organisation's procedures are being followed.

3.0 Responsibility

It is the responsibility of the Management Representative to ensure that:

- An internal audit programme is prepared to cover all elements of the quality management system.
- Suitable personnel are allocated to carry out the internal audits.

It is the responsibility of the Internal Auditor to carry out the audits, identify any non-conformances and follow them up to ensure that they are corrected.

4.0 Procedure

4.1 Planning

4.1.1 An Internal Quality Audit Programme (QF08-01) must be prepared covering all elements of the quality management system. The program will be structured in such a manner as to ensure each procedure is audited at least annually.

PROCEDURES MANUAL		
ISO 9001:2008	*Issue: 1*	*Effective Date: 1 September 2009*

Fig. 21 Example of an internal audit procedure (before approval) – page 1 of 3.
Source: [Wilgosz J., 2010]

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4.1 Planning (continued)

4.1.2 Suitably trained auditors must be assigned to carry out the audit of each element of the system. Note that the auditor should be independent of the work or area being audited.

4.1.3 The frequency of audit will take into account:

- The importance and/or complexity of the procedure or process
- Any history of problems with the procedure or process e.g. previous audit results, customer complaints, internal non-conformance, etc.

4.1.4 Additional audits may be scheduled where problems or deficiencies have been found.

4.2 Conducting the Audit

4.2.1 The Internal Auditor(s) will carry out audits in accordance with the programme.

4.2.2 Using the procedure itself as the guide, each element will be checked to ensure that its requirements are being met and that the overall purpose of the procedure is being fulfilled.

4.2.3 Written notes on variances, non-conformance and omissions will be recorded on an Internal Quality Audit Report (QF08-02) and circulated for action to appropriate personnel.

4.2.4 Supplementary notes will be taken of supporting information and records checked. e.g. job numbers, purchase orders.

4.3 Reporting and Closing Out Non-Conformances

4.3.1 The Internal Auditor will be responsible for following up designated actions and for the making of information on incomplete items available to the Management Review Meeting.

4.3.2 If the Internal Auditor believes that any procedure or method of working is not meeting its intended objectives, could be improved or that further information is required, it will be discussed with the appropriate manager and corrective action taken. This will be reported to the Management Review Meeting.

Fig. 22 Example of an internal audit procedure (before approval) – page 2 of 3.
Source: [Wilgosz J., 2010]

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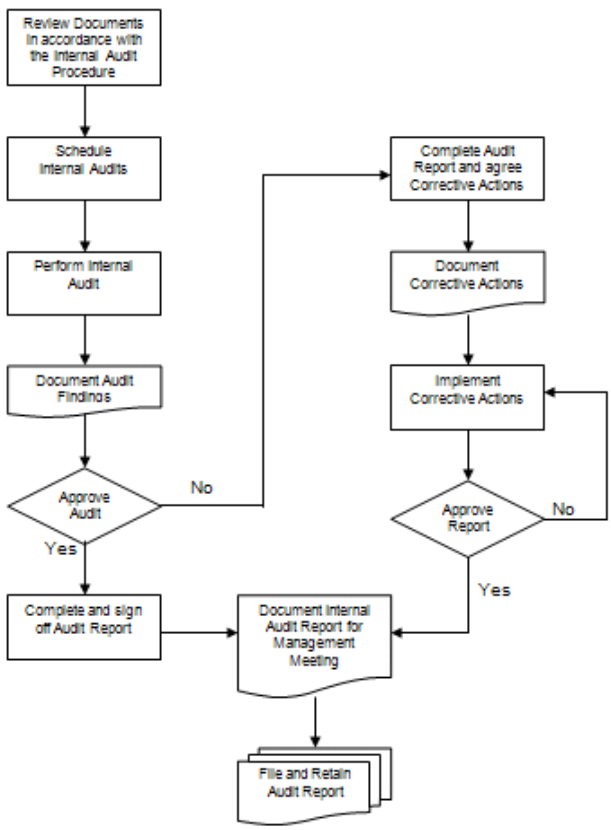
Reference Documents – Internal Audit

QF08-01 Internal Quality Audit Programme
QF08-02 Internal Quality Audit Report

Flow Chart – Internal Audit



PROCEDURES MANUAL		
ISO 9001:2008	Issue: 1	Effective Date: 1 September 2009

Fig. 23 Example of an internal audit procedure (before approval) – page 3 of 3.
Source: [Wilgosz J., 2010]

4.7. Final remarks

Meeting the requirements and guidelines of the ISO 9000 family standards is not a legal obligation. The standards have been elaborated to assist an organization with implementation, effective operation and improvement of a quality management system. The ISO 9001 standard, belonging to the family, includes basic organizational requirements, which the organization shall fulfil to demonstrate its ability to continually supply a product conforming to the customer and legal requirements and to enhance customer satisfaction as well as to obtain a certificate of conformity of its quality management system to ISO 9001.

The model of a quality management system described in the ISO 9000 family standards (and in ISO 9001 concerning the basic requirements) is based on the best and verified in practice management, directed to ensure product/service quality and customer satisfaction, and is an excellent depiction of the most important issues and their interactions. However, it is still only a model of a system – a kind of construction like a pile of bricks, which people shall transform into a house. Every system is a form but not an essence. The latter shall be filled up by people [Price F., 1994].

More and more popular becomes the view that everything depends on the way in which the essence of the ISO 9001:2008 standard requirements is transferred into practical solutions (see e.g. [Jedynak P., 2006]). Implementation and improvement of the quality management system according to ISO 9001:2008 (as previously acc. ISO 9001:2000) shall provide the organization with real benefits only when the system is thought over thoroughly, genuinely fitted to the organization's needs and saturated with pro-quality thinking of the personnel and management. The beneficial system cannot be a facade maintained only "to exhibit the certificate on the manager's office wall" but shall really assist in organization's managing and its continual improvement. The beneficial system shall be accompanied by an understanding for the need to calculate quality costs [Zymonik Z., 2002] and by the knowledge and use of quality management tools like SPC, FMEA, QFD, DoE, etc. (see e.g. [Dahlgaard J., Kristensen K., Kanji G., 1998; Hamrol A.,Mantura W.,1998; Łańcucki J., 2003])

5. Quality management systems in practice - examples

5.1. Subject 01– ISO 9001 foundations and the micro-enterprise

To begin, study Chapter 4.4 “Basic principles and concepts used in quality management systems according to ISO 9000 family of standards”, in particular subchapters: 4.4.1 “Eight quality management principles”, 4.4.2 “PDCA cycle” and 4.4.3 “Basic terminological concepts”.

Find more information about 8 quality management principles and PDCA cycle at the Website of International Organization for Standardization, www.iso.org, and at other sources from well known quality management literature.

When starting preparation to carry out the project, find the relevant definition of micro-enterprise, used in EU.

In this subchapter you will find two introductory exercises (with two ‘ready to use’ FORMS) and five steps for preparation of the project.

5.1.1. INTRODUCTORY EXERCISES

EXERCISE 5.1.1-1

1. Read the clause (or sub-clauses) of ISO 9001:2008 indicated by your lecturer, looking for reflection of 8 quality management principles in the examined part of the standard. For each of the principles try to find – in the clause (sub-clauses) content – "elements" confirming reflection of this principle in the requirements contained therein.
2. Record the results of your analysis in the table below.

FORM 01

Analysis of 8 quality management principles reflection in the ISO 9001:2008 requirements, contained in the selected clause/ sub-clause named:

……

QUALITY MANAGEMENT PRINCIPLE *(according to ISO 9000:2000, ISO 9000:2005 and also ISO 9004:2000)*	***Assess-ment of reflec-tion****	***AN ELEMENT CONFIRMING REFLECTION OF THE QUALITY MANAGEMENT PRINCIPLE IN THE EXAMINED REQUIREMENTS*** ***or a comment: why the assessment of reflection is difficult***
Customer focus: *„Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations".*		
Leadership *„Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives."*		
Involvement of People *„People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit."*		
Process Approach *„A desired result is achieved more efficiently when activities and related resources are managed as a process."*		
System Approach to Management *„Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives."*		
Continual Improvement *„Continual improvement of the organization's overall performance should be a permanent objective of the organization."*		
Factual Approach to Decision Making *„Effective decisions are based on the analysis of data and information."*		
Mutually Beneficial Supplier Relationships *„An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value"*		

*** YES** – The principle is reflected in the requirements of the examined ISO 9001:2008 clause (sub-clauses).
NO - The principle is not reflected in the requirements of the examined ISO 9001:2008 clause (sub-clauses).
UNCLEAR – I can not assess if the principle is reflected in the requirements of the examined ISO 9001:2008 clause (sub-clauses).

EXERCISE 5.1.1-2

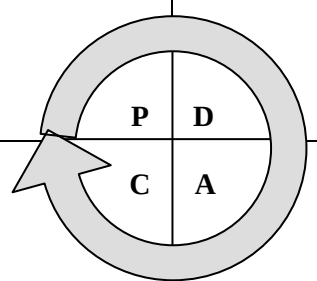
1. Read the clause (or sub-clauses) of ISO 9001:2008 indicated by your lecturer, looking for reflection of the PDCA cycle in the examined part of the standard. Try to find "elements" confirming reflection of each of the cycle steps (P, D, C, A) in the requirements described/contained therein.
2. Record the results of your analysis in the table below.

FORM 02

Analysis of PDCA cycle reflection in the ISO 9001:2008 requirements, contained in the selected clause/ sub-clause named:

……

PLAN :	**DO :**
ACT:	**CHECK:**



5.1.2. STEPS FOR PROJECT PREPARATION:

STEP 01: Set up a micro-enterprise (up to 10 employees, simple but complete structure, simple product or service) – to be developed and described / written in groups.

STEP 02: Using ISO 9000:2005 familiarize yourselves with the definitions of the concepts: „quality", „product", „requirements", „customer satisfaction", „organization", „top management", „interested parties". Try to fix the meaning of these concepts for the set-up micro-enterprise and record the results of your analysis. Additionally on this basis, adjust the earlier description of your micro-enterprise, if it is needed to ensure the consistency of its description.

STEP 03: At home read carefully full text of ISO 9001:2008 as well as the description of ISO 9001:2008 requirements in the textbook designed for this course (very important individual preparation for the next lessons!!!)

5.2. Subject 02: Quality policy and quality objectives

To begin, study subchapters 4.6 “Some technical aspects of quality management systems’ documentation” and 4.5.2 “Requirements in clause 5 titled “Management responsibility” “ and find more information about quality policy and quality objectives at sources chosen by you from well known quality management literature.

The author suggests you to study on-line some examples of real quality policies, e.g. the following available on:

- Alwero, http://alwero.pl/_20-en-1-k--4-11--.html [2.09.2010]
- Apis, http://www.apis.pl/?en-ofirmie-polityka_jakosci [31.08.2010]
- Bajcar, http://www.bajcar.pl/en/quality_policy.htm [31.08.2010]
- Bilplast, http://www.bilplast.com.pl/html/en/polityka.html [31.08.2010]
- Cedrob, http://www.cedrob.com.pl/en/polityka-jakosci%5B2%5D [31.08.2010]
- Darmex Casing Sp. z o.o., http://www.darmex.eu/Files/File/polit_jak_eng.pdf [2.09.2010]
- Detla Trans, http://www.deltatrans.pl/polityka_jakosci.html [2.09.2010]Exfolmo;http://www.tworzywa.org/index.php?id=kf5&id_f=36468&idd=kf5&id_kfp=&page=&id_k=&code=&z=2&searchall=&q=&rv=&tpo=&page=&co=&rodzaj=&gdzie= [31.08.2010]
- Hadykówka, http://www.hadykowka.pl/polityka_jakosci.html [2.09.2010]
- Inmed-Karczewscy, http://www.inmed.pl/en/articles/system-jakosci/polityka-jakosci [31.08.2010]
- TBP Interprojekt Sp. z o.o., http://tbpip.com.pl/index.php?option=com_content&task=view&id=59&lang=en [31.08.2010]
- Iwamet, http://www.iwamet.com.pl/polityka_jakosci_eng.php [31.08.2010]
- Fabryka Wyrobów Metalowych Kuźnia „Osowiec” Sp. z o.o., http://www.fwmosowiec.pl/polityka-jakosci-eng.html [31.08.2010]
- MA Art Translations Agency, http://www.maart.com/en/polityka-jakosci.html [31.08.2010]
- PKP Informatyka Sp. z o.o., http://www.pkpik.pl/en/polityka-jakosci.htm [31.08.2010]
- Zakład Obróbki Metali “SOWA”, http://www.zom-sowa.eu/www/eng/polityka-jakosci.php [31.08.2010]

In this subchapter you will find two introductory exercises (with two ‘ready to use’ FORMS) and five steps for preparation of the project (with one ‘ready to use’ MEP TEMPLATE).

5.2.1. INTRODUCTORY EXERCISES

EXERCISE 5.2.1-1

1. Read the sub-clauses 5.1, 5.3, 5.6.1 and 4.2.3 of ISO 9001:2008, looking for requirements for quality policy.
2. Analyse a chosen organization's quality policy with respect to compliance with those requirements and record the results in the table below. Try to find - in the quality policy content - "elements" confirming that requirements are met, and insert them in the table below.

FORM 03

Analysis of the quality policy established by organization called:

……

REQUIREMENT	***Compliance assessment ****	***A POLICY ELEMENT MEETING THE REQUIREMENT or a comment: where and how meeting this requirement by the organization can be checked/verified***
- The analysed quality policy **is established by top management of the organization** (see sub-clause 5.1 *Management commitment* in ISO 9001:2008)		
- The analysed quality policy **is appropriate to the purpose of the organization** (see sub-clause 5.3 *Quality policy* in ISO 9001:2008)		
- The analysed quality policy **includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system** (see sub-clause 5.3 *Quality policy* in ISO 9001:2008)		
- The analysed quality policy **provides a framework for establishing and reviewing quality objectives** (see sub-clause 5.3 *Quality policy* in ISO 9001:2008)		
- The analysed quality policy **is communicated and understood within the organization** (see sub-clause 5.1 *Quality policy* in ISO 9001:2008)		
- The analysed quality policy **is reviewed for continuing suitability** (see sub-clause 5.1 *Quality policy* in ISO 9001:2008, see also 5.6.1 in sub-clause 5.6 *Management review* in this standard)		
- The analysed quality policy **is subject to control as a document** (see sub-clause 4.2.3 *Control of documents* in ISO 9001:2008)		

* YES - Compliant with ISO 9001: 2008, NO - Not compliant with ISO 9001:2008, CHECK - Requires additional checking

EXERCISE 5.2.1-2

1. Read the sub-clauses 5.1 (b, c), 5.3 (c) and 5.4.1 of ISO 9001:2008, looking for requirements for relationship between organization's quality policy and organization's quality objectives.
2. Analyse chosen quality policy (the same as in the previous exercise) with respect to feasibility of determining quality objectives for various expressions selected from this policy.
3. Try to formulate 5 or 6 examples of quality objectives based on various expressions selected from the quality policy and record them in the table below.

FORM 04

Formulating quality objectives based on the quality policy – case of organization called:

……

EXPRESSION SELECTED FROM THE QUALITY POLICY	**QUALITY OBJECTIVE**

5.2.2.STEPS FOR PROJECT PREPARATION:

For the set-up micro-enterprise, established for the purpose of your group's project:

STEP 04: Develop an appropriate quality policy and document it in the form of a top management statement.

STEP 05: Develop its particular quality objectives consistent with the quality policy, specifying also their measures. Document these objectives in the form of a statement using MEP TEMPLETE 01 or similar.

STEP 06: Decide how to ensure that the quality policy and quality objectives are communicated and understood within the micro-enterprise, and write down your findings.

STEP 07: Additionally, if it is needed, **adjust the earlier description of your micro-enterprise** to ensure the consistency of its description including this quality policy and these quality objectives.

MEP TEMPLATE 01

QUALITY OBJECTIVES FOR MICROENTERPRISE NAMED: ……

	QUALITY OBJECTIVE /with a clearly defined parameter and a person/unit responsible for implementation/	To be achieved within **TIME PERIOD** /eg. to date /	**MEASURED** in [unit of measure]	**MEASUREMENT METHOD**	**MEASUREMENTS** will be made by /or will be ensured by/:	The way of **DOCUMENTING** obtained results	**COMMENTS**
1.							
2.							
3.							
4.							
5.							

5.3. Subject 03: Processes in QMS

To begin, study subchapters: 4.6 “Some technical aspects of quality management systems’ documentation”, 4.4.3 “Model of a process-based quality management system” and 4.5.1 “Requirements in clause 4 titled “Quality management system”” and find more information about processes of quality management system at sources chosen by you from well known quality management literature.

The author suggests you to study on-line some examples of real process maps, e.g. the following available on:

- EG, http://egqsinc.com/Processes.aspx [23.11.2010]
- Mittal, ArcelorMittal Gent, http://www.arcelormittal.com/gent/repository/Kwaliteit/proceslandkaartthumbn%20EN.jpg [02.01.2010]
- West J., Three strategies for aligning quality policies, objectives and processes, http://www.qualitydigest.com/june02/html/threestrat.html [23.11.2010]

In this subchapter you will find two introductory exercises (with two ‘ready to use’ FORMS) and five steps for preparation of the project (with two ‘ready to use’ MEP TEMPLATES).

5.3.1. INTRODUCTORY EXERCISES

EXERCISE 5.3.1-1

To better understand the process approach used in the quality management system model described in the ISO 9001:2008 standard:

- analyse the requirements contained in sub-clause 4.1 *General requirements* of the standard,
- insert these requirements for processes, found in the sub-clause 4.1, into the table below.

FORM 05 General requirements for processes in ISO 9001:2000 **ORGANIZATION SHALL:**			
No	*(verb)* **Do what?**	*(noun)* **What?**	**What kind? (or Where?)**

EXERCISE 5.3.1-2

To better understand the idea described in ISO 9001:2008 standard, concerning the planning and development of organization's processes needed for product realization:

- analyse the requirements contained in sub-clause 7.1 Planning of product realization of the standard,
- insert these requirements for processes, found in the sub-clause 7.1, into the table below.

FORM 06 Planning of product realization in ISO 9001:2008 **ORGANIZATION SHALL:**			
No	*(verb)* **Do what?**	*(noun)* **What?**	**What kind? (or Where?)**

5.3.2. STEPS FOR PROJECT PREPARATION:

For the set-up micro-enterprise, established for the purpose of your group's project:

STEP 08: Try to determine and write a full list of processes needed for the micro-enterprise's QMS, taking into account the entire text of the ISO 9001:2008 standard as well as the micro-enterprise's structure and product/service.

STEP 09: Try to develop tabular descriptions of these QMS processes, in this step restricting yourself to the processes needed for product realization in the micro-enterprise (main processes). Document these descriptions using MEP TEMPLATE 02 or similar..

STEP 10: Try to draw a map of the micro-enterprise's QMS processes, using the general "model of a process-based quality management system" (ISO 9001:2008) as a base for it. Document the map using MEP TEMPLATE 03 or in a different graphical way appropriate to you.

STEP 11: Try to develop a detailed flow chart of the selected main processes (e.g. customer-related processes, design and development process, purchasing process, production and/or service provision, other really important processes in the operation of the organization or any combination of the mentioned processes or their sub-processes), taking into account:

- "inputs" to the process (broadly defined resources, including documents, records, other information),
- "outputs" from the process (broadly defined products / services, documents, records, other information),
- decisions (including the output for YES and for NO),
- control or monitoring result of the process ("product"),
- control or monitoring of the process,
- sequence of actions (tasks),
- people responsible for specific tasks,

and add or otherwise take into account:

- process name,
- process objective,
- identification of the process owner,
- characteristics of the product being a result of the process (with units of measurement, if needed and possible),
- characteristics of the process (with units of measurement, if needed and possible),
- name of the supplier/suppliers to the process,
- name of the customer/customers of the process.

STEP 12: Additionally, if it is needed, adjust the earlier description of your micro-enterprise to ensure the consistency of its description including the developed map of processes as well as descriptions and detailed flow chart of the selected main processes.

MEP TEMPLATE 02

TABULAR DESCRIPTION OF THE PROCESS NAMED ……....……,.

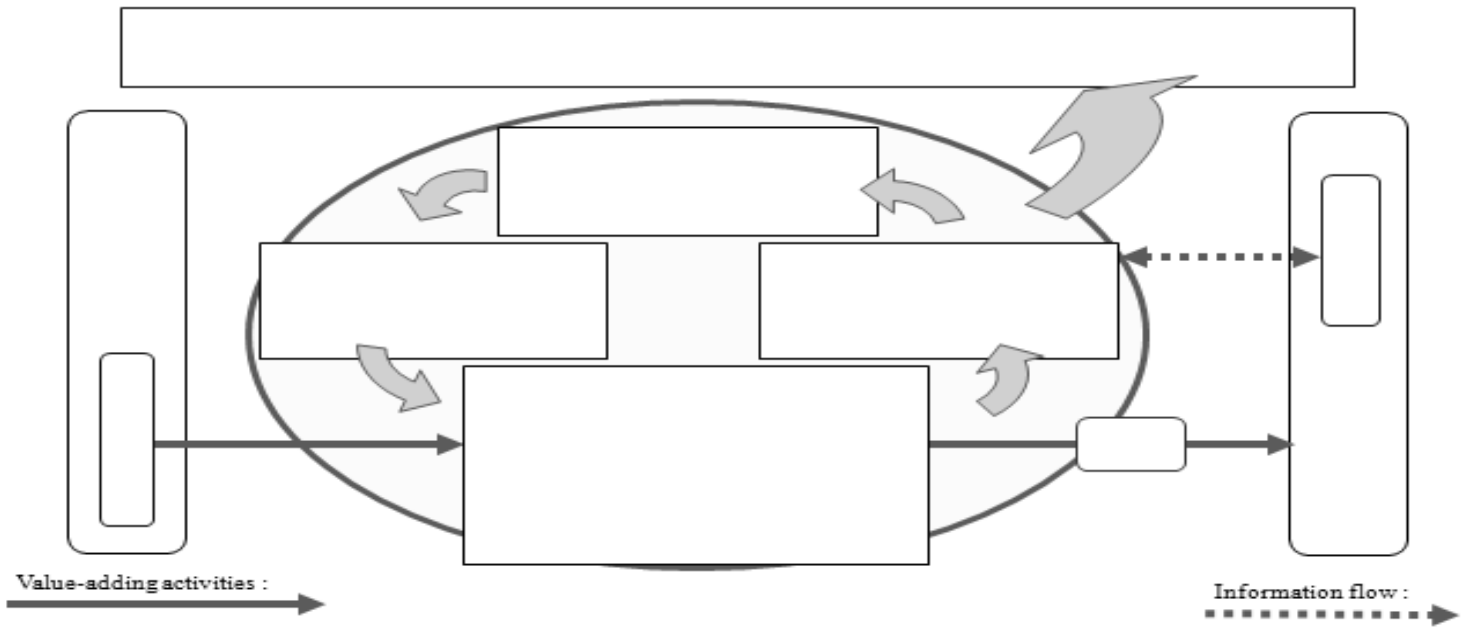
ESTABLISHED IN THE MICROENTERPRISE NAMED: ……

INPUT SUPPLIER – another process or person or organization	INPUTS	THE PROCESS - name and objective	OUTPUTS	OUTPUT RECEIVER – another process or person or organization

MEP TEMPLATE 03

MAP OF PROCESSES FOR MICROENTERPRISE NAMED: ……..……..

/Template adapted from the model of a process-based quality management system presented in ISO 9000/ 2000 / 2008/



5.4. Subject 04: Documentation, control of documents and control of records

To begin, study subchapters: 4.6 “Some technical aspects of quality management systems’ documentation” and 4.5.1 “Requirements in clause 4 titled “Quality management system”” and find more information about a process of document control and a process of records control, at sources chosen by you from well known quality management literature.

The author suggests you to study on-line some examples of flow charts of real documentation control processes, e.g. the flow chart available on:

- CogniDox Ltd, Quality Procedure “Control of Documents” for FablessSemi, http://www.cognidox.com/component/cognidox/?view=categories&id=153 [10.08.2010]

Think what computer program you will use for flow chart drawing and choose the one which should be available to use in almost every micro-enterprise.

Recall what symbols are typically used for drawing any flow chart and choose small number of the most typical symbols for your drawings.

In this subchapter you will find one introductory exercise (with one ‘ready to use’ FORM) and two steps for preparation of the project (with reference to one ‘ready to use’ MEP TEMPLATE).

5.4.1.INTRODUCTORY EXERCISES

EXERCISE 5.4.1-1

Study the requirements of ISO 9001:2008 for control of documents (sub-clause 4.2.3) and control of records (sub-clause 4.2.4), and:

1. pay attention to the relationship between the requirements included in the analysed standard's sub-clauses, looking for their similarities and differences,
2. perform and record a review of understanding regarding the requirements contained in sub-clauses 4.2.3 and 4.2.4 of ISO 9001:2008, using the table below:

FORM 07 Comparison of requirements for control of documents and records

According to ISO 9001:2008 the mentioned documented procedures shall define type of control in relation to some of the following aspects:

No	Aspect (briefly described)	It must be regulated in a documented procedure for control of documents	It must be regulated in a documented procedure for control of records
1	Approval prior to issue		
2	Review and re-approval		
3	Changes and status - identified		
4	Available at point of use		
5	When external – identified and controlled		
6	When obsolete – prevention of unintended use		
7	When obsolete and retained – application of suitable identification		
8	Legible – all the time		
9	Readily identifiable – all the time		
10	Readily retrievable – all the time		
11	Identification		
12	Storage		
13	Protection		
14	Retrieval		
15	Retention		
16	Disposition		

5.4.2.STEPS FOR PROJECT PREPARATION

For the set-up micro-enterprise established for the purpose of your group's project:

STEP 13: Try to describe (using MEP TEMPLATE 02 from page 65 or a similar template) and develop two separate but general flow charts:

- the first – for the "control of documents" process,
- the second – for the "control of records" process,

taking into account the size and structure of the organization as well as compliance of these two processes with the previously developed map of processes.

STEP 14: Additionally, if it is needed, adjust the previously prepared items (description of your micro-enterprise, its map of processes, descriptions and detailed flow charts of the selected main processes) to ensure the consistency of developed QMS description including the two developed processes: control of documents and control of records.

5.5. Subject 05: Written procedure and quality manuals

To begin, study subchapters: 4.6 “Some technical aspects of quality management systems’ documentation” and 4.5.1 “Requirements in clause 4 titled “Quality management system”” and find more information about quality management system’s procedures (especially a procedure of document control and a process of records control), at sources chosen by you from well known quality management literature.

The author suggests you to study on-line some examples of real procedures, e.g. the following available on:

- CogniDox Ltd, Quality Procedure “Control of Documents” for FablessSemi, http://www.cognidox.com/component/cognidox/?view=categories&id=153 [10.08.2010]
- ITI LIMITED, NETWORK SYSTEM UNIT IN BANGALORE, Quality System Procedure Control Of Records, issue no. 1, 180.151.36.4/nsu/iso/3-NSUQSPCR.pdf [15.09.2010]
- Lew Stoops, Quality Management-Quality Systems-Chapter3, Pearson Education 2009, http://lewstoops.com/powerpoints/QCTC1343/03%20Quality%20Systems.ppt [15.09.2010]
- VOLTERA Quality Manual publicly available on the Internet: http://www.volterra.com/vQuality/showpdf_public.php?name=quality/Volterra_quality_manual_extranet.pdf [10.01.2010]
- ASPEN TECHNOLOGIES Quality Manual publicly available on the Internet: http://www.aspentechnologies.com/files/hksjnja8h8.pdf [10.01.2010]

Think what computer program you will use for writing your procedures and choose the one which should be available to use in almost every micro-enterprise.

In this subchapter you will find one introductory exercise (with one ‘ready to use’ FORM) and two steps for preparation of the project (with reference to one ‘ready to use’ MEP TEMPLATE).

5.5.1.INTRODUCTORY EXERCISES

EXERCISE 5.5.1-1

Once more study the requirements of ISO 9001:2008 for control of documents (sub-clause 4.2.3) and control of records (sub-clause 4.2.4):

1. paying attention to the relationship between the requirements included in the analysed standard's sub-clauses, and
2. looking for elements important for choosing a format for procedures, a quality manual and forms.

5.5.2.STEPS FOR PROJECT PREPARATION

For the set-up micro-enterprise established for the purpose of your group's project:

STEP 15: Try to discuss, choose and develop the best format for your procedures, forms and quality manual, taking into account the size and structure of the organization as well as compliance with the previously developed map of processes.

STEP 16: Try to write your procedure titled „Control of documents", using the chosen format and the previously developed flow chart of this document's control process, taking into account the size and structure of the organization as well as compliance of this procedure with the previously developed flow chart of document control and map of processes.

STEP 17: Try to write your procedure titled „Control of records", using the chosen format and the previously developed flow chart of this record's control process, taking into account the size and structure of the organization as well as compliance of this procedure with the "Control of records" procedures and with the previously developed flow charts and map of processes and organization's structure.

STEP 18: Additionally, if it is needed, adjust the previously prepared items (description of your micro-enterprise, its map of processes, descriptions and detailed flow charts of the selected main processes and documentation control processes) to ensure the consistency of developed QMS description including the two developed procedures: control of documents and control of records.

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