

A MODEL OF TRANSITION FROM QUALITY MANAGEMENT SYSTEMS TO KNOWLEDGE MANAGEMENT SYSTEMS IN SOFTWARE DEVELOPING ORGANIZATIONS

Abstract:

The paper is aimed at presenting a model of transition from quality management systems to knowledge management systems in software developing organizations. The methodology focuses on presenting components of the model of transition from quality management systems to knowledge management systems. The paper defines the model of transition from the quality management systems conformable with series 9000 ISO international standards supplemented with ISO/IEC 90003:2004 to knowledge management systems. The model consists of four processes and five elements treated as the results of the process implementation. The paper demonstrates how quality system elements can be useful in the implementation of knowledge management system processes, such as localisation and the acquisition of knowledge.

Keywords: knowledge management, knowledge localisation, knowledge acquisition, quality management systems, software developing organisation.

1. Introduction

The importance of software to the contemporary civilisation is not called into question [Chaodong et al. 2011]. Numerous opinions in favour of the above thesis can be found in the literature on the subject. Especially D. Hamlet and J. Maybee's opinion [Hamlet, Maybee 2001] is worthy of notice: they say that software is undoubtedly the most interesting engineering product ever invented. They add that software is free of nearly all the limitations of the physical world, and therefore it is capable of working "evident wonders". It is worth noticing that once software is designed and implemented, its duplicating is not an expense. Software does not get used up and, basically, it can excellently solve most difficult problems.

From among different software features, the following deserve special attention:

- Software consists almost entirely of knowledge, as regards both the process of software creation (the manner in which methodology and tools are used) and use [Davenport, Prusak 2005];
- Software is an intangible asset. The magnetic carrier which the software and the user's documentation, if any, have been recorded on, is basically the only material element of the software – insignificant with respect to costs. It is incomparably less

valuable than the software itself [Bontis 1999];

- Customers acquire software for the benefits they can derive from exploiting it. The benefit that deserves special attention is the knowledge obtained from the description of material objects by means of the data which are subsequently transformed into information applied for decision-making [Soini 2007; Yeung 2011];
- Software enables the transfer of knowledge to the entity which has acquired software and intends to exploit it. The knowledge gathered by software designers consists, for instance, in identifying material objects (e.g. employees), proposing a description of the objects by means of relevant categories (e.g. surname, forename, time card number in the work time recording system) and values assigned to the descriptive categories (e.g. Smith, John, 346).

Software should also be a carrier of good quality; this feature can be furthered by a properly designed, implemented, maintained and constantly improved quality management system [Kan, Basili, Shapiro 1994; Kukko, Helander, Virtanen 2008].

The analyses of the available literature on the subject, as carried out by the author, as well as observations of numerous software developing organisations, substantiate the following conclusion: **a majority of SDOs (Software Developing Organizations) have a QMS (Quality Management System) but they usually do not have a KMS (Knowledge Management System)** [Alavi, Leidner 2001].

This conclusion reflects a certain contradiction. Software, as a result of the work conducted by an SDO, is entirely composed of knowledge, whereas formally, the SDO does not have a KMS.

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2. Notes on the definitions

At this point, at least five terms must be specified in detail. These are: knowledge, software developing organisation, knowledge management and knowledge management system, quality management system.

It has been assumed for the purpose of the paper that software is developed and maintained by a specialised organisation, i.e. a software developing organisation (SDO). Each organisation that realises at least one of the elements of the software life cycle [Firesmith1993] can be classified as a software developing organisation.

Various definitions of knowledge can be found in the literature on the subject. Without going into detail, the following definitions have been adopted for the purpose of the paper:

- knowledge, as defined by Bellinger et al. [Bellinger, Castro, Mills 2012], is a collection of information gathered for a particular purpose, intended to be useful [Batra 2010],
- knowledge management is a practice that finds valuable information and transforms it into necessary knowledge critical to decision-making and action [Van Beveren 2002],

- knowledge management system means processes aimed at finding valuable information. They can include localising, acquiring, developing, sharing, using, and maintaining [Probst, Raub, Romhardt 2002],
- quality management system is a management system (set of interrelated or interacting elements to establish policy and objectives and to archive those objectives) to direct and control an organization with regard to quality [ISO 9000:2000; Stelzer, Mellis, Herzwurm 1997].

3. The model of transition from a QMS to a KMS in an SDO

The transition from a QMS to a KMS in an SDO has been presented in the form of the model shown in Figure 1. The model also includes a method of its verification.

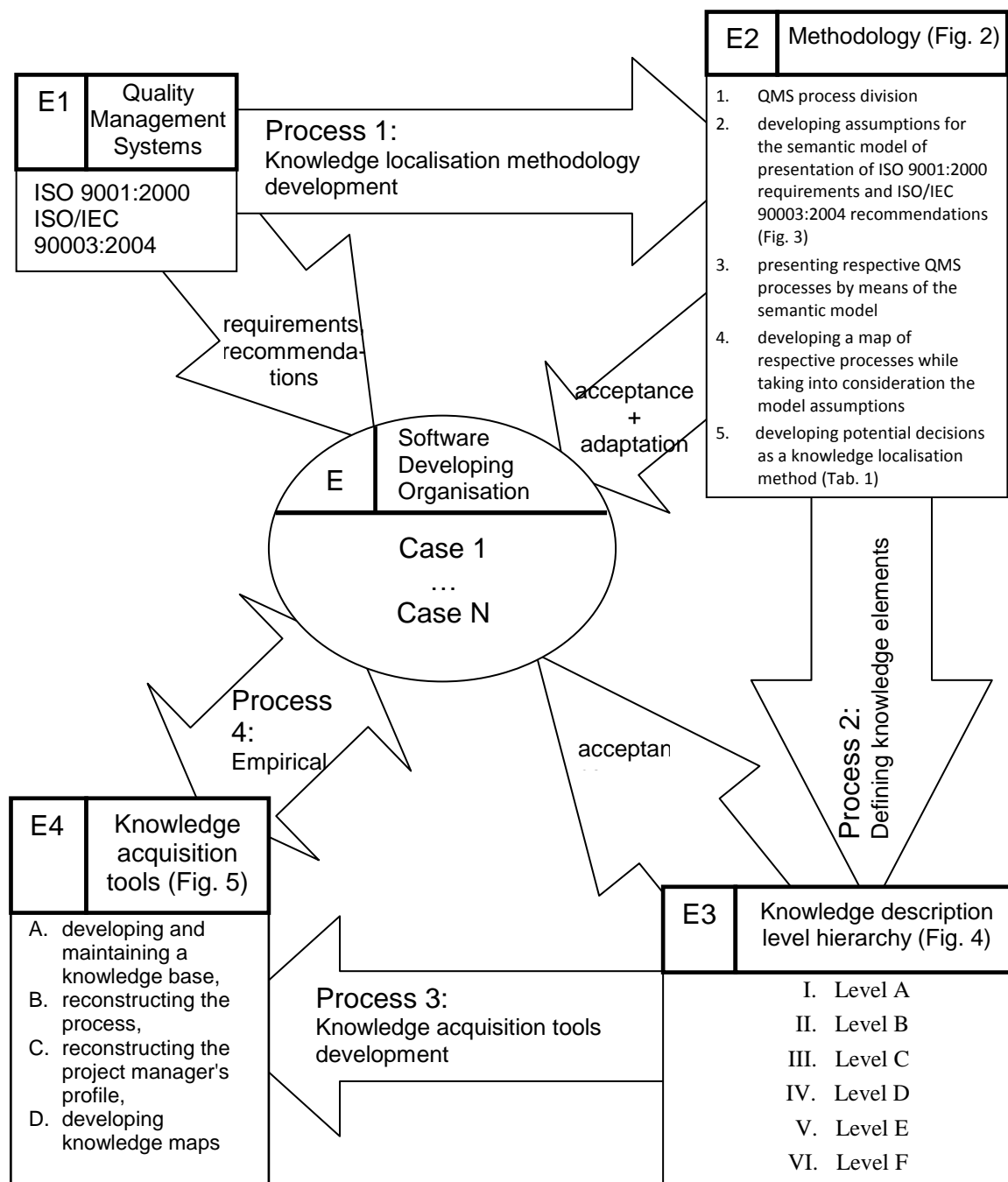


Figure 1. The model of transition from a QMS to a KMS in an SDO along with the model verification

Source: own elaboration.

The model is the author's own concept.

It consists of five elements – results (E1, E2, E3, E4, E5) and four processes (P1, P2, P3, P4). The processes are sets of activities that enable obtaining effects in the form of the indicated elements. Below, designations and names of the processes are indicated as well as the results (elements) obtained in the course of the processes. These are:

Process 1 – Developing a methodology of knowledge localisation. The process allows

to develop a methodology composed of five stages (Figure 2).

Process 2 – Defining knowledge elements. The process allows to define six elements of the hierarchy of knowledge description levels (Figure 4).

Process 3 – Developing knowledge acquisition tools. The process allows to develop four knowledge acquisition tools (Figure 5).

Process 4 – Empirical research. The process defines the method of conducting the empirical research that allows to verify the assumptions made. It constitutes a separate issue which is not a subject of this paper and thereby will not be discussed here.

4. Results in the model of transition from a QMS to a KMS in an SDO

Below are presented characteristics of the five elements of the model of transition from a QMS to a KMS in an SDO.

4.1. Quality Management Systems – E1

We have made use of the requirements indicated in ISO 9001:2000 as well as the recommendations related to the standard application in respect of the SDO as presented in ISO/IEC 90003:2004 [ISO/IEC 90003:2004].

4.2 . The methodology of localisation of knowledge in an SDO – E2

The methodology is oriented to undertaking activities which transform the QMS (quality management system) into a frame of the KMS. Suppositions that such activities are possible have appeared in the literature on the subject [Cieśliński, Perechuda, Witkowski 2005; Jashapara 2006]. The methodology is presented in Figure 2.

The article presents an outline approach to creating a KMS in the SDO, however only with regard to the QMS. This is a result of the author's many years of experience as a designer, programmer, implementation organizer and project manager in SDOs. Another field of his experience is work related to designing, documenting and implementing quality management systems (QMS) for Polish and foreign companies fulfilling the requirements of the SDO definition as quoted above.

The requirements that the above outline approach should meet may be reduced to the following elements:

- a) it refers to the idea of quality management systems (QMS) as reflected in ISO international standards since these standards are most frequently the base for designing, documenting, implementing and maintaining quality management systems. The QMS is defined as a management system (a system for setting policies and objectives as well as achieving the objectives) intended for running an organization (a group of people and infrastructure with responsibilities, authorities and relations assigned) and supervising it with regard to quality,
- b) it links the QMS, through ISO standards, with standard specifications in the form of all types of guidelines related to the SDO,
- c) it makes it possible to localise knowledge in the SDO,

- d) it makes it possible to specify elements of the KMS with the purpose of analysing them,
- e) it makes it possible to analyse elements of the KMS which should contribute to the improvement of the KMS, and this in turn affects the QMS (a delivery of efficient software that meets customers' requirements).

It follows from the requirements, which should be complied with by the outline approach to the KMS formation, that the approach is closely related to the QMS. The above thesis can also be found in publications on the subject in the form of the suggestion that the QMS may be susceptible to the KMS, i.e. it can be a carrier for such a system.

The proposed approach to the KMS formation for the SDO is composed of five stages (see Figure 2). The stages are specified below (along with their characteristics):

Stage 1: Classification of QMS processes.

A starting point for the proposed approach is a classification of QMS processes. They have been divided as follows:

- a) main processes – they apply to product (here: software) realization and reflect the product life cycle as starting from software (product) related requirements specification through requirements reviewing, product realization planning, purchases, production and service delivery and follow up activities,
- b) auxiliary processes – they support the proper functioning of management processes, main processes and auxiliary processes,
- c) management processes – they can be reduced to decisions constituting the QMS as taken by the top management. They can include documentation related requirements and management responsibility which in turn includes management commitment, customer-oriented approach, quality policy, planning, responsibility, authorities, communication, management review,
- d) improvement processes – they include continuous improvement, and preventive corrective activities.

Stage 2: Development of assumptions of a semantic model for the presentation of requirements of ISO 9001:2000 and recommendations of ISO/IEC 90003:2004 (hereinafter called “model”). [ISO/IEC 90003:2004]

The ISO 9001:2000 standard is too general to render the QMS specificity for the SDO. The standard presents the requirements that should be met by an organization (here: SDO) so that the QMS might comply with the standard requirements. The above standard has been expanded through the provision of detailed recommendations. The recommendations are included in ISO/IEC 90003:2004 (Software engineering – Guidelines for the application of ISO 9001:2000 to computer software) [ISO/IEC 90003:2004]. The semantic model should facilitate the application of both the above standards through defining the meaning of the contents of specific elements of the standards. They have been divided into the following groups:

- a) postulates, i.e. demands or requirements, and
- b) questions, i.e. issues that should be additionally considered and, if possible, resolved.

Both the postulates and the questions can be attributed with different meanings of the attached contents (extensions) as provided by the ISO 9001:2000 standard and the ISO/IEC 90003:2004 recommendations [ISO/IEC 90003:2004]. Those extensions may refer to:

- a) the proposed method of realization,
- b) specification of the scope,
- c) additional notes as regards the realization method,
- d) examples,
- e) references to other sections of ISO 9001:2000,
- f) references to other standards.

For individual sections of the ISO 9001:2000 standard and the related recommendations, the above extensions may occur in different numbers (e.g. several methods of specifying the scope, several examples, etc.) and with different intensity (e.g. only examples are given, or a number of realization methods, or some additional notes, or references to a standard other than ISO 9001:2000 are also provided). All the relations in the semantic model as described above are shown in Figure 3.

Stage 3: Presentation of individual QMS processes by means of a semantic model.

Using the model potentialities, individual QMS processes can be presented. More information on the subject can be found in some books [e.g. Chrabański, Gwioździk, Kostka-Bochenek 2007].

Stage 4: Working out of maps of individual processes while taking into account the model assumptions.

The key to the figure consists of markings of the icons applied. The process map presents in a one place a selected process in an abbreviated form, thus enabling the process analysis.

Stage 5: Working out the potential decisions as a method for knowledge localisation.

The process map prepared for reviewing the design and development process, as complying with the requirements of ISO 9001:2000 and recommendations specified in ISO/IEC 90003:2004 [ISO/IEC 90003:2004], will be used for linking the QMS with the KMS. Assuming that the key knowledge management processes include: knowledge localisation, knowledge procurement, knowledge development, knowledge sharing, knowledge dissemination, knowledge utilization, knowledge maintenance [Probst, Raub, Romhardt 2002], the hypothesis can be proposed that it is possible to elaborate the localisation of knowledge in an SDO that applies the QMS – an example of a key knowledge management process – provided that potential decisions to be taken by the implementing team are previously defined [Kisielnicki 2003].

Table 1 (appendix) presents potential decisions for selected model elements (section 7.3.2 and 7.3.3).

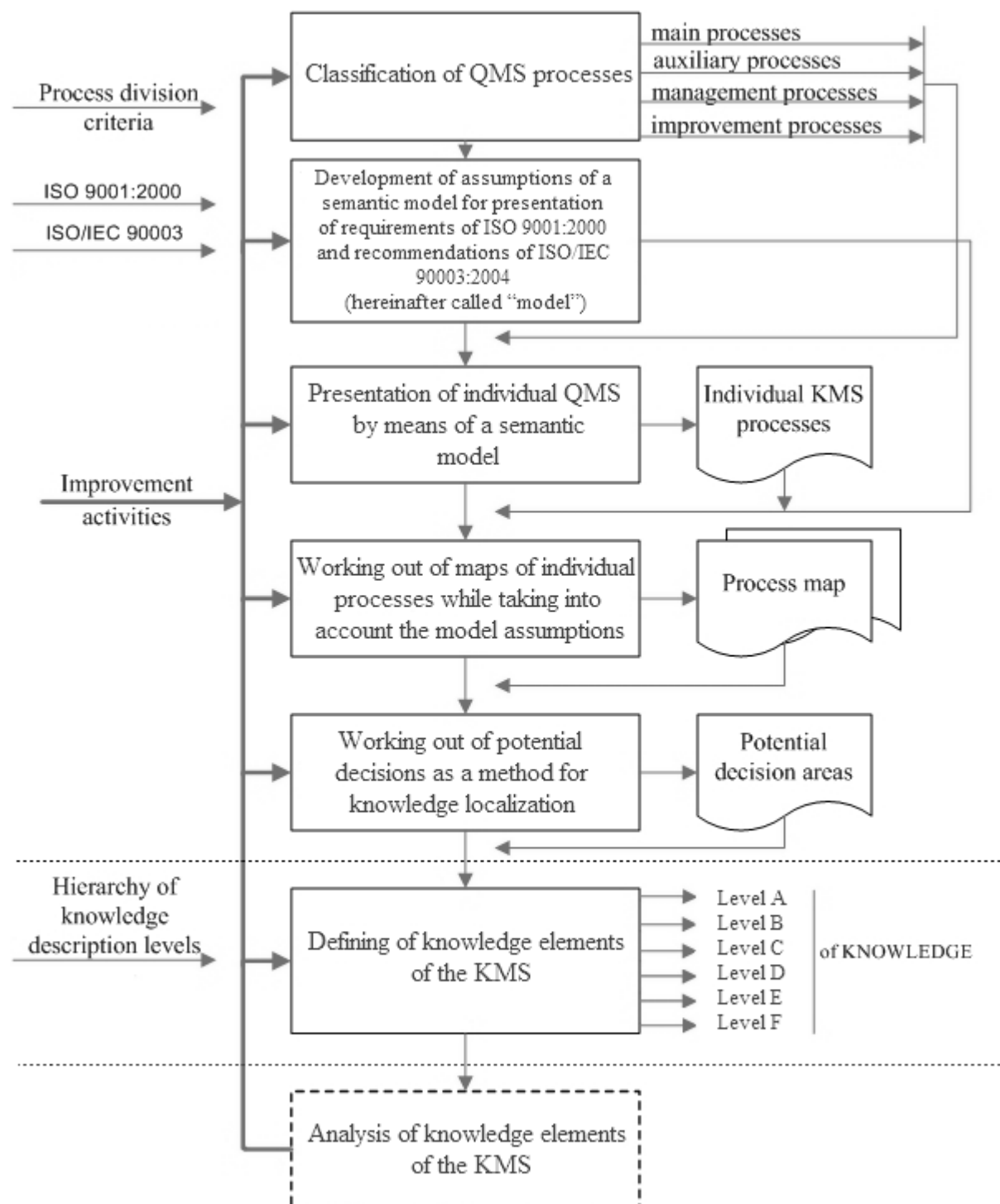


Figure 2. Elements taken onto account when specifying the method of constructing a KMS for SDOs that apply a QMSs

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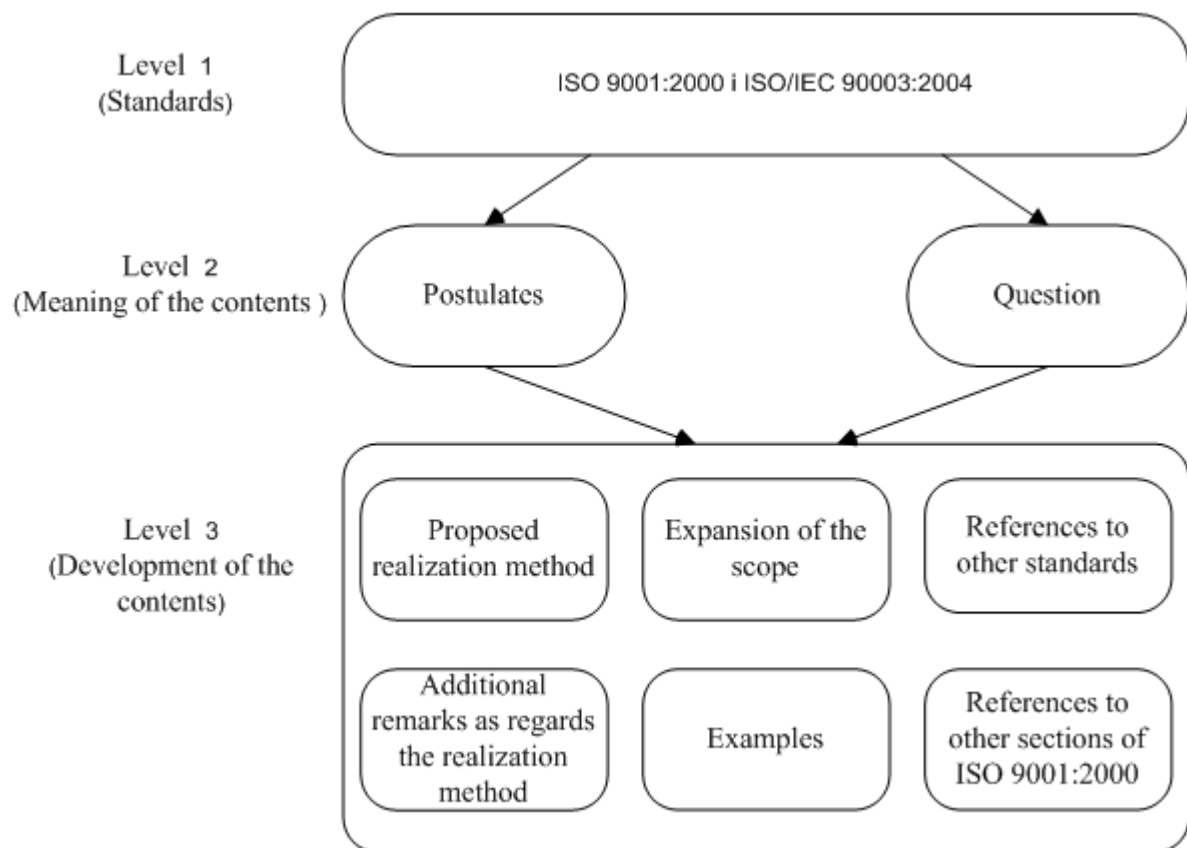


Figure 3. Relations between semantic model levels

Source:

4.3. Knowledge description level hierarchy – E3

Based on the standard structure, six levels of knowledge description have been indicated. The whole hierarchy is presented in Figure 4.

The structure of processes related to design and development includes the following elements:

Level A: Basic processes

Level B:

- 1) Planning of product realization – 7.1
- 2) Customer related processes – 7.2
- 3) Design and development – 7.3
- 4) Purchasing – 7.4
- 5) Production and service provision – 7.5

Level C (for 7.3):

- 1) Design and development planning – 7.3.1
- 2) Design and development inputs – 7.3.2

- 3) Design and development outputs – 7.3.3
- 4) Design and development review – 7.3.4
- 5) Design and development verification – 7.3.5
- 6) Design and development validation – 7.3.6
- 7) Control of design and development validation – 7.3.7

Level D (for 7.3.1):

- 1) Design and development planning – 7.3.1.1
- 2) Review, verification and validation – 7.3.1.2
- 3) Responsibilities and authorities – 7.3.1.3
- 4) Interfaces – 7.3.1.4

Level E (only 7.3.2 and 7.3.3): Potential decision areas (Table 1) for 7-3-2 (1 to 9) and for 7.3.3 (10 to 22)

Level F: Decisions taken

Only 7.3.2 and 7.3.3 have been selected for further analyses.

Below, the postulates and questions related to processes of development planning and design are presented. They are confined, however, only to that part only which pertains to design inputs (7.3.2) and design outputs (7.3.3). These are:

Postulate 1 (ISO 9001:2000, p. 7.3.2 – Design and development inputs): Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include (the below data are to specify in detail the scope):

- a) functional and performance requirements,
- b) applicable statutory and regulatory requirements,
- c) where applicable, information derived from previous similar designs, and
- d) other requirements essential for design and development.

Postulate 2 (ISO 9001:2000, p. 7.3.2 – Design and development inputs): These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

Question 1 (ISO/IEC 90003, p. 7.3.2 – Design and development inputs): In system architectural design, system requirements are allocated to hardware, software components and manual operations. The inputs to software requirements analysis are the system requirements allocated to software and specifications of the interfaces between the system components.

Question 2 (ISO/IEC 90003, p. 7.3.2 – Design and development inputs): Design and development input may be determined from functional, performance, quality, relevant safety and security requirements and system design constraints, or derived through techniques such as prototyping. Design and development input may also be determined from design change requests originating from previous phases in the iterative development model (cycle), problems to be fixed, or requirements arising from acceptance criteria. Input may also come from contract review activities.

Question 3 (ISO/IEC 90003, p. 7.3.2 – Design and development inputs): When design and development input documents are being reviewed (this often happens in conjunction with the customer), they should be checked for (the below points are additional comments on the implementation method):

- a) ambiguities and contradictions,
- b) inconsistent, incomplete or non-feasible information or requirement,
- c) unrealistic performance specifications,
- d) requirements that cannot be verified or validated,
- e) unstated or assumed requirements,
- f) inaccurate description of user environment and actions,
- g) lack of design and development decisions in a requirements document,
- h) omissions of key performance measures.

Postulate 3 (ISO 9001:2000, p. 7.3.3 – Design and development outputs): The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.

Postulate 4 (ISO 9001:2000, p. 7.3.3 – Design and development outputs): Design and development outputs shall (the following data are to specify in detail the scope):

- a) meet the input requirements for design and developments,
- b) provide appropriate information for purchasing, production and for service provision,
- c) contain or reference product acceptance criteria,
- d) specify the characteristics of product that are essential for its safe and proper use.

Question 4 (ISO/IEC 90003, p. 7.3.3 – Design and development outputs): The output of the design and development process should be defined and documented in accordance with the prescribed or chosen method.

Question 5 (ISO/IEC 90003, p. 7.3.3 – Design and development outputs): The output should be complete, accurate and consistent with the requirements, and may be produced using computer design and development tools.

Question 6 (ISO/IEC 90003, p. 7.3.3 – Design and development outputs): Design and development outputs may be expressed in textual form, by diagrams or using symbolic modelling notation, and may include (the following data have the status of means of specifying the scope):

- a) design, development and test specifications,
- b) data models,
- c) pseudo code or source code,
- d) user guides, operator documentation, training material, maintenance documentation,
- e) development product,

f) formal methods.

Question 7 (ISO/IEC 90003, p. 7.3.3 – Design and development outputs): Prototyping, when used, should result in design and development (output) documentation.

Question 8 (ISO/IEC 90003, p. 7.3.3 – Design and development outputs): The acceptance criteria for design and development outputs should be defined in order to demonstrate that the inputs to each design and development stage are correctly reflected in the outputs.

Question 9 (ISO/IEC 90003, p. 7.3.3 – Design and development outputs): Tools should be validated for their specific intended use (see 7.3.6 and 7.6).

4.4. Knowledge acquisition tools – E4

Figure 4 presents knowledge acquisition tools. They have been selected from the point of view of new forms of organisations, such as learning, virtual, and intelligent organisations, etc.

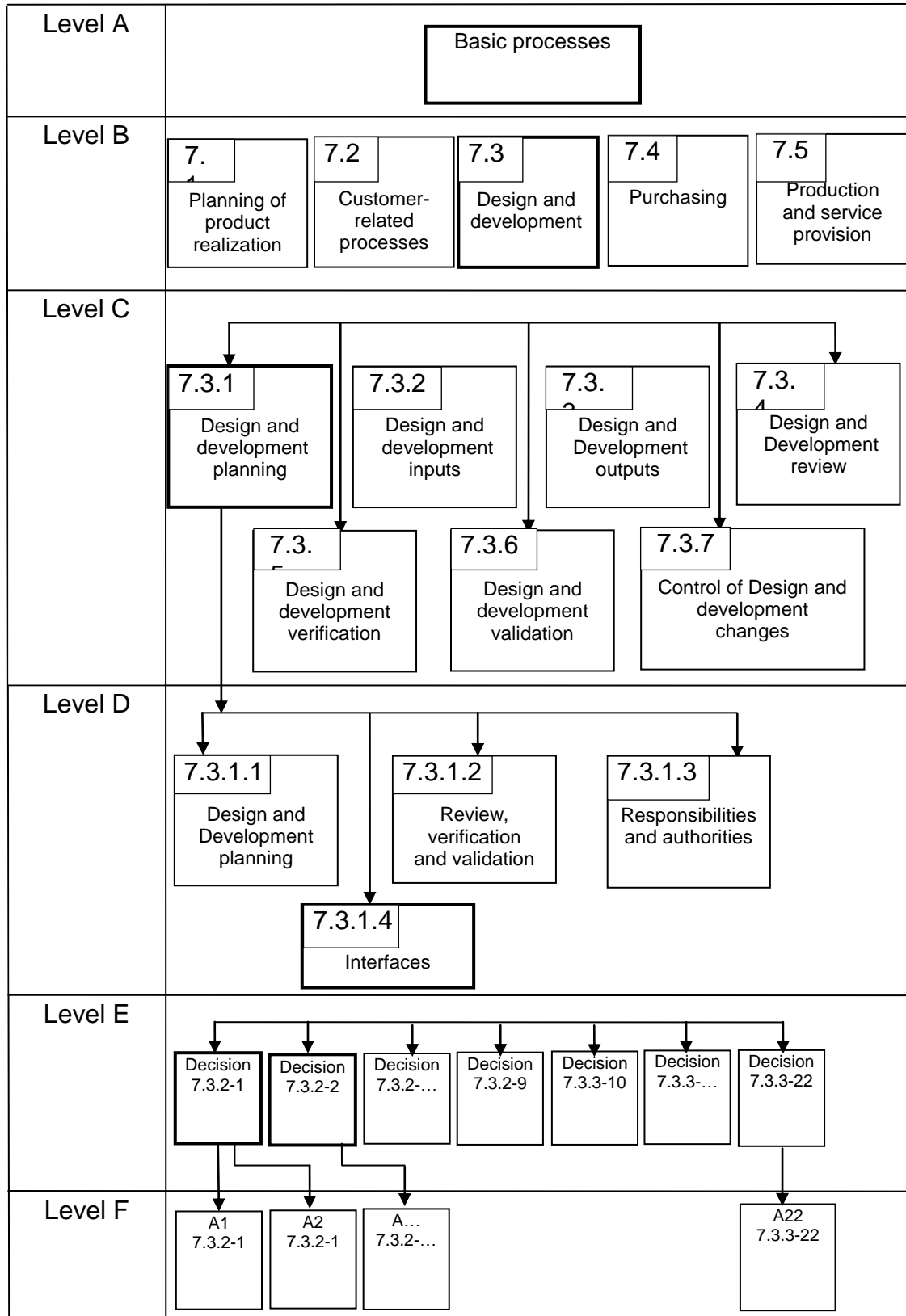


Figure 4. Defining knowledge elements in software developing organisations with the application of the knowledge description level hierarchy

Source:

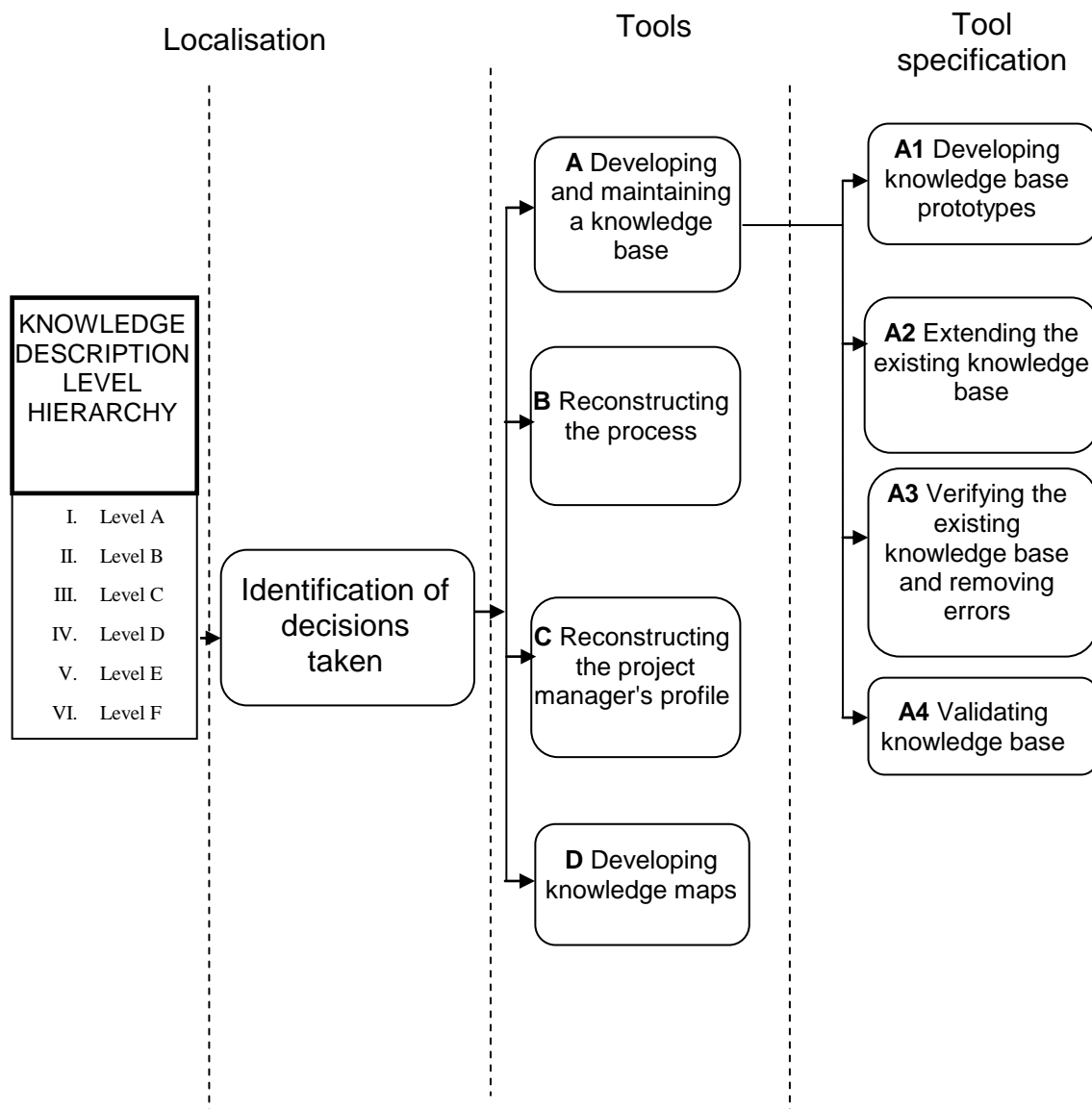


Figure 5. Tools for localising and acquiring knowledge from the point of view of new forms of an organisation

Source:

Knowledge in the SDO is localised by potential decision areas and decisions taken, whereas knowledge acquisition is carried out with the application of the following four tools (Figure 5). They are characterised below.

Developing and maintaining a knowledge base

According to the knowledge description level hierarchy (Figure 4), level F, knowledge atoms (proper decisions – settlements) are a specific "charge" to the knowledge base. They can be supplied in knowledge atoms in different ways, and also in the course of realisation of respective undertakings (projects) or after the performance of specific works. Certainly, the knowledge bases so created are subject to the constant

verification of their contents from the point of view of their usefulness, at least in respect of projects currently conducted or, if need be, those prepared for implementation in future (i.e. offered, negotiated, etc.). The assessment of knowledge atoms can be formal and it can also contain subjective elements. They can become a component of the notion of validation. It should be noticed that the contents of knowledge bases which will prove to be useless will be erased. Activities related to the tool application produce the result in the form of filled up knowledge bases. They are applied in such processes as introducing, erasing, etc., which are of a continuous nature. The factors they apply to activate the indicated processes (including those of acceptance or rejection) have features of the collective learning process. It starts with the question whether or not the criteria have been properly selected and whether the knowledge base has been completed as a result of the criteria application.

The organisation's employees are motivated to introduce (fill up) knowledge bases. They expect that it will be profitable from the point of view of the proper performance of their work in future since they will use the knowledge atoms (settlements) in subsequent projects. They compare the current situation (project – undertaking) with those previously implemented for which definite records have occurred in the knowledge base.

Employees are also motivated by the assessment of the usefulness of the created knowledge base as made on the basis of such criteria as implementation in due time, delivery of a product with specific features which have been agreed upon with the customer, and non-exceeding of the budget appropriated for financing the project. The tools for placing knowledge atoms in knowledge bases created conditions for continuous learning. The tools discipline the organisation's members as regards the method of gaining the "charge", regularity in introducing it (e.g. immediately after the occurrence of a particular event and the related settlement), recalling of the method of operating (introducing, erasing, etc.) knowledge bases, connecting the decisions taken with results of the project (undertaking) conducted.

Process reconstruction

In the course of the research conducted, the author managed to identify 177 potential decisions for the stage of design and development (section 7.3 of ISO 9000:2000). Not all decisions were made by respective decision-makers (participants of the design and development process) in the course of the real process. The said decisions are a specific pattern applied to the actually realised design and development process which takes place in the consciousness of the process participants. It materialises (manifests itself), as it were, in the decision-making process (177 times). The decisions made will allow to reconstruct the design and development process. The process reconstruction is actually possible through analysing the same or similar (approximate) undertakings by different process participants. It is also possible to indicate the most frequently taken decisions. The participants learn from each other by comparing their decisions with those taken by others. They relate their decision to the "group pattern" which has originated as a dominant (the decisions most frequently taken). The participants are motivated to reporting (recalling) – in the reconstruction process – proper (actual) decisions. In subsequent periods the pattern changes, which may result, for instance, from the different experiences of the organisation's members. The pattern may be subject to constant modifications, for instance, through a change of configuration (other arrangements of the same elements). Pattern analysis in

subsequent periods allow to follow the evolution in respect of the reconstruction of the design and development process.

Reconstruction of the project manager's profile

A regular application of the tool consisting in reconstructing the project manager's profile allows to maintain the continuity of learning by project managers (it may be the same manager or a group of persons performing the function). The process consists in recalling and applying the tool (the reconstruction of the project manager's profile) after each project. The project manager's profile obtained is analysed and used for learning purposes, in the first place prior to the time when management of the subsequent project is undertaken. The project manager's profile, when reconstructed, has little chance for duplication (application without any changes in subsequent projects). Due to the learning process, the project manager as an important member of the organisation has an opportunity to develop. However, not all members of the organisation participate in defining the project manager's profile unless the team evaluates the project manager's profile together with other elements (the atmosphere in the workplace, communicativeness, efficiency in achieving aims, etc.). The consciousness of learning is reflected through repeated confrontations of the obtained (defined) profile of the project manager with the results (even partial) of the projects managed.

Developing knowledge maps

Knowledge maps create conditions for the development of the organisation's personnel. They facilitate knowledge dissemination in the organisation, for instance through a convenient form of presentation.

The presented model of transition from a QMS to a KMS in an SDO is a suitable basis for its verification in practice.

5. Summary

Quality management systems are usually designed, documented, implemented and maintained in SDOs, however the organisations do not have knowledge management systems. The author has become interested in the suppositions which occurred during the literature analysis and which suggest the possibility of treating the QMS as a basis for the KMS. The paper presents the model of transition from the QMS to the KMS. The model can be verified empirically. It consists of three processes and four modules – the results of those processes.

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Model przejścia od systemów zarządzania jakością do systemów zarządzania wiedzą w organizacjach wytwarzających oprogramowanie

Streszczenie:

Celem artykułu jest prezentacja modelu przejścia od systemów zarządzania jakością do systemów zarządzania wiedzą w organizacjach wytwarzających oprogramowanie. Metodologia skupia się na zaprezentowaniu komponentów modelu przejścia od systemów zarządzania jakością do systemów zarządzania wiedzą. Artykuł definiuje model przejścia od systemów zarządzania jakością zgodnych z wymaganiami międzynarodowego standardu ISO 9001 uzupełnionymi o zalecenia ich stosowania, które są podane w normie ISO/IEC 90003:2004. Model składa się z czterech procesów i pięciu elementów, traktowanych jako rezultat wdrożenia tych procesów.

W tekście wskazano, jak elementy systemu zarządzania jakością mogą być użyte w implementacji systemu zarządzania wiedzą w takich procesach, jak jej lokalizacja i pozyskiwanie.

Słowa kluczowe: zarządzanie wiedzą, lokalizacja wiedzy, pozyskanie wiedzy , systemy zarządzania jakością, organizacje wytwarzające oprogramowanie.

Appendix

Table 1. Level E of the knowledge description hierarchy intended for the knowledge localisation in the SDO for level B (design and development – 7.3) and level C, i.e. design and development inputs (7.3.2) and design and development outputs (7.3.3)

No.	MODEL ELEMENT	POTENTIAL DECISIONS LOCALISING KNOWLEDGE IN THE SDO
1.	Postulate 1 (7.3.2)	1. Inputs relating to product requirements shall be determined and quality records maintained – in respect of functional and performance requirements
		2. Inputs relating to product requirements shall be determined and quality records maintained – in respect of applicable statutory and regulatory requirements
		3. Inputs relating to product requirements shall be determined and quality records maintained – information derived from previous similar designs
		4. Inputs relating to product requirements shall be determined and quality records maintained – other requirements essential for design and development
2.	Postulate 2 (7.3.2)	5. Design and development inputs shall be complete
		6. Design and development inputs shall be unambiguous
		7. Design and development inputs shall not be in conflict with each other
3.	Question 1 (7.3.2)	8. Determination of the system requirements allocated to software and specification of the interfaces between the system components for the purpose of software requirement analysis
4.	Question 2 (7.3.2)	9. Determination of design and development input (e.g. on the basis of functional, performance, quality, relevant safety and security requirements, system design constraints, derived through prototyping techniques, design change requests originating from previous phases in iterative development model, problems to be fixed, or requirements arising from acceptance criteria, etc.)
5.	Postulate 3 (7.3.3)	10. The outputs of design and development shall be provided in a form that enables verification against design and development input

		11. The outputs of design and development shall be approved prior to release
6.	Postulate 4 (7.3.3)	12. Design and development outputs shall meet the input requirements for design and development
		13. Design and development outputs shall provide appropriate information for purchasing production and for service provision
		14. Design and development outputs shall contain or reference product acceptance criteria
		15. Design and development outputs shall specify the characteristics of the product that are essential for its safe and proper use
7.	Question 4 (7.3.3)	16. Determination whether the outputs from the design and development process are defined and documented in accordance with the prescribed and chosen method
8.	Question 5 (7.3.3)	17. Determination whether the outputs from design and development are complete
		18. Determination whether the outputs from design and development are accurate and consistent with the requirements
9.	Question 6 (7.3.3)	19. Determination of the form of expressing design and development outputs, e.g. a text, a diagram, a symbolic modelling notation (e.g. data models, pseudo code or source code, etc.)
10.	Question 7 (7.3.3)	20. Determination whether design and development documentation has been worked out for the prototyping applied
11.	Question 8 (7.3.3)	21. Defining of acceptance criteria for design and development in order to demonstrate that the inputs to each design and development stage is correctly reflected in the outputs
12.	Question 9 (7.3.3)	22. Have the tools been validated for their specific intended use?

Source: own elaboration.