

# Towards ISO 9001:201X: Transitioning from process quality to product quality

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**Abstract:** This paper seeks to develop the foundations for a set of technical practices that address the process activities implied in ISO 9001 requirements. The activities of the process reference model are identified by examining the ‘unpacked’ requirements. It is demonstrated that many practices in the process reference model are ‘implicit’ in ISO 9001 requirements, rather than ‘explicit’. This fact accounts for the perceived weakness of many ISO 9001 conformity audit results, and consequently ineffective management systems implementations.

**Keywords:** ISO 9001:2008, process reference models

## 1. Introduction

The stated intent of ISO 9001 [1] is to present ‘requirements for quality management systems’. The Standard requires users to:

‘determine and manage numerous linked activities. An activity or set of activities using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the “process approach”.

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.’ ISO 9001:2008 0.2

Notwithstanding this intent, ISO 9001 provides little support for identifying the technical foundations of the processes that it identifies.

The project reported upon in this paper attempts to identify the processes (overtly and covertly identified in the Standard) and the technical foundations of these processes.

Standards outside of the domain of ISO TC 176 are applied for this purpose, notably ISO/IEC JTC1 SC7 ISO/IEC 24774 (System and software engineering – Life Cycle Management – Guidelines for process definition) [6].

## 2. Intent of this mapping exercise

### 2.1 Intent 1: identify the ‘missing’ process activities

The primary goal of this ISO 9001 process reference model (PRM) is to identify the technical elements of processes that address the intent of the Standard. ISO 9001 in its published form does not satisfy this objective for many of its processes.

Example: Design activities are implied in ISO 9001, but nowhere in the Standard does it explicitly identify what the technical activities are that are associated with design.

Example: Audit: In contrast to the design process, the activities associated with an Audit process are well described.

### 2.2 Intent 2: Identify the ‘missing’ informational items associated with these processes

ISO 9001 famously identifies six procedures that need to be documented. This requirement has been widely used for marketing purposes as to how ‘easy’ it is to implement such a management system.

The analysis presented in this report identifies a large additional number of ‘information items’ that are needed to support process activities.

In most cases, the need for these items is overlooked in management system audits.

### 2.3 Intent 3: Identify the ‘missing’ process(es) associated with the management of the enterprise.

All the published management systems standards (e.g. ISO 9001, ISO 14001, ISO/IEC 20000-1, ISO/IEC 27001) stop short of identifying the process that is 'parent' (or basic) to the processes listed in the referenced standard.

This basic process is the missing element that is necessary for the coherence of all management system activities.

### 3. The nature of the processes in the process reference model

The following content attempts to clarify the basic concepts regarding the purpose and intent of a process reference model.

#### 3.1 How the processes are described in the process reference model

All the processes are described using the approach identified in ISO/IEC 24774, as follows:

##### 3.1.1 Process name

The title of a process is a short noun phrase intended to summarize the scope of the process, identify the principal concern of the process, and distinguish it from other processes within the scope of a process model.

##### 3.1.2 Process purpose

The purpose of the process is stated as a high level, overall goal for performing the process. In cases where processes might be thought to overlap, the purpose should be used to characterize the scope or bounds of the process.

##### 3.1.3 Process outcome

An outcome is an observable result of the successful achievement of the process purpose. Outcomes are measurable, tangible, technical or business results that are achieved by a process, for example the results that are used by other processes. Outcomes are observable and assessable.

#### 3.2 Identifying process outcomes from management system requirements

The analogy of a jigsaw puzzle will be used for this purpose.

##### 3.2.1 The requirements support all the process outcomes.

Figure 2.1 shows a puzzle with all the pieces present.



Figure 2.1 An analogy – a process where all the outcomes are traceable to requirements in the Standard

An example is the Human Resource Management process in ISO 9001. There are quality management system requirements that support all the indicated outcomes.

Other processes where all the outcomes are traceable to requirements include: Measurement, MS Establishment and Maintenance, Product Changes, Product Procurement, and Supplier Evaluation and Selection.

3.2.2 The requirements support a limited number of process outcomes.

Figure 2.2 shows the puzzle with some pieces missing.



Figure 2.2 A process with limited number of outcomes supported by requirements in the Standard

This is analogous to the more general situation in ISO 9001. Many processes are identified, but their technical foundations (i.e. practices) are not.

An example of a process with an outcome not supported by the requirements is the Audit process, where the outcome ‘nonconformities are communicated to those responsible for corrective action and resolution’ is not specifically addressed in the Standard. A reaction by the reader to this outcome could be – ‘well – this is obvious and does not need to be stated’. What is obvious in one situation may well not be obvious in another situation.

The outcome ‘nonconformities are communicated to those responsible for corrective action and resolution’ is included in the outcome list for the Audit process since it is required by other process standards (e.g. ISO/IEC 20000-1).

3.2.3 Requirements do not support any of the process outcomes.

Example: Product Design: Clearly, a process for product design is needed, but none of the requirements in ISO 9001 actually indicates that a product design is accomplished.

There are two essential outcomes for a product design process:

- a design for each product component is developed; and
- external and internal interfaces for each product component are defined.

If either (or both) of these outcomes are missing, product design cannot be said to be implemented.

3.3 Information items that support process outcomes

3.3.1 About ‘information items’

A ‘work product’ is defined ISO/IEC 15504-1 3.55: an artefact associated with the execution of a process.

ISO 9000 refers to ‘documents’ and ‘records’.

Document: ISO 9000: 3.7.2 information and its supporting medium.

Record: ISO 9000: 3.7.6 Document stating results achieved or providing evidence of activities performed.

An ‘information item’ isolates the ‘information’ from the ‘supporting medium’.

What we are interested in in management systems is the information content – the ‘what’ of the artifact – not the ‘how’ of the storage and representation, and preservation methods.

### 3.3.2 Identifying the information items

The questions to be asked in process execution are:

- a) ‘what are the results of the execution of the process’ and secondly,
- b) ‘what inputs are required by the process to produce the required results’?

Some process outputs are overt in the stated requirements.

For example: ISO 9001: 7.2.1: The organization shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities.

An obvious implication is that there is an output ‘customer requirements’ that lists the informational content of what the customer wants.

For example: ISO 9001: 7.3.3: Design and development outputs shall a) meet the input requirements for design and development.

This is a ‘covert’ reference to a design result, which might be taken to be ‘product design’ and/or ‘product interface specification’.

Clearly, the auditor will need to have domain specific knowledge in order to be able to ask the right questions regarding the basis of the ‘good practice’ content used for product designs and product interface specifications.

## 4. Approach used to develop this Process Reference Model

In order to provide a rigorous foundation to demonstrate the conformity of the process outcomes to the requirements of the ISO 9001 management system standard, the following methodology has been used:

- a. Prepare a list of unique and traceable requirements from the ISO 9001 sub-clauses. To achieve this the sub-clauses have to be ‘unpacked’ i.e. where the requirement as presented in the Standard has more than one ‘shall’ implication, the sentence is split up into as many statements as is needed to ensure that each requirement is unique and singular in its intent.
- b. For each process identify the outcomes: Compare the requirements to the outcomes and develop, update or modify the outcomes to i) ensure that only the technical practices associated with this process are implied; ii) identify the requirements that will have to be satisfied by outcomes of a process other than the one of interest.
- c. Link each requirement to an outcome: Link the set of requirements to outcomes of processes, starting with the process which is the subject of interest.
- d. Identify the information items from the requirements: Parse the requirements to identify overt or covert references to information items to be created, transformed or stored. Identify these as unique information items.
- e. Link each outcome to one (or more) information items: Link the set of information items to outcomes of processes, starting with the process which is the subject of interest.
- f. Confirm requirements coverage: Confirm that all requirements and all information items have been treated, and all process outcomes are linked.

## 5. Comments on processes in the process reference model

Reference	Process Name	Comments
01	Audit	The scope of this process is entirely contained in 8.2.2.
02	Configuration Management	The need for this process is implied by certain requirements, notably in subclauses 7.5.1, 7.5.3, and 7.5.5.
03	Customer relationship management	There are references to ‘customer’ scattered throughout ISO 9001, which consequently lack focus. This process is an attempt to pull together the various strands of the concern for the customer’s interests into a single process.

Reference	Process Name	Comments
04	Equipment management	This process that embraces more than measuring devices – it considers the larger picture of the management of equipment – especially equipment applied to monitoring and measuring of processes and product.
05	Human resource management	This process restricts attention to the provision of competent personnel to the enterprise.
06	Improvement	This process is relatively unfocussed in ISO 9001. This process attempts to consolidate this focus.
07	Information item management	Blends together the intent of the sub-clause 4.2, and pull together the many references to 'documented' in the Standard.
08	Infrastructure and work environment	Addresses the needs of sub-clauses 6.3 and 6.4.
09	Management review	Attempts to pull together the intents of sub-clauses 5.1, and 5.6
10	Measurement	Pulls together the intents of many requirements addressing the need for measurement and the analysis of results.
11	MS establishment and maintenance	Is the process for implementing the processes of the management system.
12	Organisational leadership and management	The 'basis' or overarching process to the whole management system. Identifies the needs for outcomes that are outside of the scope of the management system.
13	Process maintainability management	A first attempt to provide a name and context for perhaps the most challenging area of ISO 9001 – that of 'preventive action'.
14	Process planning and monitoring	This draws together many requirements related to 'process planning'.
15	Process validation	Attempts to provide a basis for a process validation process, based on sub-clause 7.5.2.
16	Product changes	Addresses the need for managing product changes.
17	Product design	Addresses the need for managing product design.
18	Product implementation	Addresses the need for managing product implementation.
19	Product maintainability management	A first attempt to provide a name and context for perhaps the second most challenging area of ISO 9001 – that of 'corrective action'.
20	Product planning and monitoring	This draws together many requirements related to 'product planning'.
21	Product procurement	Addresses sub-clauses 7.4.1,2, 3 concerns.
22	Product quarantine	This process addresses what is called 'non-conforming product' into a process name that is generally more recognisable in its intent.
23	Product release	Addresses the need for managing product release, and brings together requirements associated with the controlled conditions, and handling, storage and delivery of product.
24	Product requirements	Brings together the concerns for identifying the customer requirements and the consequent product requirements.
25	Product review	This process brings together the activities related to review of product.
26	Product validation	Attempts to provide a basis for a validation process, from several requirements concerned with validation activities.
27	Product verification	Attempts to provide a basis for a product verification process, from several requirements concerned with verification activities.
28	Product/service fulfilment	ISO 9001 does poor justice to a identifying the activities associated with 'order fulfilment'. The ideas are latent in ISO 9001, but not overtly expressed. This process produces the outputs that enterprise actually bills the client for.
29	Quality assurance	The primary objective of this process is to focus on defining quality objectives, and seeking evidence for the meeting of those objectives.
30	Supplier evaluation and selection	This focuses on the sub-clauses 7.4.1 and 8.4.

## 5. The implications of enterprise maturity levels

### 5.1 About enterprise maturity levels

The process reference model also associates the concept of an 'enterprise maturity level' with a process.

Although it is generally understood that the processes in ISO 9001 are all needed for an effective and efficient management system, experience indicates that not all of these processes have same degree of urgency when the management system is implemented.

ISO/IEC 15504-7 [3] has identified the framework for allocating processes to differing levels of ‘enterprise maturity’. At the lowest level (Level 1) the processes that produce the product/service that the enterprise ‘sells’ are identified – as the most important.

At the next level (Level 2) processes are identified that colloquially may be described as ‘housekeeping’ processes.

In general terms, the processes at the lowest levels are the highest risk processes. If process failures occur here, the impacts are felt by the customer most keenly and quickly.

At the higher levels, process failures will be experienced with urgency for remedy that is (roughly speaking) inversely proportional to the maturity level at which they are placed.

## 5.2 Assignment of an enterprise maturity level to a process

Reference	Process Name	Maturity Level assignment
16	Product changes	1
17	Product design	1
18	Product implementation	1
23	Product release	1
24	Product requirements	1
28	Product/service fulfilment	1
02	Configuration Management	2
07	Information item management	2
20	Product planning and monitoring	2
21	Product procurement	2
22	Product quarantine	2
25	Product review	2
26	Product validation	2
27	Product verification	2
29	Quality assurance	2
01	Audit	3
03	Customer relationship management	3
04	Equipment management	3
05	Human resource management	3
06	Improvement	3
08	Infrastructure and work environment	3
09	Management review	3
10	Measurement	3
11	MS establishment and maintenance	3
14	Process planning and monitoring	3
19	Product maintainability management	3
30	Supplier evaluation and selection	3
13	Process maintainability management	4
15	Process validation	4
12	Organisational leadership and management	5

## 6. Comments on a sample mapping

An illustrative example is given below of the application of the methodology introduced in Section 3.

ISO 9001 sub-clause 6.2 Human resources is used for illustrative purposes.

The step by step sequence of activities followed in producing this PRM is illustrated, starting with the content from the Standard.

### 6.1 Requirements as presented in ISO 9001:2008

#### 6.2.1 General

Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, training and awareness

The organization shall

- a) determine the necessary competence for personnel performing work affecting conformity to product requirements,
- b) where applicable, provide training or take other actions to achieve the necessary competence,
- c) evaluate the effectiveness of the actions taken,
- d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
- e) maintain appropriate records of education, training, skills and experience.

6.2 Prepare a list of unique and traceable requirements

ISO 9001 4ED 6.2.1 Resource management: Human Resources: General

1 Personnel performing work affecting conformity to product requirements are competent, based on appropriate education, training, skills and experience.

2 Personnel competency is based on appropriate education, training, skills and experience.

ISO 9001 4ED 6.2.2 Resource management: Human Resources: Competence, training and awareness

1 The organisation determines the necessary competence for personnel performing work affecting conformity to product requirements.

2 Where applicable, [the organisation] provides training or takes other actions to achieve the necessary competence.

3 The organisation evaluates the effectiveness of the actions taken.

4 The organisation ensures that its personnel are aware of the relevance and the importance of their activities and how they contribute to the achievement of the quality objectives.

5 The organisation maintains appropriate records of education, training, skills and experience.

6.3 For each process requirements set: Link the set of requirements to outcomes of processes

REQ Sequence No.	REQ Description	Outcome No.	Process: Outcome
	ISO 9001 4ED 6.2.1 Resource management: Human Resources: General		
2	Personnel competency is based on appropriate education, training, skills and experience.	1	the competencies required by the organization for product/service provision are identified;
1	The organisation determines the necessary competence for personnel performing work affecting conformity to product requirements.		
2	Where applicable, [the organisation] provides training or takes other actions to achieve the necessary competence.	2	identified competency gaps are filled through training or recruitment;
3	The organisation evaluates the effectiveness of the actions taken.	3	individual competencies and their development are monitored;
4	The organisation ensures that its personnel are aware of the relevance and the importance of their activities and how they contribute to the achievement of the quality objectives.	4	each individual demonstrates their understanding of their role in achieving product/ service provision objectives.
5	The organisation maintains appropriate records of education, training, skills and experience.	4	information items are maintained in accordance with planned arrangements;

Linking a requirement to an outcome is a matter of technical judgement. The challenge is to find the outcome that best addresses the intent of the requirement.

6.4 For each process: Parse the requirements to identify overt or covert references to information items to be created, transformed or stored

Reference	Name
ISO 9001 4ED 6.2.2.01	Competency criteria
ISO 9001 4ED 6.2.2.03	Competency provision effectiveness criteria
ISO 9001 4ED 6.2.2.04	Competency provision effectiveness result
ISO 9001 4ED 6.2.2.08	Education, training, skills and experience record
ISO 9001 4ED 6.2.2.02	Organisational skill needs
ISO 9001 4ED 6.2.2.05	Organisational training needs assessment
ISO 9001 4ED 6.2.2.06	Organisational training plan
ISO 9001 4ED 6.2.2.09	Personnel performance evaluation criteria
ISO 9001 4ED 6.2.2.10	Personnel performance evaluation record
ISO 9001 4ED 6.2.2.07	Training resources

6.5 For each information items set: Link the set of information items to outcomes of processes

Process outcome	Information Item	Input	Output
Human resource management			
1 the competencies required by the organization for product/service provision are identified;			
	ISO 9001 4ED 6.2.2.02 Organisational skill needs	✓	
	ISO 9001 4ED 6.2.2.01 Competency criteria		✓
	ISO 9001 4ED 6.2.2.06 Organisational training plan		✓
	9001 4ED 6.2.2.05 Organisational training needs assessment		✓
2 identified competency gaps are filled through training or recruitment;			
	ISO 9001 4ED 6.2.2.02 Organisational skill needs	✓	
	ISO 9001 4ED 6.2.2.06 Organisational training plan	✓	
	ISO 9001 4ED 6.2.2.07 Training resources	✓	
	ISO 9001 4ED 6.2.2.08 Education, training, skills and experience record		✓
3 individual competencies and their development are monitored;			
	ISO 9001 4ED 6.2.2.08 Education, training, skills and experience record	✓	
	ISO 9001 4ED 6.2.2.09 Personnel performance evaluation criteria	✓	
	ISO 9001 4ED 6.2.2.10 Personnel performance evaluation record		✓
4 each individual demonstrates their understanding of their role in achieving product/ service provision objectives.			
	ISO 9001 4ED 6.2.2.03 Competency provision effectiveness criteria	✓	
	ISO 9001 4ED 6.2.2.10 Personnel performance evaluation record	✓	
	ISO 9001 4ED 6.2.2.04 Competency provision effectiveness result		✓

#### 6.6 Information items and data groups

The concept of 'data group' from ISO/IEC 19761 [4] is a valuable aid in the identification of the content of information items.

The data group for each identified information item from the text of the ISO 9001 requirement is often sparse – indicated sometimes by nothing more than the name of the item.

In other instances the information item content (i.e. data group) is considered to be an integral whole. Omissions of elements from this data group imply that the integrity of the data group is compromised. Under these circumstances it is unlikely that the requirement can be satisfied.

For this reason the information items and their content are considered to be normative.

## 7. Discussion

The results [7] achieved in the current body of work would have been impossible without the use of advanced software tools, in particular the ability to treat the 'information' in ISO 9001 as 'data' and to be able to manipulate it using powerful query facilities.

A tool, known as MAP (SPI-LAB Standards Mapping Support Tool), makes use of powerful relational database and client software. The tool has been evolved over the past four years with the objective of providing a framework for manipulating requirements, model elements, information item content, and the links between these objects.

The primary consequences of this process model development are:

- future conformity audits to the Standard will need to take account of accepted process practice content, as applicable to the domain of interest;
- future conformity audits will have to take serious account of the expected information content of process outputs.

## 8. References

- [1] ISO 9001: 2008 (Requirements – Quality management systems)
- [2] ISO/IEC 12207:2008 (Software Engineering – Software Lifecycle Processes)
- [3] ISO/IEC 15504-7: 2008 (Information technology – Process assessment – Part 7: Assessment of Organizational Maturity)
- [4] ISO/IEC 19761: 2003 (Software engineering — COSMIC-FFP — A functional size measurement method)
- [5] ISO 20000-1: 2005 (IT service management - Part 1: Specification for service management)
- [6] ISO/IEC 24774: 2009 (DTR) (System and software engineering – Life Cycle Management – Guidelines for process definition)
- [7] A Conformant Process Reference Model for ISO 9001:2008. (HRD-065-PRD-01) Issue 1, August 2009, SPI Laboratory (Pty) Ltd