TECHNICAL REPORT

ISO/IEC TR 90005

First edition
2008-07-15

Systems engineering — Guidelines for the application of ISO 9001 to system life cycle processes

Ingénierie des systèmes — Lignes directrices pour l'application de l'ISO 9001 aux processus de cycle de vie des systèmes

Reference number
ISO/IEC TR 90005:2008(E)

© ISO/IEC 2008

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS

Not for Resale

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.



COPYRIGHT PROTECTED DOCUMENT

© ISO/IEC 2008

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS

Not for Resale

© ISO/IEC 2008 – All rights reserved

Contents

Page

Foreword iv

Introduction v

1 Scope 1
1.1 Purpose 1
1.2 Field of Application 1
1.3 Limitations 1

2 Terms and definitions 2

3 System Life Cycle Guidelines 3

4 ISO 9001 Sections not yet invoked in Table 5 133

Bibliography 135

© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale

Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work. In the field of information technology, ISO and IEC have established a joint technical committee, ISO/IEC JTC 1.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of the joint technical committee is to prepare International Standards. Draft International Standards adopted by the joint technical committee are circulated to national bodies for voting. Publication as an International Standard requires approval by at least 75 % of the national bodies casting a vote.

In exceptional circumstances, the joint technical committee may propose the publication of a Technical Report of one of the following types:

— type 1, when the required support cannot be obtained for the publication of an International Standard, despite repeated efforts;

— type 2, when the subject is still under technical development or where for any other reason there is the future but not immediate possibility of an agreement on an International Standard;

— type 3, when the joint technical committee has collected data of a different kind from that which is normally published as an International Standard (“state of the art”, for example).

Technical Reports of types 1 and 2 are subject to review within three years of publication, to decide whether they can be transformed into International Standards. Technical Reports of type 3 do not necessarily have to be reviewed until the data they provide are considered to be no longer valid or useful.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO and IEC shall not be held responsible for identifying any or all such patent rights.

ISO/IEC TR 90005, which is a Technical Report of type 3, was prepared by Joint Technical Committee ISO/IEC JTC 1, *Information technology*, Subcommittee SC 7, *Software and systems engineering*.

© ISO/IEC 2008 – All rights reserved
Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale

Introduction

This Technical Report has been prepared based on a number of concepts.

1. **Enterprise versus Project –** ISO/IEC 15288 uses the term **Enterprise** to represent the organization within which **projects** are conducted using the system life cycle processes defined. It mainly considers the processes that provide support and resources to projects rather than an exhaustive set of processes that cover all aspects of the organization's business. ISO 9001:2000 does not use the term project but focuses on what an organization needs to do to satisfy customer requirements through **product realization**. It is possible to interpret a project in ISO 9001:2000 as either instantiated through the management processes or as an instance of product realization. This Technical Report therefore includes references to Clause 5 (Management in ISO 9001:2000) and Clause 7 (Product realization) in many cases as alternative ways to interpret ISO 9001:2000.

2. **Rationale & Explanation –** Each activity in ISO/IEC 15288 is discussed in terms of how it relates to sections of ISO 9001:2000. In many cases there is not a single section of ISO 9001 but a combination of sections that cover this relationship. Where possible only the sentence or sentences that deal with the relationship are stated rather than the complete section or clause from ISO 9001:2000. However, the reference to an ISO 9001:2000 clause number is normally to a complete clause unless a precise bullet or subclause covers the requirement explicitly.

3. **Outcomes –** Since for the most part ISO 9001:2000 does not cover outcomes, these are not discussed in this Technical Report and are omitted from the ISO/IEC 15288 text column. In any case the outcomes are the results of the activities specified, so this treatment does not miss any requirements.

4. **Other missing sections of ISO/IEC 15288 –** The purpose of each process is included in the Rationale/explanation section rather than in the ISO/IEC 15288 text section for ease of referencing. Notes in ISO/IEC 15288 are excluded because they contain no activities (requirements). The sections describing the contents of ISO/IEC 15288 and those discussing systems are omitted since there is no similar content in ISO 9001:2000.

5. **4.1 Quality management system – General requirements –** This section in ISO 9001:2000 is not generally used as a reference relationship to ISO/IEC 15288 because it is a summary of the requirements specified in 4.2 and Clauses 5 to 8 of ISO 9001:2000. To include it would have meant many cross-references to 4.1 and duplication of the specific sections where the precise requirement is specified. However in 5.2.2.3 f) of ISO/IEC 15288:2002, 4.1 of ISO 9001:2000 is used to cover outsourced processes since this is the only part of ISO 9001:2000 that describes outsourced processes.

6. **Other items in ISO 9001:2000 not referenced –** There are a few items in ISO 9001 where no relationship to ISO/IEC 15288 could be found. These are listed in a separate table at the back of this Technical Report for completeness.

7. **Intended use of this Technical Report –** This Technical Report has been prepared to enable a reader who is interested in comparing or contrasting the different treatment of systems in ISO/IEC 15288 and ISO 9001:2000 to quickly find the relationship and understand why a particular relationship is cited by way of the rationale and explanation text. It does not try to explain why a particular requirement exists in either International Standard.

It identifies the issues that should be addressed and is independent of the technology, life cycle models, development processes, sequence of activities and organizational structure used by an organization. The guidance and identified issues are intended to be comprehensive but not exhaustive. Where the scope of an organization's activities includes areas other than system development, the relationship between the computer system elements of that organization's quality management system and the remaining aspects should be clearly documented within the quality management system as a whole.

--`,,```,,,,````-`-`,,`,,`,`,,`---

© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale

Clauses 4, 5 and 6 and parts of Clause 8 of ISO 9001:2000 are applied mainly at the “global” level in the organization, although they do have some effect at the “project/product level”. Each project or product development may tailor the associated parts of the organization's quality management system to suit project/product-specific requirements.

Throughout ISO/IEC 15288, “shall” is used to express a provision that is binding between two or more parties, “should” to express a recommendation among possibilities and “may” to indicate a course of action permissible within the limits of ISO 9001:2000. On the other hand, ISO 9001:2000 uses only “shall” to express a provision that is binding between two or more parties. In this Technical Report, “should” and “may” have the same meaning as stated above, i.e. “should" to express a recommendation among possibilities and “may” to indicate a course of action permissible within the limits of ISO 9001:2000 and ISO/IEC 15288. Organizations with quality management systems for developing, operating or maintaining systems based on this Technical Report may choose to use processes from ISO/IEC 15288 and ISO/IEC 12207 to support or complement the ISO 9001:2000 process model.

--`,,```,,,,````-`-`,,`,,`,`,,`---
© ISO/IEC 2008 – All rights reserved
Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale

Systems engineering — Guidelines for the application of ISO 9001 to system life cycle processes

1 Scope

This Technical Report provides guidance for organizations in the application of ISO 9001:2000 to the acquisition, supply, development, operation and maintenance of systems and related support services. It does not add to or otherwise change the requirements of ISO 9001:2000. The guidelines provided in this Technical Report are not intended to be used as assessment criteria in quality management system registration or certification.

1.1 Purpose

This Technical Report adopts ISO/IEC 15288 systems life cycle processes as a starting point for system development, operation or maintenance and identifies those equivalent requirements in ISO 9001:2000 that have a bearing on the implementation of ISO/IEC 15288.

1.2 Field of Application

The application of this Technical Report is appropriate to systems that are

— part of a commercial contract with another organization,

— a product available for a market sector,

— used to support the processes of an organization,

— embedded in a hardware product, or

— related to software services.

Some organizations may be involved in all of the above activities; others may specialize in one area. Whatever the situation, the organization's quality management system should cover all aspects (system related and non-system related) of the business.

1.3 Limitations

This Technical Report provides guidance for software intensive systems. For guidance in software development, operation and maintenance see the companion document ISO/IEC 90003.

© ISO/IEC 2008 All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
system (1)
combination of interacting elements organized to achieve one or more stated purposes

NOTE 1 A system may be considered as a product or as the services it provides.

NOTE 2 In practice, the interpretation of its meaning is frequently clarified by the use of an associative noun, e.g. aircraft system. Alternatively the word system may be substituted simply by a context dependent synonym, e.g. aircraft, though this may then obscure a system principles perspective.

[ISO/IEC 15288:2002]

NOTE 3 This is the definition used in the ISO/IEC 15288 column of Clause 3.

2.2
system (2)
set of interrelated or interacting elements

[ISO 9000:2005]

NOTE This is the definition used in the ISO 9001 column of Clause 3.

© ISO/IEC 2008 – All rights reserved
Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

3 System Life Cycle Guidelines

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
5 System Life Cycle Processes			
5.1 Introduction			
This clause describes the requirements for the life cycle processes. It defines their purposes and outcomes, and the activities required to achieve them. An organization conducts the life cycle processes selectively to fulfil the purpose and outcomes of life cycle stages. The life cycle processes are described in four process groups as follows: Agreement processes; Enterprise processes; Project processes; Technical processes.	No Comment	N/A	N/A
5.2 Agreement Processes			
5.2.1 Introduction			
This subclause specifies the requirements for the establishment of agreements with organizational entities external and internal to the organization. The Agreement Processes consist of the following: a) Acquisition Process – used by organizations for acquiring products or services; b) Supply Process – used by organizations for supplying products or services. These processes define the activities necessary to establish an agreement between two organizations. If the Acquisition Process is invoked, it provides the means for conducting business with a supplier of products that are supplied for use as an operational system, of services in support of an operational system, or of elements of a system being developed by a project. If the Supply Process is invoked, it provides the means for conducting a project in which the result is a product or service that is delivered to the acquirer.	No Comment	N/A	N/A

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
5.2.2 Acquisition Process			
5.2.2.1 Purpose of the Acquisition Process	The purpose of the Acquisition Process is to obtain a product or service in accordance with the acquirer's requirements.	N/A	N/A
5.2.2.3 Acquisition Process Activities			
The acquirer shall implement the following activities in accordance with applicable organizational policies and procedures with respect to the Acquisition Process.	No Comment	N/A	N/A
a) Establish a plan for how the acquisition will be conducted.	Conceptually, in ISO 9001, this requirement relates to purchasing. However, the establishment of the plan for acquisition can be recognized as a part of quality planning of a product.	7.1	The organization shall plan and develop the processes needed for product realization.
	Once an organization has decided to acquire something from others, concerns may include the evaluation and selection of suppliers.	7.4.1	The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements.
b) Prepare a request for the supply of a product or service.	This requirement refers to the selection of suppliers.	7.4.1	The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements.
	To implement this requirement means the identification of the requirements of the product to be purchased. The requirement of purchasing may include the criteria of the approval of receipt.	7.4.2	Purchasing information shall describe the product to be purchased, including where appropriate a) requirements for approval of product, procedures, processes and equipment, b) requirements for qualification of personnel, and c) quality management system requirements.

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.
c) Communicate the request for the supply of a product or service to identified suppliers.	This requirement is partly equivalent to 7.4.1 of ISO 9001	7.4.1	The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.
	This requirement is partly equivalent to 7.4.2 of ISO 9001	7.4.2	Purchasing information shall describe the product to be purchased, including where appropriate a) requirements for approval of product, procedures, processes and equipment, b) requirements for qualification of personnel, and c) quality management system requirements. The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.
d) Select a supplier.	From the view point of ISO 9001, this requirement is covered in 7.4.1 under selection followed by evaluation.	7.4.1	The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements.
e) Negotiate an agreement with the supplier.	The intent of this requirement may include the negotiation between organization and supplier	7.4.1	The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.
	The negotiation may include the definition of purchasing information.	7.4.2	Purchasing information shall describe the product to be purchased, including where appropriate

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
	From the perspective of ISO 9001, purchasing information is decided by the organization. Where an agreement means contract, it relate to the requirement of 7.4.2 of ISO 9001, since purchasing information is included in the contract.		a) requirements for approval of product, procedures, processes and equipment, b) requirements for qualification of personnel, and c) quality management system requirements. The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.
f) Assess the execution of the agreement.	If this requirement relates to an out-sourced process, the requirement of 4.1 of ISO 9001:2000 can be considered as relevant.	4.1	Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.
	The assessment of the execution of the agreement can be considered as a part of the control of the supplier, by the organization.	7.4.1	The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.
	One of the execution aspects of the agreement can be receiving inspection.	7.4.3	The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.
g) Confirm that the delivered product or service complies with the agreement.	Confirmation of the compliance with the agreement can be considered as receiving inspection or other actions described in 7.4.3 of ISO 9001.	7.4.3	The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.
h) Make payment or provide other agreed consideration to the supplier for the product or service rendered.	ISO 9001 does not include financial issues.	None	None

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
5.2.3 Supply Process			
5.2.3.1 Purpose of the Supply Process	The purpose of the Supply Process is to provide an acquirer with a product or service that meets agreed requirements.		
5.2.3.3 Supply Process Activities			
The supplier shall implement the following activities in accordance with applicable organizational policies and procedures with respect to the Supply Process.	No Comment	N/A	N/A
a) Determine the existence and identity of an acquirer who has, or who represents a party or parties having, a need for a product or service.	ISO 9001 does not include pre-sales activities	None	None
b) Evaluate a request for the supply of a product or service to determine feasibility and how to respond.	The intent of this requirement can be recognized as the definition of the product from an ISO 9001 point of view. Then 7.2.1 and 7.2.2 may relate to this requirement.	7.2.1 7.2.2	The organization shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements related to the product, and d) any additional requirements determined by the organization. The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			a) product requirements are defined, b) contract or order requirements differing from those previously expressed are resolved, and c) the organization has the ability to meet the defined requirements. Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4). Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance. Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements. NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.
c) Prepare a response that satisfies the solicitation.	The intent of the preparation of response of satisfaction may be recognized as an issue of the ability of the organization. Customer communication is in 7.2.3	7.2.2. 7.2.3	This review shall be conducted prior to the organization's commitment to supply a product to the customer and shall ensure that c) the organization has the ability to meet the defined requirements. The organization shall determine and implement effective arrangements for communicating with customers in relation to b) enquiries, contracts or order handling, including amendments, and

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale

© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
d) Negotiate an agreement with the acquirer.	The same concern as 7.2.3 b) of ISO 9001 From the view point of ISO/IEC 15288, agreement is established between supplier and organization, so this requirement relates also to 5.2.2.3 d) of ISO/IEC 15288	7.2.3 b)	The organization shall determine and implement effective arrangements for communicating with customers in relation to b) enquiries, contracts or order handling, including amendments,
e) Execute the agreement according to the Supplier's established project plans and in accordance with the agreement.	ISO 9001 takes a strong qualitative rather than project management or commercial stance.	7.1	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
f) Assess the execution of the agreement.	ISO 9001 takes a strong qualitative rather than project management or commercial stance. From the view point of ISO 9001:2000, receiving inspection and monitoring of processes may be relevant. Further 8.2.2 of ISO 9001:2000 has a consideration on the monitoring of the effectiveness of a quality management system. Monitoring and measurement may also apply (8.2.3)	7.4.3 8.2.2 8.2.3	The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. The organization shall conduct internal audits at planned intervals to determine whether the quality management system a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and b) is effectively implemented and maintained. The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.
g) Deliver the product or service in accordance with the agreement criteria.	The same concern is described in 7.5.1 f) of ISO 9001:2000.	7.5.1 f)	The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable f) the implementation of release, delivery and post-delivery activities.
h) Accept and acknowledge payment or other agreed consideration.	There is no direct reference on payment in ISO 9001:2000.	None	None
i) Transfer the responsibility for the product or service to the acquirer, or other party, as directed by the agreement.	“Transfer of the responsibility” can be recognized as a part of the requirement of 7.5.1 f).	7.5.1 f)	The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable f) the implementation of release, delivery and post-delivery activities.

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
5.3 Enterprise Processes			
5.3.1 Introduction			
The Enterprise Processes manage the organization's capability to acquire and supply products or services through the initiation, support and control of projects. They provide resources and infrastructure necessary to support projects and ensure the satisfaction of organizational objectives and established agreements. They are not intended to be a comprehensive set of business processes that enable strategic management of the organization's business. The Enterprise Processes consist of the following: a) Enterprise Environment Management Process; b) Investment Management Process; c) System Life Cycle Processes Management Process; d) Resource Management Process; e) Quality Management Process.	No Comment	N/A	N/A
5.3.2 Enterprise Environment Management Process			
5.3.2.1 Purpose of the Enterprise Environment Management Process	The purpose of the Enterprise Environment Management Process is to define and maintain the policies and procedures needed for the organization's business with respect to the scope of this International Standard.		
5.3.2.3 Enterprise Environment Management Process Activities			
The organization shall implement the following activities in accordance with applicable organization policies and procedures with respect to the Enterprise Environment Management Process.	No Comment	N/A	N/A

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
a) Establish plans for each business area.	ISO 9001:2000 does not differentiate between short term and strategic objectives. However, the establishment of "quality" objectives is a requirement of ISO 9001:2000 (5.4.1). The intent of this requirement may be equivalent to the description of 5.4.1 and 5.4.2 a) of ISO 9001:2000. Since 5.4.1 of ISO 9001 focuses on the requirements of the QMS of the organization including the statement of policy and objectives and the requirement of 5.4.2 a) of ISO 9001, describe the requirement for planning to establish the QMS, then the establishment of a business plan may be equivalent to the overall concept of ISO 9001:2000.	5.4.1 5.4.2	Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy. Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.
b) Prepare system life cycle policies and procedures that implement the requirements of this International Standard and are consistent with enterprise strategic and business area plans.	In ISO 9001:2000 the requirement for "quality" policy is defined in 5.3 a) to c)	5.3	Top management shall ensure that the quality policy a) is appropriate to the purpose of the organization, b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system, c) provides a framework for establishing and reviewing quality objectives,

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
	Also 5.4.1 where Objectives are established.	5.4.1	Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.
c) Define, integrate, and communicate the roles, responsibilities and authorities to facilitate implementation of system life cycle processes and the strategic management of system life cycles.	Responsibility and authority are treated in 5.5.1 of ISO 9001:2000	5.5.1	Top management shall ensure that responsibilities and authorities are defined and communicated within the organization
d) Define business criteria that control progression through the system life cycle.	From the view point of ISO 9001, business criteria are defined before the implementation of a QMS. The decision making of the scope of QMS is not discussed in ISO 9001:2000	None	None
e) Conduct periodic reviews of the system life cycle model used by a project.	This concept may be considered equivalent to the top management review of ISO 9001:2000.	5.6.1	Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained (see 4.2.4).
	Also reviews in this context may be expressed as internal audit.	8.2.2 a)	The organization shall conduct internal audits at planned intervals to determine whether the quality management system a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
f) Communicate to projects the policies and procedures adopted by the enterprise in order to implement the requirements of this standard.	The concern included in this requirement is expressed in several parts of ISO 9001:2000. The most relevant part for policy is 5.3 d). As for procedures there is a basic concept in ISO 9001:2000 that the necessary documentation has to be established as a part of the QMS (5.4.1).	5.3 d) 5.4.1	Top management shall ensure that the quality policy d) is communicated and understood within the organization, and Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1a)], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy
5.3.3 Investment Management Process			
5.3.3.1 Purpose of the Investment Management Process	The purpose of the Investment Management Process is to initiate and sustain sufficient and suitable projects in order to meet the objectives of the organization.		
This process commits the investment of adequate organization funding and resources, and sanctions the authorities needed to establish selected projects. It performs continued qualification of projects to confirm they justify, or can be redirected to justify, continued investment.	No Comment	N/A	N/A
5.3.3.3 Investment Management Process Activities			
The organization shall implement the following activities in accordance with applicable organization policies and procedures with respect to the Investment Management Process.	No Comment	N/A	N/A

Not for Resale

© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS

© ISO/IEC 2008 – All rights reserved

Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
a) Establish new business opportunities, ventures or undertakings consistent with the business strategy and action plans of the organization.	The basic concepts of ISO 9001:2000 do not address financial/investment issues. ISO 9001 covers control of established strategies rather than development of strategies, new business lines, etc. However, planning and conduct of projects is covered in clause 7.1 of ISO 9001	None	None
b) Define projects, accountabilities and authorities.	There is no direct reference of this requirement in ISO 9001 – from an investment viewpoint. However, design and development planning responsibilities is covered in clause 7.3.1 c) of ISO 9001	None	None
c) Identify the expected outcomes of the projects.	There is no direct reference of this requirement in ISO 9001 – from an investment viewpoint. However, planning and conduct of projects is covered in clause 7.1 a) and c) of ISO 9001	None	None
d) Allocate resources for the achievement of project objectives.	There is no direct reference of this requirement in ISO 9001 – from an investment viewpoint. However, planning and conduct of projects is covered in clause 7.1 of ISO 9001, and resources are provisioned in 6.1	None	None
e) Identify any multi-project interfaces that must be managed or supported by the project. This includes the use of enabling systems used by more than one project and the use of common system elements by more than one project.	There is no direct reference of this requirement in ISO 9001 – However, planning and conduct of projects is covered in clause 7.1 of ISO 9001	None	None

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
f) Specify the project reporting requirements and review milestones that will govern the execution of the project.	There is no direct reference of this requirement in ISO 9001 –. However, design and development planning is covered in clause 7.3.1 of ISO 9001	None	None
g) Authorize the project to commence execution of approved project plans, including the technical plans.	There is no direct reference of this requirement in ISO 9001 – However, design and development planning is covered in clause 7.3.1 of ISO 9001	None	None
h) Evaluate ongoing projects to confirm that: 1) projects are making progress towards achieving established goals; 2) projects are complying with project directives; 3) projects are being conducted according to system life cycle plans and procedures; 4) projects remain viable, as indicated by, for example, continuing need for the service, practicable product implementation, acceptable investment benefits.	There is no direct reference of this requirement in ISO 9001 – However, design and development planning is covered in clause 7.3.1 of ISO 9001. Also h) 1) may be part of Management Review (5.6) and h) 2) to 8.2.2 Internal audit.	None	None
i) Act to continue or redirect projects that are satisfactorily progressing or can be expected to progress satisfactorily by appropriate redirection.	There is no direct reference of this requirement in ISO 9001 – However, planning and conduct of projects is covered in clause 7.1 of ISO 9001.	None	None
j) Act to cancel or suspend projects whose disadvantages or risks to the organization outweigh the benefits of continued investments, where agreements permit this.	There is no direct reference of this requirement in ISO 9001 – However, planning and conduct of projects is covered in clause 7.1 of ISO 9001	None	None

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
5.3.4 System Life Cycle Processes Management Process			
5.3.4.1 System Life Cycle Processes Management Process Purpose	The purpose of the System Life Cycle Processes Management Process is to assure that effective system life cycle processes are available for use by the organization.		
This process provides system life cycle processes that are consistent with the organization's goals and policies, that are defined, adapted and maintained in a consistent way in order to meet the nature of individual projects, and that are capable of being applied using effective, proven methods and tools.	No Comment	N/A	N/A
5.3.4.3 System Life Cycle Processes Management Process Activities			
The organization shall implement the following activities in accordance with applicable organization policies and procedures with respect to the System Life Cycle Processes Management Process.	No Comment	N/A	N/A
a) Establish standard sets of system life cycle processes for applicable system life cycle stages.	The establishment of a QMS is expressed in 2 stages in ISO 9001:2000, i.e., definition in 4.1 a) and implementation in 5.4.2 a).	5.4.2 a)	Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives,
b) Establish acceptable tailoring and application policies and procedures, with approval requirements.	The establishment of a QMS is expressed in 2 stages in ISO 9001:2000, i.e., definition in 4.1 a) and implementation in 5.4.2 a).	5.4.2 a)	Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives,
c) Identify methods and tools that support system life cycle process execution.	The establishment of a QMS is expressed in 2 stages in ISO 9001:2000, i.e., definition in 4.1 a) and implementation in 5.4.2 a).	5.4.2 a)	Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives,

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
d) Establish measures wherever possible that determine performance of the implemented standard processes.	The monitoring of the QMS is directly expressed in 8.2.2 and 8.2.3 of ISO 9001:20000	8.2.3	The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product
e) Monitor process execution, store and analyze process measures, and identify trends with respect to enterprise criteria.	ISO 9001:2000 includes the requirement of monitoring of the QMS in 8.2.3	8.2.3	The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product
	The analysis of data is included in 8.4 in ISO 9001:2000.	8.4	The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources. The analysis of data shall provide information relating to a) customer satisfaction (see 8.2.1), b) conformity to product requirements (see 7.2.1), c) characteristics and trends of processes and products including opportunities for preventive action, and d) suppliers.

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale

© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
f) Identify opportunities for improvement of standard system life cycle process implementation.	ISO 9001:2000 expresses the opportunity for improvement in the management review section.	5.6.1	Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.
g) Improve processes, methods and tools as determined.	Improvement is included in 8.5.1 of ISO 9001:2000.	8.5.1	The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review
5.3.5 Resource Management Process			
5.3.5.1 Purpose of the Resource Management Process	The purpose of the Resource Management Process is to provide resources to projects.		
This process provides resources, materials and services to projects to support organization and project objectives throughout the life cycle. This includes a supply of educated, skilled and experienced personnel qualified to perform life cycle processes. This process assures that there is effective co-ordination and sharing of resources, information and technologies.	No Comment	N/A	N/A
5.3.5.3 Resource Management Process Activities			
The organization shall implement the following activities in accordance with applicable organization policies and procedures with respect to the Resource Management Process:	No Comment	N/A	N/A
a) Determine and provide the resource infrastructure support needed to implement the requirements of this International Standard within the organization and provide project support.	The concern of this activity may relate to the contents of the planning expressed in 5.4.2 b)	5.4.2 b)	Top management shall ensure that b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
	This requirement is mostly expressed in 6.3	6.3	The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport or communication).
	and 6.4 of ISO 9001:2000.	6.4	The organization shall determine and manage the work environment needed to achieve conformity to product requirements
b) Obtain resources other than personnel that are needed to implement and support projects.	This requirement is expressed in 6.3 and 6.4 of ISO 9001:2000.	6.3	The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport or communication).
		6.4	The organization shall determine and manage the work environment needed to achieve conformity to product requirements
c) Maintain and manage the pool of personnel necessary to staff ongoing projects.	ISO 9001:2000 includes the issue of human resource in 6.1,	6.1	The organization shall determine and provide the resources needed a) to implement and maintain the quality management system and continually improve its effectiveness, and b) to enhance customer satisfaction by meeting customer requirements

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
	6.2.1 and 6.2.2 a) to c)	6.2.1 6.2.2 a) to c)	Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience. The organization shall a) determine the necessary competence for personnel performing work affecting product quality, b) provide training or take other actions to satisfy these needs, c) evaluate the effectiveness of the actions taken,
d) Motivate staff, e.g. through career development and reward mechanisms.	ISO 9001:2000 does not have a direct reference to this requirement, but the concern may be relevant to awareness issue described in 6.2.2 d).	6.2.2 d)	The organization shall 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) Control multi-project management interfaces to resolve schedule conflicts:	ISO 9001:2000 does not have a direct reference to this requirement, but the concern may be relevant to the resource requirements described in 6.1 and 6.3.	6.1 6.3	The organization shall determine and provide the resources needed a) to implement and maintain the quality management system and continually improve its effectiveness, and b) to enhance customer satisfaction by meeting customer requirements The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements.
1) of capacity in organizational infrastructure and supporting services and resources among ongoing projects,	Especially for design and development, ISO 9001:2000 expresses a related concern in 7.3.1	7.3.1	The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.
2) from project personnel being over-committed.	No direct reference	None	None

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
5.3.6 Quality Management Process			
5.3.6.1 Quality Management Process Purpose	The purpose of the Quality Management Process is to assure that products, services and implementations of life cycle processes meet enterprise quality goals and achieve customer satisfaction.		
5.3.6.3 Quality Management Process Activities			
The organization shall implement the following activities in accordance with applicable organization policies and procedures with respect to the Quality Management Process.	No Comment	N/A	N/A
a) Establish quality management policies, standards and procedures.	ISO 9001 specifically documents the quality policy, objectives and references to procedures in a quality manual (4.2.2).	4.2.2	The organization shall establish and maintain a quality manual that includes a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2), b) the documented procedures established for the quality management system, or reference to them, and c) a description of the interaction between the processes of the quality management system.
	ISO 9001:2000 includes a similar requirement in 5.1 b) : Policy	5.1 b)	Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by b) establishing the quality policy,
	and 5.4.2 a) : establishment of QMS.	5.4.2 a)	Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
b) Establish organization quality management goals and objectives based on business strategy for customer satisfaction.	No direct reference can be seen in ISO 9001:2000 but the concern is expressed as these requirements for top management (5.1 & 5.4.1).	5.1 5.4.1	Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements, b) establishing the quality policy, c) ensuring that quality objectives are established, d) conducting management reviews, and e) ensuring the availability of resources. Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.
c) Define responsibilities and authority for implementation of quality management.	Direct reference is in 5.5.1 of ISO 9001:2000,	5.5.1	Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.
d) Assess customer satisfaction and report.	ISO/IEC 15288 requires assessment of customer satisfaction but does not require to improve it. ISO 9001:2000 describes customer satisfaction issues in several relevant sections such as 5.5.2 c), 5.5.3,	5.5.2 c) 5.5.3	Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes c) ensuring the promotion of awareness of customer requirements throughout the organization. Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
	5.6.2 b),	5.6.2 b)	The input to management review shall include information on b) customer feedback
	5.6.3	5.6.3	The output from the management review shall include any decisions and actions related to a) improvement of the effectiveness of the quality management system and its processes, b) improvement of product related to customer requirements, and c) resource needs.
	and 8.2.1.	8.2.1	As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.
e) Conduct periodic reviews of project quality plans.	ISO 9001:2000 requires top management review as a wider concept than just quality plans so 5.6.1 is partly relevant, however, if the project is recognized as a product level of ISO 9001, periodic review is not specifically mentioned.	5.6.1	Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained (see 4.2.4).
f) Monitor the status of quality improvements on products and services.	There is no direct reference to quality improvement of product in ISO 9001:2000, but it is expressed the relating concern in 8.4.	8.4	The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			The analysis of data shall provide information relating to b) conformity to product requirements (see 7.2.1), c) characteristics and trends of processes and products including opportunities for preventive action,
5.4 Project Processes			
5.4.1 Introduction			
The Project Processes are used to establish and evolve project plans, to assess actual achievement and progress against the plans and to control execution of the project through to fulfilment. Individual Project Processes may be invoked at any time in the life cycle and at any level in a hierarchy of projects, as required by project plans or unforeseen events. The Project Processes are applied with a level of rigour and formality that depends on the risk and complexity of the project. The Project Processes consist of the following processes: a) Project Planning Process; b) Project Assessment Process; c) Project Control Process; d) Decision-making Process; e) Risk Management Process; f) Configuration Management Process; g) Information Management Process.	No Comment	N/A	N/A

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
5.4.2 Project Planning Process			
5.4.2.1 Purpose of the Project Planning Process	The purpose of the Project Planning Process is to produce and communicate effective and workable project plans.		
This process determines the scope of the project management and technical activities, identifies process outputs, project tasks and deliverables, establishes schedules for project task conduct, including achievement criteria, and required resources to accomplish project tasks.	No Comment	N/A	N/A
5.4.2.3 Project Planning Process Activities			
The project shall implement the following activities in accordance with applicable organization policies and procedures with respect to the Planning Process.	No Comment	N/A	N/A
a) Identify the project objectives and constraints.	The term “Project” used in ISO/IEC 15288 is equivalent to the term “System” used in ISO 9001. In this sense, the relevant requirement of ISO 9001:2000 to this requirement is 5.4.1. If a project is recognized as part of product realization, then 7.1 is applicable. In this situation where design and development are conducted, 7.3.1 is considered to be included.	5.4.1 7.1	Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a]], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy. The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate:

Not for Resale

© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements(see 4.2.4). The output of this planning shall be in a form suitable for the organization's method of operations.
b) Define the project scope as established in the agreement.	From the viewpoint of ISO 9001:2000 the project scope has been defined at the time of establishing the QMS. There is no specific requirement for the establishment of scope in ISO 9001:2000. However the requirement may be implemented in the requirement of 5.4.2 a). If a project is recognized as part of product realization, then 7.1a) is applicable.	5.4.2 a) 7.1 a)	Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1. The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product;

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
c) Establish a work breakdown structure based on the evolving system architecture.	This requirement can be considered as an issue for Project Management. ISO 9001:2000 does not explicitly present a similar issue. However ISO 9001:2000 requires planning of product realization that is similar (7.1).	7.1	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; The output of this planning shall be in a form suitable for the organization's method of operations.
d) Define and maintain a project schedule based on project objectives and work estimates.	This requirement can be considered as an issue for Project Management. ISO 9001:2000 does not explicitly present a similar issue. If a project is recognized as part of product realization, then 7.1 a), b) and c) is applicable.	7.1 b) and c)	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
e) Define project achievement criteria for the life cycle stage decision gates, delivery dates and major dependencies on external inputs or outputs.	This requirement can be considered as an issue for Project Management. ISO 9001:2000 does not explicitly present a similar issue. However ISO 9001:2000 require the establishment of requirements for a product, this can be recognized as similar to it (7.2.1). If a project is recognized as part of product realization, then 7.1b) and c) is applicable	7.2.1 7.1 b) and c)	The organization shall determine b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements related to the product, and d) any additional requirements determined by the organization. The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;
f) Define the project costs and plan a budget.	ISO 9001:2000 does not include financial issues as a requirement.	None	None
g) Establish the structure of authorities and responsibilities for project work.	In ISO 9001:2000 Top management set responsi-bilities and authorities within the organisation (5.5.1) and at a project level. If a project is recognized as part of product realization, then 7.1b) and c) is applicable and	5.5.1 7.1 b) and c)	Top management shall ensure that responsibilities and authorities are defined and communicated within the organization. The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
	by inference 7.3.1 where design and development is carried out.		consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;
h) Define the infrastructure and services required by the project.	The same concern is expressed in 6.3	6.3	The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport or communication).
	and 6.4 of ISO 9001:2000	6.4	The organization shall determine and manage the work environment needed to achieve conformity to product requirements
	If a project is recognized as part of product realization, then 7.1b) is also applicable	7.1 b)	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: b) the need to establish processes, documents, and provide resources specific to the product;

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
i) Plan the acquisition of materials, goods and enabling system services supplied from outside the project.	Acquisition issues are handled in several parts of ISO 9001:2000. One is in 7.1 as outsourced processes.	7.1	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements(see 4.2.4). The output of this planning shall be in a form suitable for the organization's method of operations.
	and in 7.4.1.	7.4.1	The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			actions arising from the evaluation shall be maintained (see 4.2.4).
j) Generate and communicate a plan for technical management of the project, including reviews.	If a project is recognized as part of product realization, then 7.1 b) and c) is applicable	7.1 b) and c)	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;
k) Define the project measures to be generated and the associated data to be collected, validated and analyzed.	The requirement covers from the definition of measures through to collection and analysis of them. This relates to 8.2.3 and 8.4 of ISO 9001:2000.	8.2.3 8.4	The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources. The analysis of data shall provide information relating to

Not for Resale

© ISO/IEC 2008 – All rights reserved

--`,,```,,,,````-`-`,,`,,`,`,,`---

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS

© ISO/IEC 2008 – All rights reserved

Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			a) customer satisfaction (see 8.2.1), b) conformity to product requirements (see 7.2.1), c) characteristics and trends of processes and products including opportunities for preventive action, and d) suppliers.
l) Generate a project quality plan.	The intent of this requirement can be considered as the implementation of the established plan. From this viewpoint this concern is covered by the overall concept of ISO 9001:2000 in 5.4.2 a). Mainly 7.1 covers this requirement.	5.4.2 a) 7.1	Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements(see 4.2.4). The output of this planning shall be in a form suitable for the organization's method of operations.

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
5.4.3 Project Assessment Process			
5.4.3.1 Purpose of the Project Assessment Process	The purpose of the Project Assessment Process is to determine the status of the project.		
This process evaluates, periodically and at major events, the progress and achievements against requirements, plans and overall business objectives. Information is communicated for management action when significant variances are detected.	No Comment	N/A	N/A
5.4.3.3 Project Assessment Process Activities			
The project shall implement the following activities in accordance with applicable organization policies and procedures with respect to the Project Assessment Process.	No Comment	N/A	N/A
a) Assess project status against appropriate project plans to determine actual and projected cost, schedule and quality variations.	ISO 9001:2000 does not have an equivalent concept of assessment of QMS other than internal audit.	8.2.2	The organization shall conduct internal audits at planned intervals to determine whether the quality management system a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and b) is effectively implemented and maintained. An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

Not for Resale

© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS

© ISO/IEC 2008 – All rights reserved

Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure. The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).
	However, the statement of this requirement can be considered as equivalent to the monitoring of processes, as in 8.2.3 of ISO 9001:2000.	8.2.3	The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product
b) Perform quality assurance in accordance with project plans.	Quality assurance is the base concept of ISO 9001:2000, so there is no explicit explanation of performance of quality assurance requirements. However, Quality assurance in ISO/IEC 15288 is closer in concept to quality review, verification and validation in ISO 9001:2000. Some of the requirements of ISO 9001:2000 may be found as relevant such as 7.3,	7.3.4	At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1) a) to evaluate the ability of the results of design and development to meet requirements, and b) to identify any problems and propose necessary actions. Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
		7.3.5	Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).
		7.3.6	Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).
	7.4,	7.4.3	The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information
	7.5,	7.5.1	The organization shall plan and carry out production and service provision under controlled conditions.
		7.5.2	The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			Validation shall demonstrate the ability of these processes to achieve planned results. The organization shall establish arrangements for these processes including, as applicable a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures, d) requirements for records (see 4.2.4), and e) revalidation.
	7.6,	7.6	Where necessary to ensure valid results, measuring equipment shall a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded; when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected.
	8.2.2 a) b),	8.2.2 a) and b)	The organization shall conduct internal audits at planned intervals to determine whether the quality management system a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and b) is effectively implemented and maintained.

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
	8.2.4	8.2.4	The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4). Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer
c) Assess the effectiveness of project team structure, roles and responsibilities.	There is no requirement to assess the project team in ISO 9001:2000, but the requirement of 8.2.2	8.2.2 (part of)	The organization shall conduct internal audits at planned intervals to determine whether the quality management system a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and b) is effectively implemented and maintained.
	and 8.2.3 may be considered as equivalent to the intent of this requirement.	8.2.3	The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.
d) Assess the adequacy and availability of the project's supporting infrastructure.	The concept of this requirement can be considered as equivalent to 8.2.2	8.2.2 (part of)	The organization shall conduct internal audits at planned intervals to determine whether the quality management system

Not for Resale

© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS

© ISO/IEC 2008 – All rights reserved

Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and b) is effectively implemented and maintained.
	and 8.2.3 of ISO 9001:2000.	8.2.3	The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.
e) Assess project progress using measured achievement and milestone completion.	There is no explicit requirement to assess project progress in ISO 9001:2000, however the requirement of internal audit may cover this concern (8.2.2)	8.2.2	The organization shall conduct internal audits at planned intervals to determine whether the quality management system a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and b) is effectively implemented and maintained.
	and top management review also (5.6.1).	5.6.1	Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.
	The review of the progress of any process can be considered as a part of monitoring of the process, in which case 8.2.3 is relevant.	8.2.3	The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.
	Also if the project is considered part of product realization 8.2.4 is applicable.	8.2.4 (part of)	The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1).
f) Conduct required management and technical reviews, audits and inspections to determine readiness to proceed to the next stage of the system life cycle or project milestone.	The concern of this requirement may be covered in several parts of ISO 9001:2000, i.e. top management review (5.6.1),	5.6.1	Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.
	design and development review (7.3.4),	7.3.4	At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1) a) to evaluate the ability of the results of design and development to meet requirements, and b) to identify any problems and propose necessary actions. Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).
	internal audit (8.2.2).	8.2.2	The organization shall conduct internal audits at planned intervals to determine whether the quality management system

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS

© ISO/IEC 2008 – All rights reserved

Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and b) is effectively implemented and maintained.
	Also if the project is considered part of product realization 8.2.4 is applicable.	8.2.4	The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1).
g) Monitor critical processes and new technologies.	The meaning of "critical process" is not specific. It may relate to two concepts of ISO 9001:2000, i.e. one is processes which need to be validated and the other is processes that have a critical situation. The former is covered in 7.5.2	7.5.2	The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results. The organization shall establish arrangements for these processes including, as applicable a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures, d) requirements for records (see 4.2.4), and e) revalidation.
	and the latter is covered in 8.2.3.	8.2.3	The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.
h) Analyze data and measures to identify deviations or variations from planned values or status and make appropriate recommendations for corrections.	Monitor and measurement of processes is covered in 8.2.3 of ISO 9001:2000.	8.2.3	The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.
	If the coverage of this requirement extends to product monitoring and measurement, the intent may be covered by 8.2.4 of ISO 9001:2000.	8.2.4	The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4). Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.
	The analysis of data is covered in 8.4 of ISO 9001:2000.	8.4	The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources. The analysis of data shall provide information relating to

Not for Resale

© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			a) customer satisfaction (see 8.2.1), b) conformity to product requirements (see 7.2.1), c) characteristics and trends of processes and products including opportunities for preventive action, and d) suppliers
	ISO 9001:2000 handles the recommendation for correction in 8.5.2	8.5.2	The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure shall be established to define requirements for a) reviewing nonconformities (including customer complaints), b) determining the causes of nonconformities, c) evaluating the need for action to ensure that nonconformities do not recur, d) determining and implementing action needed, e) records of the results of action taken (see 4.2.4), and f) reviewing corrective action taken
	and 8.5.3 as a part of preventive action.	8.5.3	The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems. A documented procedure shall be established to define requirements for

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			a) determining potential nonconformities and their causes, b) evaluating the need for action to prevent occurrence of nonconformities, c) determining and implementing action needed, d) records of results of action taken (see 4.2.4), and e) reviewing preventive action taken.
i) Provide periodic status reports and required deviation reports as designated in the agreement, policies and procedures.	There is no explicit requirement for status reporting in ISO 9001:2000. Some correspondence can be given to the requirement of top management review (5.6.1	5.6.1	Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.
	And 5.6.2)	5.6.2	The input to management review shall include information on c) process performance and product conformity, d) status of preventive and corrective actions,
	But the requirement of internal audit (8.2.2) may cover this concern.	8.2.2	The organization shall conduct internal audits at planned intervals to determine whether the quality management system a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and b) is effectively implemented and maintained.
	Monitoring of process (8.2.3) may be relevant to this requirement of ISO/IEC 15288	8.2.3	The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
	If the status report is related to the product, it may be treated in the monitoring of product	8.2.4	system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product. The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4). Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.
5.4.4 Project Control Process			
5.4.4.1 Purpose of the Project Control Process	The purpose of the Project Control Process is to direct project plan execution and ensure that the project performs according to plans and schedules, within projected budgets and it satisfies technical objectives.		
This process includes redirecting the project activities, as appropriate, to correct identified deviations and variations from other project management or technical processes. Redirection may include re-planning as appropriate.	No Comment	N/A	N/A

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
5.4.4.3 Project Control Process Activities			
The project shall implement the following activities in accordance with applicable organization policies and procedures with respect to the Project Control Process.	No Comment	N/A	N/A
a) Manage project requirements and changes to requirements in accordance with the project plans.	This requirement is an overall concern of ISO 9001:2000. It is difficult to find a specific requirement in ISO 9001:2000. However, the definition of QMS and its implementation (5.4.2) may be relevant to this requirement.	5.4.2 a) and b)	Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.
	However, if a project is recognized as part of product realization, planning in 7.1 is applicable.	7.1	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).
	and change of requirements in 7.2.2	7.2.2	Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.
b) Initiate the corrective actions needed to achieve the goals and outputs of project tasks that have deviated outside acceptable or defined limits.	Similarly this concern is treated in 8.5.2 of ISO 9001:2000.	8.5.2	The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure shall be established to define requirements for

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS

© ISO/IEC 2008 – All rights reserved

Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			a) reviewing nonconformities (including customer complaints), b) determining the causes of nonconformities , c) evaluating the need for action to ensure that nonconformities do not recur, d) determining and implementing action needed, e) records of the results of action taken (see 4.2.4), and f) reviewing corrective action taken
c) Initiate preventive actions, as appropriate, to ensure achievement of the goals and outputs of the project.	Similarly this concern is treated in 8.5.3 of ISO 9001:2000.	8.5.3	The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems. A documented procedure shall be established to define requirements for a) determining potential nonconformities and their causes, b) evaluating the need for action to prevent occurrence of nonconformities, c) determining and implementing action needed, d) records of results of action taken (see 4.2.4), and e) reviewing preventive action taken
d) Initiate problem resolution actions to correct non-conformances.	If the problem resolution occurs at the product, 8.3 of ISO 9001:2000 may be relevant.	8.3	The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			product shall be defined in a documented procedure. The organization shall deal with nonconforming product by one or more of the following ways: a) by taking action to eliminate the detected nonconformity; b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer; c) by taking action to preclude its original intended use or application. Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4). When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements. When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.
	If the problem resolution occurs at the process level, 8.2.3 0f ISO 9001:2000 may be relevant.	8.2.3	The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity
	Correction may be recognized as a part of corrective action.	8.5.2	The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence.

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure shall be established to define requirements for a) reviewing nonconformities (including customer complaints), b) determining the causes of nonconformities , c) evaluating the need for action to ensure that nonconformities do not recur, d) determining and implementing action needed, e) records of the results of action taken (see 4.2.4), and f) reviewing corrective action taken
e) Evolve with time the scope, definition and the related breakdown of the work to be carried out by the project in response to the corrective action decisions taken and the estimated changes they introduce.	The concern of this requirement may be relevant to the concept of corrective action (partially).	8.5.2 d)	The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure shall be established to define requirements for d) determining and implementing action needed
f) Initiate change actions when there is a contractual change to cost, time or quality due to the impact of an acquirer or supplier request	If this issue is discussed at the production level, it may be covered in the discussion on customer communication. The customer feedback may relate to the action needed to initiate the change, in which	7.2.3 b) 7.2.3 c)	The organization shall determine and implement effective arrangements for communicating with customers in relation to b) enquiries, contracts or order handling, including amendments, The organization shall determine and implement effective arrangements for communicating with customers in relation to

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
	case the requirement of 7.2.3 c) may be relevant.		c) customer feedback, including customer complaints.
	If this issue is discussed in the design stage, it may relate to 7.3.7 of ISO 9001:2000.	7.3.7	Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).
g) Act to correct defective provision of acquired goods and services through constructive interaction with the supplier.	The concern expressed in this requirement may relate to the requirement of purchasing in ISO 9001:2000.	7.4.1	The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.
	The inspection of the purchased product is relevant, including correction of defective product as in 7.4.3 of ISO 9001:2000.	7.4.3	The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information. The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
	If the acquired product is found inadequate during the process, it should be treated as a non-conforming product.(8.3)	8.3	The organization shall deal with nonconforming product by one or more of the following ways: a) by taking action to eliminate the detected nonconformity; b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer; c) by taking action to preclude its original intended use or application. Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).
h) Authorize the project to proceed toward the next milestone or event if justified.	There is no explicit requirement in ISO 9001:2000. However, if the project is considered part of product realization 7.3.1	7.3.1	The organization shall plan and control the design and development of product. During the design and development planning, the organization shall determine a) the design and development stages, b) the review, verification and validation that are appropriate to each design and development stage, and c) the responsibilities and authorities for design and development. The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output shall be updated, as appropriate, as the design and development progresses.
	and 8.2.4 is applicable	8.2.4	The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1).

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4). Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.
5.4.5 Decision-making Process			
5.4.5.1 Purpose of the Decision-making Process	The purpose of the Decision-making Process is to select the most beneficial course of project action where alternatives exist.		
This process responds to a request for a decision encountered during the system life cycle, whatever its nature or source, in order to reach specified, desirable or optimized outcomes. Alternative actions are analyzed and a course of action selected and directed. Decisions and their rationale are recorded to support future decision- making.	No Comment	N/A	N/A
5.4.5.3 Decision-making Process Activities			
The project shall implement the following activities in accordance with applicable organization policies and procedures with respect to the Decision-making Process.	No Comment	N/A	N/A
a) Define a decision-making strategy.	No explicit requirement can be found in ISO 9001:2000.	None	None
b) Involve relevant parties in the decision-making in order to draw on experience and knowledge.	No explicit requirement can be found in ISO 9001:2000. But involvement of other parties may be the issue of 5.5.3	5.5.3	Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS

© ISO/IEC 2008 – All rights reserved

Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
	and 7.2.3 of ISO 9001:2000.	7.2.3	The organization shall determine and implement effective arrangements for communicating with customers in relation to a) product information, b) enquiries, contracts or order handling, including amendments, and c) customer feedback, including customer complaints.
c) Identify the circumstances and need for a decision.	This issue is not specifically covered in ISO 9001:2000.	None	None
d) Select and declare the decision-making strategy for each decision situation. Identify desired outcomes and measurable success criteria.	No specific requirement relating to this issue can be found in ISO 9001:2000.	None	None
e) Evaluate the balance of consequences of alternative actions, using the defined decision-making strategy, to arrive at an optimization of, or an improvement in, an identified decision situation.	No specific requirement relating to this issue can be found in ISO 9001:2000.	None	None
f) Record, track, evaluate and report decision outcomes to confirm that problems have been effectively resolved, adverse trends have been reversed and advantage has been taken of opportunities.	This issue can be considered to be relevant to corrective action of ISO 9001:2000. [8.5.2 e) f)].	8.5.2 e) and f)	The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure shall be established to define requirements for e) records of the results of action taken (see 4.2.4), and f) reviewing corrective action taken
g) Maintain records of problems and opportunities and their disposition, as stipulated in agreements or organizational procedures and in a manner that permits auditing and learning from experience.	The control of records of ISO 9001:2000 may be relevant to this requirement.	4.2.4	Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
	Especially record requirement for corrective action as stated in 8.5.2 e) of ISO 9001:2000.	8.5.2 e)	A documented procedure shall be established to define requirements for e) records of the results of action taken (see 4.2.4).
5.4.6 Risk Management Process			
5.4.6.1 Purpose of the Risk Management Process	The purpose of the Risk Management Process is to reduce the effects of uncertain events that may result in changes to quality, cost, schedule or technical character-istics.		
This process identifies, assesses, treats and monitors risks during the entire life cycle, responding to each risk in terms of appropriate treatment or acceptance.	No Comment	N/A	N/A
5.4.6.3 Risk Management Process Activities			
The project shall implement the following activities in accordance with applicable organization policies and procedures with respect to the Risk Management Process.	No Comment	N/A	N/A
a) Establish a systematic approach to risk identification, assessment and treatment.	ISO 9001:2000 doesn't include risk management but does include the concept of preventing loss of quality as preventive action (8.5.3)	8.5.3	The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.
b) Identify and define the risks.	Identification of risk may be relevant to determination of potential cause. (8.5.3)	8.5.3	A documented procedure shall be established to define requirements for a) determining potential nonconformities and their causes,
c) Determine the probability associated with risk occurrence using the established risk criteria.	Determination of probability may be relevant to deter-mination of potential cause. (8.5.3)	8.5.3	A documented procedure shall be established to define requirements for a) determining potential nonconformities and their causes, b) evaluating the need for action to prevent occurrence of nonconformities,

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
d) Evaluate the risks in terms of their possible consequences using the established criteria.	Evaluation of risk probability may be relevant to evaluation of the need to prevent occurrence. (8.5.3)	8.5.3	A documented procedure shall be established to define requirements for b) evaluating the need for action to prevent occurrence of nonconformities,
e) Prioritize the risks in terms of their probability and consequences.	Prioritization of risk may be relevant to the evaluation of needs to prevent occurrence. (8.5.3)	8.5.3	A documented procedure shall be established to define requirements for b) evaluating the need for action to prevent occurrence of nonconformities,
f) Determine the risk treatment strategies.	Determination of risk may be relevant to determination of action for preventive action. (8.5.3)	8.5.3	A documented procedure shall be established to define requirements for c) determining and implementing action needed
g) Define a threshold of acceptability for each identified risk.	No specific requirement can be found in ISO 9001:2000	None	None
h) Identify the risk treatment actions to follow if the threshold of acceptability is exceeded.	No specific requirement can be found in ISO 9001:2000	None	None
i) Communicate the risk treatment actions and their status in accordance with the agreement, policies and procedures.	No specific requirement can be found in ISO 9001:2000	None	None
j) Maintain a register of risk throughout the life cycle.	Maintenance of a register can be considered as a requirement of record control. (8.5.3)	8.5.3	A documented procedure shall be established to define requirements for d) records of results of action taken (see 4.2.4).
5.4.7 Configuration Management Process			
5.4.7.1 Purpose of the Configuration Management Process	The purpose of the Configuration Management Process is to establish and maintain the integrity of all identified outputs of a project or process and make them available to concerned parties.		

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
5.4.7.3 Configuration Management Process Activities			
The project shall implement the following activities in accordance with applicable organization policies and procedures with respect to the Configuration Management Process.	No Comment	N/A	N/A
a) Define a configuration management strategy.	There is no explicit requirement on configuration management strategy in ISO 9001:2000	None	None
b) Identify items that are subject to configuration control.	There is no explicit requirement on configuration management in ISO 9001:2000, however, in 7.5.3 Identification & traceability - a relationship to configuration management is noted	7.5.3	Where appropriate, the organization shall identify the product by suitable means throughout product realization. The organization shall identify the product status with respect to monitoring and measurement requirements. Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4).
c) Maintain information on configurations with an appropriate level of integrity and security.	There is no explicit requirement on configuration management in ISO 9001:2000, however, in 7.5.3 Identification & traceability – a relationship to configuration management is noted	7.5.3	Where appropriate, the organization shall identify the product by suitable means throughout product realization. The organization shall identify the product status with respect to monitoring and measurement requirements. Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4).
d) Ensure that changes to configuration baselines are properly identified, recorded, evaluated, approved, incorporated, and verified.	There is no explicit requirement on configuration management in ISO 9001:2000, however, in 7.5.3 Identification & traceability – a relationship to configuration management is noted	7.5.3	Where appropriate, the organization shall identify the product by suitable means throughout product realization. The organization shall identify the product status with respect to monitoring and measurement requirements.

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4).
5.4.8 Information Management Process			
5.4.8.1 Purpose of the Information Management Process	The purpose of the Information Management Process is to provide relevant, timely, complete, valid and, if required, confidential information to designated parties during and, as appropriate, after the system life cycle.		
This process generates, collects, transforms, retains, retrieves, disseminates and disposes of information. It manages designated information, including technical, project, enterprise, agreement and user information.	No Comment	N/A	N/A
5.4.8.3 Information Management Process Activities			
The project shall implement the following activities in accordance with applicable organization policies and procedures with respect to the Information Management Process.	No Comment	N/A	N/A
a) Define the items of information that will be managed during the system life cycle and, according to organizational policy or legislation, maintained for a defined period beyond.	There is no explicit requirement on information management in ISO 9001:2000. However the equivalent requirement may be found in some QMS's as a process defined by the organization. There are specific requirements for documentation in 4.2.1	None 4.2.1	None The quality management system documentation shall include a) documented statements of a quality policy and quality objectives, b) a quality manual,

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
	and records in 4.2.4.	4.2.4	c) documented procedures required by this International Standard, d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and e) records required by this International Standard (see 4.2.4). Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.
b) Designate authorities and responsibilities regarding the origination, generation, capture, archiving and disposal of items of information.	There is no explicit requirement on information management in ISO 9001:2000 But overall responsibility and authority is expressed in 5.5.1 of ISO 9001:2000.	5.5.1	Top management shall ensure that responsibilities and authorities are defined and communicated within the organization
c) Define the rights, obligations and commitments regarding the retention of, transmission of and access to information items.	There is no explicit requirement on information management in ISO 9001:2000 If the information items can be considered as document and records, 4.2.3	4.2.3	Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4. A documented procedure shall be established to define the controls needed a) to approve documents for adequacy prior to issue, b) to review and update as necessary and re-approve documents, c) to ensure that changes and the current revision status of documents are identified,

Not for Resale

© ISO/IEC 2008 – All rights reserved

--`,,```,,,,````-`-`,,`,,`,`,,`---

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
	and 4.2.4 of ISO 9001:2000 may relate.	4.2.4	d) to ensure that relevant versions of applicable documents are available at points of use, e) to ensure that documents remain legible and readily identifiable, f) to ensure that documents of external origin are identified and their distribution controlled, and g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.
d) Define the content, semantics, formats and medium for the representation, retention, transmission and retrieval of information.	There is no explicit requirement on information management in ISO 9001:2000 If this concern can be considered as about documents and records, 4.2.3	4.2.3	Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4. A documented procedure shall be established to define the controls needed a) to approve documents for adequacy prior to issue, b) to review and update as necessary and re-approve documents, c) to ensure that changes and the current revision status of documents are identified, d) to ensure that relevant versions of applicable documents are available at points of use,

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			e) to ensure that documents remain legible and readily identifiable, f) to ensure that documents of external origin are identified and their distribution controlled, and g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose
	and 4.2.4 of ISO 9001:2000 may relate.	4.2.4	Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.
e) Obtain the identified items of information.	From the point of ISO 9001:2000 view, there is no need to obtain information – it is automatically provided.	None	None
f) Maintain information items and their storage records according to integrity, security and privacy requirements.	The concern of this requirement can be considered as related to record control.	4.2.4	Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
g) Define information maintenance actions.	The concern of this requirement can be considered as related to record control.	4.2.4	Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.
h) Retrieve and distribute information to designated parties as required by agreed schedules or defined circumstances.	The concern of this requirement can be considered as control of documents (4.2.3 f) and records (4.2.4)	4.2.3 f) 4.2.4	f) to ensure that documents of external origin are identified and their distribution controlled, and Records shall remain legible, readily identifiable and retrievable.
i) Provide official documentation as required.	If there is some regulatory and statutory requirement, some of the requirements of ISO 9001:2000 may relate. (6.2.2 e) and 7.5.2 b)	6.2.2 e) 7.5.2 b)	e) maintain appropriate records of education, training, skills and experience (see 4.2.4). b) approval of equipment and qualification of personnel,
j) Archive designated information, in accordance with the audit and knowledge retention purposes.	The concern of this requirement can be considered as related to record control.	4.2.4	Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.
k) Dispose of unwanted, invalid or unverifiable information according to organization policy, and security and privacy requirements.	The concern of this requirement can be considered as related to record control. (4.2.4)	4.2.4	A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
5.5 Technical Processes			
5.5.1 Introduction			
The Technical Processes are used to define the requirements for a system, to transform the requirements into an effective product, to permit consistent reproduction of the product where necessary, to use the product to provide the required services, to sustain the provision of those services and to dispose of the product when it is retired from service. The Technical Processes define the activities that enable enterprise and project functions to optimize the benefits and reduce the risks that arise from technical decisions and actions. These activities enable products and services to possess the timeliness and availability, the cost effectiveness, and the functionality, reliability, maintainability, producibility, usability and other qualities required by acquiring and supplying organizations. They also enable products and services to conform to the expectations or legislated requirements of society, including health, safety, security and environmental factors. The Technical Processes consist of the following processes: a) Stakeholder Requirements Definition Process; b) Requirements Analysis Process; c) Architectural Design Process; d) Implementation Process; e) Integration Process; f) Verification Process; g) Transition Process; h) Validation Process; i) Operation Process; j) Maintenance Process; k) Disposal Process.	No Comment	N/A	N/A

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale

© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
5.5.2 Stakeholder Requirements Definition Process			
5.5.2.1 Purpose of the Stakeholder Requirements Definition Process	The purpose of the Stakeholder Requirements Definition Process is to define the requirements for a system that can provide the services needed by users and other stakeholders in a defined environment. It identifies stakeholders, or stakeholder classes, involved with the system throughout its life cycle, and their needs and desires. It analyzes and transforms these into a common set of stakeholder requirements that express the intended interaction the system will have with its operational environment and that are the reference against which each resulting operational service is validated in order to confirm that the system fulfils needs.		
5.5.2.3 Stakeholder Requirements Definition Process Activities			
The project shall implement the following activities in accordance with applicable organization policies and procedures with respect to the Stakeholder Requirements Definition Process.	No Comment	N/A	N/A
a) Identify the individual stakeholders or stakeholder classes who have a legitimate interest in the system throughout its life cycle.	From the perspective of ISO 9001 stakeholder means only customer, which may include end users.	None	None

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
b) Elicit stakeholder requirements.	ISO 9001 addresses customer requirements related to the product only. [7.2.1 a) to b)]	7.2.1 a) to b)	The organization shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known,
c) Define the constraints on a system solution that are unavoidable consequences of existing agreements, management decisions and technical decisions.	ISO 9001 could be interpreted to cover but does not specifically address determination of constraints that are unavoidable consequences of existing agreements, management decisions and technical decisions. [7.2.1 b) to d)]	7.2.1 b), c) and d)	The organization shall determine b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements related to the product, and d) any additional requirements determined by the organization.
d) Define a representative set of activity sequences to identify all required services that correspond to anticipated operational and support scenarios and environments.	ISO 9001 does not refer to the sequence definition. Could be interpreted to cover it if the requirements of specified, intended use, or ones by the organization address activity sequences. [7.2.1 c) d)]	7.2.1 c) and d)	The organization shall determine c) statutory and regulatory requirements related to the product, and d) any additional requirements determined by the organization.
e) Identify the interaction between users and the system.	ISO 9001 does not refer to the interaction identification. Could be interpreted to cover it if the requirements of specified, intended use, or ones by the organization address the interaction. [7.2.1 b) and d)]	7.2.1 b) and d)	The organization shall determine b) requirements not stated by the customer but necessary for specified or intended use, where known, d) any additional requirements determined by the organization.
f) Specify health, safety, security, environment and other stakeholder requirements and functions that relate to critical qualities.	ISO 9001 does not specifically refer to requirements on health, safety, security, environment.	7.2.1 b) and d)	The organization shall determine b) requirements not stated by the customer but necessary for specified or intended use, where known,

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS

© ISO/IEC 2008 – All rights reserved

Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
	Could be interpreted to cover it if the requirements of specified, intended use, statutory and regulatory requirements, or ones by the organization address customer requirements on health, safety, security, environment. [7.2.1 b) and d)]		d) any additional requirements determined by the organization.
g) Analyze the complete set of elicited requirements.	ISO 9001 could be interpreted to cover this when the requirement determination goes through requirement analysis. (7.2.1)	7.2.1	The organization shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements related to the product, and d) any additional requirements determined by the organization.
h) Resolve requirements problems.	This issue may be relevant to the determination of product requirement. (7.2.1)	7.2.1	The organization shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements related to the product, and d) any additional requirements determined by the organization.
	Control of nonconforming product in ISO 9001 covers resolution of requirement problems (8.3).	8.3	The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure. The organization shall deal with nonconforming product by one or more of the following ways: a) by taking action to eliminate the detected nonconformity; b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer; c) by taking action to preclude its original intended use or application. Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4). When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements. When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.
i) Feed back the analyzed requirements to applicable stakeholders to ensure that the needs and expectations have been adequately captured and expressed.	Parts of ISO 9001 requirement only where “stakeholders” is interpreted as “customers”. (7.2.2	7.2.2	The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that a) product requirements are defined, b) contract or order requirements differing from those previously expressed are resolved, and

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			c) the organization has the ability to meet the defined requirements. Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4). Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance. Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.
	and 7.2.3.)	7.2.3	The organization shall determine and implement effective arrangements for communicating with customers in relation to a) product information, b) enquiries, contracts or order handling, including amendments, and c) customer feedback, including customer complaints
j) Establish with stakeholders that their requirements are expressed correctly.	Parts of ISO 9001 requirement only where “stakeholders” is interpreted as “customers”. (7.2.2	7.2.2	The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that a) product requirements are defined, b) contract or order requirements differing from those previously expressed are resolved, and

--`,,```,,,````-`-`,,`,,`,`,,`---

© ISO/IEC 2008 – All rights reserved

Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			c) the organization has the ability to meet the defined requirements. Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4). Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance. Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.
	and 7.2.3)	7.2.3	The organization shall determine and implement effective arrangements for communicating with customers in relation to a) product information, b) enquiries, contracts or order handling, including amendments, and c) customer feedback, including customer complaints
k) Record the stakeholder requirements in a form suitable for requirements management through the life cycle and beyond.	ISO 9001 for requirements management is in 7.2.2 a)	7.2.2 a)	The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that a) product requirements are defined
	And 7.5.3	7.5.3	Where traceability is a requirement, the organization shall control and record the unique identification of the product

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale

© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
l) Maintain stakeholder requirements traceability to the sources of stakeholder need.	Parts of ISO 9001 requirement only where "stakeholders" is interpreted as "customers". (7.3.7,	7.3.7	Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).
	and 7.5.3)	7.5.3	Where traceability is a requirement, the organization shall control and record the unique identification of the product
5.5.3 Requirements Analysis Process			
5.5.3.1 Purpose of the Requirements Analysis Process	The purpose of the Requirements Analysis Process is to transform the stakeholder, requirement-driven view of desired services into a technical view of a required product that could deliver those services.		
This process builds a representation of a future system that will meet stakeholder requirements and that, as far as constraints permit, does not imply any specific implementation. It results in measurable system requirements that specify, from the developer's perspective, what characteristics it is to possess and with what magnitude in order to satisfy stakeholder requirements.	No Comment	N/A	N/A
5.5.3.3 Requirements Analysis Process Activities			
The project shall implement the following activities in accordance with applicable organization policies and procedures with respect to the Requirements Analysis Process.	No Comment	N/A	N/A

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
a) Define the functional boundary of the system in terms of the behaviour and properties to be provided.	ISO 9001 does not distinguish between Stakeholder and System requirements. (7.2.1 a)	7.2.1 a)	The organization shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,
b) Define each function that the system is required to perform, how well the system, including its operators, is required to perform that function, the conditions under which the system is to be capable of performing the function, the conditions under which the system is to commence performing that function and the conditions under which the system is to cease performing that function.	ISO 9001 could be interpreted to cover but does not specifically address the area or item of requirements. (7.2.1)	7.2.1	The organization shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements related to the product, and d) any additional requirements determined by the organization.
c) Define necessary implementation constraints that are introduced by stakeholder requirements or are unavoidable solution limitations.	ISO 9001 could be interpreted to cover but does not specifically address determination of constraints that are introduced by stakeholder requirements or are unavoidable solution limitations. 7.2.1 b) and d)	7.2.1 b) and d)	The organization shall determine b) requirements not stated by the customer but necessary for specified or intended use, where known, d) any additional requirements determined by the organization.
d) Define technical and quality in use measures that enable the assessment of technical achievement.	ISO 9001 does not address technical measures specifically.(7.1 a)	7.1 a)	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product;

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
	and 7.2.1 d) partly apply.	7.2.1 d)	The organization shall determine d) any additional requirements determined by the organization.
e) Specify system requirements and functions, as justified by risk identification or criticality of the system, that relate to critical qualities, such as health, safety, security, reliability, availability and sup-portability.	ISO 9001 could be interpreted to cover but does not specifically address the way the requirements are specified. [7.2.1 d)]	7.2.1 d)	The organization shall determine d) any additional requirements determined by the organization.
f) Analyze the integrity of the system requirements to ensure that each requirement, pairs of requirements or sets of requirements possess overall integrity.	ISO 9001 could be interpreted to cover this when the requirement determination goes through requirement analysis from the integrity point of view, therefore 7.2.1	7.2.1	The organization shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements related to the product, and d) any additional requirements determined by the organization.
	and 7.2.2. apply.	7.2.2	The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that a) product requirements are defined, b) contract or order requirements differing from those previously expressed are resolved, and c) the organization has the ability to meet the defined requirements.

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4). Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance. Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.
g) Demonstrate traceability between the system requirements and the stakeholder requirements.	ISO 9001:2000 does not primarily distinguish between Stakeholder and System requirements (7.5.3).	7.5.3	Where appropriate, the organization shall identify the product by suitable means throughout product realization. The organization shall identify the product status with respect to monitoring and measurement requirements. Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4).
h) Maintain throughout the system life cycle the set of system requirements together with the associated rationale, decisions and assumptions.	ISO 9001 requires the definition of the controls needed for the record retention time, not specifically the system life cycle in 7.2.2 and 7.3.7.	7.2.2 7.3.7	Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements. Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale

© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).
5.5.4 Architectural Design Process			
5.5.4.1 Purpose of the Architectural Design Process	The purpose of the Architectural Design Process is to synthesize a solution that satisfies system requirements. This process encapsulates and defines areas of solution expressed as a set of separate problems of manageable, conceptual and, ultimately, realizable proportions. It identifies and explores one or more implementation strategies at a level of detail consistent with the system's technical and commercial requirements and risks. From this, an architectural design solution is defined in terms of the requirements for the set of system elements from which the system is configured. The specified requirements resulting from this process are the basis for verifying the realized system and for devising an assembly and verification strategy.		
5.5.4.3 Architectural Design Process Activities			
The project shall implement the following activities in accordance with applicable organization policies and procedures with respect to the Architectural Design Process.	No Comment	N/A	N/A

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
a) Define appropriate logical architectural designs.	If a project is recognized as part of product realization, then 7.1 is applicable. In this situation where design and development are conducted, 7.3.1 is considered to be included.	7.1	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements(see 4.2.4). The output of this planning shall be in a form suitable for the organization's method of operations. NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan. NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.
	and this concept may contain the output form design and development [7.3.3 b)]	7.3.3 b)	Design and development outputs shall b) provide appropriate information for purchasing, production and for service provision,

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
b) Partition the system functions identified in requirements analysis and allocate them to elements of system architecture. Generate derived requirements as needed for the allocations.	The intermediate product of architectural analysis is an output of design and development stage. The system function is identified in the input of design and development (7.3.2),	7.3.2	Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include 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.
	and it is an output of design and development (7.3.3).	7.3.3	These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other. 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. Design and development outputs shall a) meet the input requirements for design and development, b) provide appropriate information for purchasing, production and for service provision, c) contain or reference product acceptance criteria, and d) specify the characteristics of the product that are essential for its safe and proper use.

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
c) Analyze the resulting architectural design to establish design criteria for each element.	The design result is analyzed in the design and development review.(7.3.4)	7.3.4	At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1) a) to evaluate the ability of the results of design and development to meet requirements, and b) to identify any problems and propose necessary actions. Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).
d) Determine which system requirements are allocated to operators.	Allocation of operators of a system requirement is determined in the planning of product realization (7.1).	7.1	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS

© ISO/IEC 2008 – All rights reserved

Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
e) Determine whether hardware and software elements that satisfy the design and interface criteria are available off-the-shelf.	Determine purchasing products (7.3.3).	7.3.3	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. Design and development outputs shall a) meet the input requirements for design and development, b) provide appropriate information for purchasing, production and for service provision, c) contain or reference product acceptance criteria, and d) specify the characteristics of the product that are essential for its safe and proper use.
f) Evaluate alternative design solutions, modelling them to a level of detail that permits comparison against the specifications expressed in the system requirements and the performance, costs, time scales and risks expressed in the stakeholder requirements.	This includes in ISO 9001, using the information derived from previous similar designs. To complete the evaluation and develop a design (output) 7.3.3 applies	7.3.2. c) 7.3.3	Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include c) where applicable, information derived from previous similar designs, and 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. Design and development outputs shall a) meet the input requirements for design and development, b) provide appropriate information for purchasing, production and for service provision, c) contain or reference product acceptance criteria, and d) specify the characteristics of the product that are essential for its safe and proper use

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
	and 7.3.4 to review the output(s)	7.3.4	At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1) a) to evaluate the ability of the results of design and development to meet requirements, and b) to identify any problems and propose necessary actions. Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see4.2.4).
	and potentially verification activities (7.3.5)	7.3.5	Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).
g) Define and document the interfaces between system elements and at the system boundary with external systems.	Define and document as the design and development output (7.3.3).	7.3.3	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. Design and development outputs shall a) meet the input requirements for design and development, b) provide appropriate information for purchasing, production and for service provision, c) contain or reference product acceptance criteria, and d) specify the characteristics of the product that are essential for its safe and proper use.

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
h) Specify the selected physical design solution as an architectural design baseline in terms of its functions, performance, behaviour, interfaces and unavoidable implementation constraints.	Specify as the design and development output (7.3.3).	7.3.3	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. Design and development outputs shall a) meet the input requirements for design and development, b) provide appropriate information for purchasing, production and for service provision, c) contain or reference product acceptance criteria, and d) specify the characteristics of the product that are essential for its safe and proper use.
i) Record the architectural design information.	ISO 9001:2000 requires records generally to be kept in 4.2.4 And specifically to record the information on the output, review, verification, and validation of design and development in 7.3.3.	4.2.4 7.3.3	Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. 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. Design and development outputs shall a) meet the input requirements for design and development, b) provide appropriate information for purchasing, production and for service provision, c) contain or reference product acceptance criteria, and d) specify the characteristics of the product that are essential for its safe and proper use.

© ISO/IEC 2008 – All rights reserved

Not for Resale

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
j) Maintain mutual traceability between architectural design and system requirements.	Identify the product, and maintain mutual traceability to it, is included in 7.5.3 of ISO 9001:2000.	7.5.3	Where appropriate, the organization shall identify the product by suitable means throughout product realization. The organization shall identify the product status with respect to monitoring and measurement requirements. Where traceability is a requirement, the organization shall control and record the unique identification of the product(see 4.2.4). NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.
5.5.5 Implementation Process			
5.5.5.1 Purpose of the Implementation Process	The purpose of the Implementation Process is to produce a specified system element.		
This process transforms specified behaviour, interfaces and implementation constraints into fabrication actions that create a system element according to the practices of the selected implementation technology. The system element is constructed or adapted by processing the materials and/or information appropriate to the selected implementation technology and by employing appropriate technical specialisms or disciplines. This process results in a system element that satisfies architectural design requirements through verification and stakeholder requirements through validation.	No Comment	N/A	N/A

Not for Resale

© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
5.5.5.3 Implementation Process Activities			
The project shall implement the following activities in accordance with applicable organization policies and procedures with respect to the Implementation Process.	No Comment	N/A	N/A
a) Generate an implementation strategy.	The common strategy for the organization is planned as part of the quality management system (5.4.2).	5.4.2	Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.
	The planning of product realization, in design and development defines the strategy of each project (7.1).	7.1	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
b) Identify the constraints that the implementation strategy and implementation technology impose on the design solution.	The constraints are identified by the planning of product realization (7.1), and determination of requirements related the product.	7.1	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).
	Constraints should include statutory and regulatory requirements [7.2.1 c)]	7.2.1 c)	The organization shall determine c) statutory and regulatory requirements related to the product, and
	And a review of requirements [7.2.2 a)]	7.2.2 a)	The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that a) product requirements are defined
	Constraints should include statutory and regulatory requirements as design inputs [7.3.2.b)].	7.3.2 b)	Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			a) functional and performance requirements, b) applicable statutory and regulatory requirements,
c) Realize or adapt system elements using the implementation enabling systems and specified materials according to the defined implementation procedures for hardware fabrication, software creation and/or operator training.	A design and development input is transformed into output. (7.3.3)	7.3.3	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. Design and development outputs shall a) meet the input requirements for design and development, b) provide appropriate information for purchasing, production and for service provision, c) contain or reference product acceptance criteria, and d) specify the characteristics of the product that are essential for its safe and proper use.
	ISO 9001 emphasis is on control in 7.5.1.	7.5.1	The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, and f) the implementation of release, delivery and post-delivery activities.
		7.5.2	

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
	Also consider validation of processes as an aspect of code implementation (7.5.2).		The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results. The organization shall establish arrangements for these processes including, as applicable a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures, d) requirements for records (see 4.2.4), and e) revalidation.
1) Hardware Fabrication Fabricate hardware elements using the conditioning, forming and fabrication techniques relevant to the physical implementation technology and materials selected. As appropriate, hardware elements are tested to confirm specified product quality characteristics.	There is no clear requirement relating to hardware fabrication in ISO 9001:2000. The usage of suitable equipment is expressed in 7.5.1 of ISO 9001:2000 as related to Hardware fabrication.	7.5.1	The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices,
2) Software Creation Code software elements and, as appropriate, compile, inspect and test to assure their conformance to the design criteria. ISO/IEC 12207:1995/AMD.1:2002 applies to system elements realized in software.	There is no clear requirement relating to software creation in ISO 9001:2000. Software creation can be considered as part of design and development (7.3.1)	7.3.1	The organization shall plan and control the design and development of product. During the design and development planning, the organization shall determine a) the design and development stages, b) the review, verification and validation that are appropriate to each design and

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			development stage, and c) the responsibilities and authorities for design and development. The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output shall be updated, as appropriate, as the design and development progresses.
	Software creation can also be related to the provision of information or equipment (7.5.1).	7.5.1	The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable a) the availability of information that describes the characteristics of the product, c) the use of suitable equipment,
3) Operator Training Deliver appropriate training to prepare operators for performing tasks in accordance with required performance standards and operational procedures and, as appropriate, confirm that the specified range and level of competence has been attained. This may include awareness of the operational environment, including appropriate failure detection and isolation instruction.	If operation is the responsibility of supplier, ISO 9001 includes evaluating competence as well. [6.2.2 b)]	6.2.2 b)	The organization shall b) provide training or take other actions to satisfy these needs
	If operation is the responsibility of acquirer, education is one of service provided by supplier. [7.5.1 f)]	7.5.1 f)	The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable f) the implementation of release, delivery and post-delivery activities.
d) Record evidence that the system element meets supplier agreements, legislation and organizational policy.	Similar concerns are described in 4.2.4 of ISO 9001:2000.	4.2.4	Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.
	The identification of what records should be kept is defined in 7.1 d)	7.1 d)	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).
	This is performed under design review (7.3.4),	7.3.4	At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1) a) to evaluate the ability of the results of design and development to meet requirements, and to identify any problems and propose necessary actions. Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).
	verification, (7.3.5)	7.3.5	Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).
	and validation, (7.3.6)	7.3.6	Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale

© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
	Together with the monitoring and measurement of product (8.2.4).	8.2.4	to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4). The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4). Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.
e) Package the system element and store as appropriate.	This concern may be covered as the issue of preservation in ISO 9001:2000. (7.5.5)	7.5.5	The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.
5.5.6 Integration Process			
5.5.6.1 Purpose of the Integration Process	The purpose of the Integration Process is to assemble a system that is consistent with the architectural design.		
This process combines system elements to form complete or partial system configurations in order to create a product specified in the system requirements.	No Comment	N/A	N/A

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
5.5.6.3 Integration Process Activities			
The project shall implement the following activities in accordance with applicable organization policies and procedures with respect to the Integration Process.	No Comment	N/A	N/A
a) Define an assembly sequence and strategy that minimizes system integration risks.	The common strategy to organization is planned as part of the quality management system. (5.4.2)	5.4.2	Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented
	The planning of product realization, in design and development defines the strategy of each project (7.1).	7.1	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
	Where design and development are required 7.3.1 is applicable.	7.3.1	The organization shall plan and control the design and development of product. During the design and development planning, the organization shall determine a) the design and development stages, b) the review, verification and validation that are appropriate to each design and development stage, and c) the responsibilities and authorities for design and development. The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output shall be updated, as appropriate, as the design and development progresses
	And associated verification (7.3.5)	7.3.5	Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).
	And validation (7.3.6).	7.3.6	Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4)

© ISO/IEC 2008 – All rights reserved

Not for Resale

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
b) Identify the constraints on the design arising from the integration strategy.	Integration is not defined as such in 9001, however if an organisation wants to do it they can define it in the quality planning activity (7.1).	7.1	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).
c) Obtain integration enabling systems and specified materials according to the defined integration procedures.	The enabling system is considered to be infrastructure (6.3).	6.3	The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport or communication).
	Acquisition of specified materials is carried out by purchasing (7.4.1).	7.4.1	The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control

© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).
	Integration enabling systems may be planned and carried out under production and service provision (7.5.1).	7.5.1	The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, and f) the implementation of release, delivery and post-delivery activities
d) Obtain system elements in accordance with agreed schedules.	System element received from suppliers is carried out by purchasing (7.4.1).	7.4.1	The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).
	This is implemented if defined in quality plan (7.1) during 7.5.1.	7.5.1	The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, and f) the implementation of release, delivery and post-delivery activities
	Otherwise, system elements are received from preservation and storage (7.5.5).	7.5.5	The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
e) Assure that the system elements have been verified against acceptance criteria specified in an agreement.	Verification is performed by design review,	7.3.4	At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1) a) to evaluate the ability of the results of design and development to meet requirements, and b) to identify any problems and propose necessary actions. Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see4.2.4).
	verification	7.3.5	Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).
	and validation.	7.3.6	Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).
	If system elements are acquired from outside then 7.4.3 applies.	7.4.3	The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.
	And the verification that product requirements have been met is included in 8.2.4.	8.2.4	The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4). Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.
f) Integrate system elements in accordance with applicable interface control descriptions and defined assembly procedures, using the specified integration facilities.	Integration is not defined as such in 9001, however if an organisation wants to do it they can define it in the quality planning activity.	7.5.1	The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, and f) the implementation of release, delivery and post-delivery activities

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS

© ISO/IEC 2008 – All rights reserved

Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
	A design and development input is transformed into output (7.3.3).	7.3.3	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. Design and development outputs shall a) meet the input requirements for design and development, b) provide appropriate information for purchasing, production and for service provision, c) contain or reference product acceptance criteria, and d) specify the characteristics of the product that are essential for its safe and proper use.
g) Record integration information in an appropriate database.	Record integration is carried out according to control of records.	4.2.4	Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.
	And is planned as part of product realization 7.1 d)	7.1 d)	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).
	Resolution of problems is carried out according to continual improvement (8.5.1)	8.5.1	The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
	and corrective action (8.5.2).	8.5.2	The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure shall be established to define requirements for a) reviewing nonconformities (including customer complaints), b) determining the causes of nonconformities, c) evaluating the need for action to ensure that nonconformities do not recur, d) determining and implementing action needed, e) records of the results of action taken (see 4.2.4), and f) reviewing corrective action taken
5.5.7 Verification Process			
5.5.7.1 Purpose of the Verification Process	The purpose of the Verification Process is to confirm that the specified design requirements are fulfilled by the system.		
This process provides the information required to effect the remedial actions that correct non-conformances in the realized system or the processes that act on it.	No Comment	N/A	N/A

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale

© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
5.5.7.3 Verification Process Activities			
The project shall implement the following activities in accordance with applicable organization policies and procedures with respect to the Verification Process.	No Comment	N/A	N/A
a) Define the strategy for verifying the system entities throughout the life cycle.	Defining the strategy is a part of the organizations' quality management system planning (5.4.2).	5.4.2	Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.
	Defining the strategy is a part of the organizations' design and development planning (7.3.1).	7.3.1	The organization shall plan and control the design and development of product. During the design and development planning, the organization shall determine a) the design and development stages, b) the review, verification and validation that are appropriate to each design and development stage, and c) the responsibilities and authorities for design and development. The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output shall be updated, as appropriate, as the design and development progresses.

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
b) Define a verification plan based on system requirements.	Verification planning is a part of the product realization planning (7.1).	7.1	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).
c) Potential constraints on design decisions are identified and communicated.	ISO 9001 do not have any direct reference to potential constraints on design decisions.	None	None
d) Ensure that the enabling system for verification is available and associated facilities, equipment and operators are prepared to conduct the verification.	To make available the enabling system and associated facilities, equipment and operators need the necessary resources, (6.1) infrastructure (6.3)	6.1 6.3	The organization shall determine and provide the resources needed a) to implement and maintain the quality management system and continually improve its effectiveness, and b) to enhance customer satisfaction by meeting customer requirements The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport or communication).
	and work environment.(6.4)	6.4	The organization shall determine and manage the work environment needed to achieve conformity to product requirements.
	Project specific verification may be considered to be planned as part of product realization planning [7.1 c)]	7.1 c)	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;
e) Conduct verification to demonstrate compliance to the specified design requirements.	Verification is planned in 7.1 and implemented only in 7.5.1 and 8.2.4	7.5.1	The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, and f) the implementation of release, delivery and post-delivery activities

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
		8.2.4	The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4). Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.
f) Make available verification data on the system.	The verification data should be maintained under the "Control of records" (4.2.4) And specifically for verification records 7.3.5 applies.	4.2.4 7.3.5 (part)	Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).
g) Analyze, record and report verification, discrepancy and corrective action information.	"Analyze" "verification, discrepancy and corrective action information" relates to 8.4.	8.4	The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources. The analysis of data shall provide information relating to a) customer satisfaction (see 8.2.1), b) conformity to product requirements (see 7.2.1),

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			c) characteristics and trends of processes and products including opportunities for preventive action, and d) suppliers
	“Corrective action” relates to 8.5.2.	8.5.2	The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure shall be established to define requirements for a) reviewing nonconformities (including customer complaints), b) determining the causes of nonconformities, c) evaluating the need for action to ensure that nonconformities do not recur, d) determining and implementing action needed, e) records of the results of action taken (see 4.2.4), and f) reviewing corrective action taken
	Analyzed verification data may be used for “Preventive action” in future (8.5.3)	8.5.3	The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems. A documented procedure shall be established to define requirements for a) determining potential nonconformities and their causes, b) evaluating the need for action to prevent occurrence of nonconformities,

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			c) determining and implementing action needed, d) records of results of action taken (see 4.2.4), and e) reviewing preventive action taken.
5.5.8 Transition Process			
5.5.8.1 Purpose of the Transition Process	The purpose of the Transition Process is to establish a capability to provide services specified by stakeholder requirements in the operational environment.		
This process installs a verified system, together with relevant enabling systems, e.g. operating system, support system, operator training system, user training system, as defined in agreements.	No Comment	N/A	N/A
5.5.8.3 Transition Process Activities			
The project shall implement the following activities in accordance with applicable organization policies and procedures with respect to the Transition Process.	No Comment	N/A	N/A
a) Prepare a transition strategy.	Transition can be considered as a change of the system. Preparation of the transition strategy is recognized as a part of quality planning of a system which ISO 9001 as required. in 5.4.2 a) and b)	5.4.2 a) and b)	Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.
	In some situations the transition may relate to product changes. This requirement can be considered as a part of the integrity of the system which is an ISO 9001 concern (7.1).	7.1	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).
	This activity shows the relation to installation which is the requirement of ISO 9001 7.5.1.	7.5.1	The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, and f) the implementation of release, delivery and post-delivery activities.
	Since this also concerns Human resource, it is the concern of ISO 9001 section 6.2.1.	6.2.1	Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
b) Prepare the site of operation in accordance with installation requirements.	Preparation of the site of operation can be recognized as a part of resource management including the identification of work environment. It relates to the requirement of 6.3	6.3	The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport or communication).
	and 6.4 of ISO 9001.	6.4	
	This may be part of product and service provision 7.5.1 f).	7.5.1 f)	The organization shall determine and manage the work environment needed to achieve conformity to product requirements The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable f) the implementation of release, delivery and post-delivery activities
c) Deliver the system for installation at the correct location and time.	From the view point of ISO 9001, delivery means the execution of the system. It can be considered to relate to the requirement of 7.5.1 i.e. production, in ISO 9001.	7.5.1	The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, and f) the implementation of release, delivery and post-delivery activities

Not for Resale

© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
d) Install the system in its operational location and interfaced to its environment according to its system specification.	Installation of a system can be considered as a part of production (7.5.1) from the view point of ISO 9001.	7.5.1	The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, and f) the implementation of release, delivery and post-delivery activities
	Also it may include the relation to the environment which is the issue of 6.4 of ISO 9001.	6.4	The organization shall determine and manage the work environment needed to achieve conformity to product requirements
e) Demonstrate proper installation of the system.	The demonstration of the proper installation may be verified from three perspectives, i.e. proper control of production, verification of process implementation and verification of product (7.5.1).	7.5.1	The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, and f) the implementation of release, delivery and post-delivery activities
	The proper installation can be verified by monitoring of the processes (8.2.3).	8.2.3	The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
	The proper installation can be verified by monitoring of the product (8.2.4).	8.2.4	system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product. The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4). Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.
f) Activate the system.	When this issue is considered in a so-called quality plan, it may cover the activities to execute a quality plan. Since the requirements of 7.5.1 are considered as the implementation of a quality plan, the activation of a system is thought as equivalent to the implementation of the quality plan, that is 7.5.1 Otherwise ISO 9001 does not have any relation to this activity.	7.5.1 or None	The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, and f) the implementation of release, delivery and post-delivery activities

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
g) Demonstrate the installed system is capable of delivering its required services.	When this issue is considered in a so-called quality plan, it may cover the activities of executing a quality plan (7.5.1).	7.5.1	The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, and f) the implementation of release, delivery and post-delivery activities
	To demonstrate that the installed system is capable of delivering its required services., the adequacy of the product has to be monitored and measured (8.2.4).	8.2.4	The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4). Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.
h) Record the installation data, including the operational configuration, anomalies detected, actions taken and lessons learned.	There is no concept of operation and maintenance records in ISO 9001.	4.2.4	Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
	However ISO 9001 require the control of records in general in 4.2.4.		
5.5.9 Validation Process			
5.5.9.1 Purpose of the Validation Process	The purpose of the Validation Process is to provide objective evidence that the services provided by a system when in use comply with stakeholders' requirements.		
This process performs a comparative assessment and confirms that the stakeholders' requirements are correctly defined. Where variances are identified, these are recorded and guide corrective actions. System validation is ratified by stakeholders.	No Comment	N/A	N/A
5.5.9.3 Validation Process Activities			
The project shall implement the following activities in accordance with applicable organization policies and procedures with respect to the Validation Process.	No Comment	N/A	N/A
a) Define the strategy for validating the services in the operational environment and achieving stakeholder satisfaction.	Defining the strategy is a part of the organizations' quality management system planning (5.4.2).	5.4.2	Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.
	Defining the strategy is a part of the organization's product realization (7.1).	7.1	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
	Defining the strategy is a part of the organization's design and development planning (7.3.1).	7.3.1	In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4). The organization shall plan and control the design and development of product. During the design and development planning, the organization shall determine a) the design and development stages, b) the review, verification and validation that are appropriate to each design and development stage, and c) the responsibilities and authorities for design and development. The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output shall be updated, as appropriate, as the design and development progresses
b) Prepare a validation plan.	Validation planning is a part of the product realization planning (7.1).	7.1	The organization shall plan and develop the processes needed for product realization. Planning of product realization

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).
	Defining the validation steps is a part of the organizations' design and development planning (7.3.1).	7.3.1	The organization shall plan and control the design and development of product. During the design and development planning, the organization shall determine a) the design and development stages, b) the review, verification and validation that are appropriate to each design and development stage, and c) the responsibilities and authorities for design and development. The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output shall be updated, as appropriate, as the design and development progresses

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
	The validation plan should be in accordance with the organizations' validation of processes for production and service provisions (7.5.2).	7.5.2	The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results. The organization shall establish arrangements for these processes including, as applicable a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures, d) requirements for records (see 4.2.4), and e) revalidation.
c) Ensure that any operators, enabling system for validation and associated facilities are ready in order to conduct validation.	To conduct validation, planning (7.1) should be conducted.	7.1	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).
	To ensure the validation and associated facilities there is a need to consider the conditions as described in 7.5.1.	7.5.1	The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, and f) the implementation of release, delivery and post-delivery activities
	To ensure the validation and associated facilities there is a need to consider the processes as described in 7.5.2.	7.5.2	The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results. The organization shall establish arrangements for these processes including, as applicable a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel,

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			c) use of specific methods and procedures, d) requirements for records (see 4.2.4), and e) revalidation.
	To ensure the validation, associated facilities may need to be controlled as described in 7.6.	7.6	The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1). The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements. Where necessary to ensure valid results, measuring equipment shall a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded; b) be adjusted or re-adjusted as necessary; c) be identified to enable the calibration status to be determined; d) be safeguarded from adjustments that would invalidate the measurement result; e) be protected from damage and deterioration during handling, maintenance and storage. In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4). When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary. NOTE See ISO 10012-1 and ISO 10012-2 for guidance.
d) Conduct validation to demonstrate conformance of services to stakeholder requirements.	To demonstrate conformance of services to stakeholder requirements there is a need to consider the processes as described in 7.5.2.	7.5.2	The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results. The organization shall establish arrangements for these processes including, as applicable a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures, d) requirements for records (see 4.2.4), and e) revalidation.
	To demonstrate conformance of services to stakeholder requirements meet the requirements as described in 7.3.6.	7.3.6	Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).
e) Make available validation data on the system according to legal, regulatory or product sector requirements.	To make available validation data there is a need to consider the processes as described in 7.5.2.	7.5.2	The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results. The organization shall establish arrangements for these processes including, as applicable a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures, d) requirements for records (see 4.2.4), and e) revalidation.
	To make available validation data there is a need to consider whether to meet the requirements as described in 7.3.6.	7.3.6	Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
f) As appropriate to agreement terms or organizational objectives, conduct validation to isolate that part of the system giving rise to a non-conformance.	To conduct validation to isolate the non-conformance part of the system there is a need to meet the requirements as described in 7.3.6.	7.3.6	Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).
g) Analyze, record and report validation data according to criteria defined in the validation strategy.	To analyze, record and report validation data, planning (7.1) should be carried out.	7.1	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;
	Validation of processes may also be involved (7.5.2)	7.5.2	The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results. The organization shall establish arrangements for these processes including, as applicable a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel,

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			c) use of specific methods and procedures, d) requirements for records (see 4.2.4), and e) revalidation.
	To analyze, record and report validation data, generally, 8.1a) is also appropriate.	8.1 a)	The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed a) to demonstrate conformity of the product,
	Specifically, 8.4 covers the analysis of data	8.4	The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources. The analysis of data shall provide information relating to a) customer satisfaction (see 8.2.1), b) conformity to product requirements (see 7.2.1), c) characteristics and trends of processes and products including opportunities for preventive action, and d) suppliers.
5.5.10 Operation Process			
5.5.10.1 Purpose of the Operation Process	The purpose of the Operation Process is to use the system in order to deliver its services.		
This process assigns personnel to operate the system, and monitors the services and operator-system performance. In order to sustain services it identifies and analyzes operational problems in relation to agreements, stakeholder requirements and organizational constraints.			

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
5.5.10.3 peration Process Activities			
The project shall implement the following activities in accordance with applicable organization policies and procedures with respect to the Operation Process.	No Comment	N/A	N/A
a) Prepare a strategy for operation.	The preparation of a strategy for operation can be considered as quality planning of the system (5.4.2).	5.4.2	Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.
	Operation may cover the requirement for production, in which case this issue may have a relation to quality planning of a product (7.1).	7.1	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS

© ISO/IEC 2008 – All rights reserved

Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
b) Obtain other services related to operation of the system.	The concept of this issue relates to purchasing in ISO 9001 (7.4.1). Especially the evaluation of suppliers.	7.4.1	The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).
	When an organization gets something from outside of the system, it can be controlled under controlled conditions to maintain the control of the production (7.5.1)	7.5.1	The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, and f) the implementation of release, delivery and post-delivery activities
c) Assign trained, qualified personnel to be operators.	Human resource issues are treated in 6.2 of ISO 9001	6.2.1	Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
		6.2.2	The organization shall a) determine the necessary competence for personnel performing work affecting product quality, b) provide training or take other actions to satisfy these needs, 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 (see 4.2.4).
d) Activate the system in its intended operational situation to deliver instances of service or continuous service according to its intended purpose.	No concept of operation exists in ISO 9001 but one could be defined. If a system operation needs planning this would be carried out in ISO 9001:2000 7.5.1	7.5.1	The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, and f) the implementation of release, delivery and post-delivery activities.

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
e) Consume materials, as required, to sustain the services.	To consume materials the material has to be procured before hand. To obtain the materials, ISO 9001 uses the requirements in 7.4.1.	7.4.1	The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).
	To keep the quality, production shall be controlled. This control is described in 7.5.1 of ISO 9001	7.5.1	The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, and f) the implementation of release, delivery and post-delivery activities
	To sustain the production, resource have to be managed. For this purpose ISO 9001 describes the requirements in 6.1 in summary.	6.1	The organization shall determine and provide the resources needed a) to implement and maintain the quality management system and continually improve its effectiveness, and

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			b) to enhance customer satisfaction by meeting customer requirements
	To sustain the production, resources other than human resource are defined in 6.3	6.3	The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport or communication).
	and 6.4 of ISO 9001	6.4	The organization shall determine and manage the work environment needed to achieve conformity to product requirements.
f) Monitor operation to ensure that the system is operated in accordance with the operations plans, in a safe manner and compliant with legislated guidelines concerning occupational safety and environmental protection.	Monitoring described here is the same concern of 8.2.3 of ISO 9001.	8.2.3	The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product
	To keep the controlled condition of operation, i.e., production, the requirements are described in 7.5.1 of ISO 9001.	7.5.1	The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices,

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			e) the implementation of monitoring and measurement, and f) the implementation of release, delivery and post-delivery activities
g) Monitor the system operation to confirm that service performance is within acceptable parameters.	The requirement here is just same concern as 8.2.3 of ISO 9001	8.2.3	The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product
h) Perform failure identification actions when a non-compliance has occurred in the delivered services.	The requirement here is just the same concern as 8.3 of ISO 9001	8.3	The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure. The organization shall deal with nonconforming product by one or more of the following ways: a) by taking action to eliminate the detected nonconformity; b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer; c) by taking action to preclude its original intended use or application. Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements. When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.
i) Determine the appropriate course of action when corrective action is required to remedy failings due to changed need.	The requirement here is just the same concern as 8.5.2 of ISO 9001	8.5.2	The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure shall be established to define requirements for a) reviewing nonconformities (including customer complaints), b) determining the causes of nonconformities, c) evaluating the need for action to ensure that nonconformities do not recur, d) determining and implementing action needed, e) records of the results of action taken (see 4.2.4), and f) reviewing corrective action taken.

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
j) Introduce remedial changes to operating procedures, the operator environment, human-machine interfaces and operator training as appropriate when human error contributed to failure.	When change occurs ISO 9001 requires the integrity of the system to be kept, including operations. This issue can be considered as equivalent to 5.4.2 b) of ISO 9001	5.4.2 b)	Top management shall ensure that b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.
	When the change influences to the operator environment, 6.4 of ISO 9001 may relate.	6.4	The organization shall determine and manage the work environment needed to achieve conformity to product requirements.
	The change of system operation may be triggered by monitoring the processes of the system (8.2.3).	8.2.3	The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product
	As described in this issue human resource including operator training has to be introduced. In this situation the requirement of 6.2.2 of ISO 9001 relate closely.	6.2.2	The organization shall a) determine the necessary competence for personnel performing work affecting product quality, b) provide training or take other actions to satisfy these needs, 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 (see 4.2.4).

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
k) Continuously or routinely communicate with users to determine the degree to which delivered services satisfy their needs.	This issue is equivalent to the requirement of 7.2.3 of ISO 9001	7.2.3	The organization shall determine and implement effective arrangements for communicating with customers in relation to a) product information, b) enquiries, contracts or order handling, including amendments, and c) customer feedback, including customer complaints.
5.5.11 Maintenance Process			
5.5.11.1 Purpose of the Maintenance Process	The purpose of the Maintenance Process is to sustain the capability of the system to provide a service.		
This process monitors the system's capability to deliver services, records problems for analysis, takes corrective, adaptive, perfective and preventive actions and confirms restored capability.			
5.5.11.3 Maintenance Process Activities			
The project shall implement the following activities in accordance with applicable organization policies and procedures with respect to the Maintenance Process.	No Comment	N/A	N/A
a) Prepare a maintenance strategy.	This concern may be covered in planning of QMS establishment (5.4.2).	5.4.2	Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.
	Also ISO 9001:2000 states the provision of suitable equipment as resource management in 6.3.	6.3	The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements

Not for Resale

© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
	If a project is considered part of product realization the preparation of a maintenance strategy could be considered part of planning [7.1 a) b) c)].	7. 1 a) b) c)	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; The output of this planning shall be in a form suitable for the organization's method of operations.
b) Define the constraints on system requirements that are unavoidable consequences of the maintenance strategy.	If maintenance is defined in the quality plan, the following ISO 9001 requirements may relate (5.4.2b) and 7.1).	5.4.2 b) 7.1	Top management shall ensure that b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented. The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate:

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
			a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4). The output of this planning shall be in a form suitable for the organization's method of operations.
c) Obtain the enabling systems, system elements and services to be used during maintenance of the system.	Acquire an enabling system may refer to the product realization process of ISO 9001 (7.1). If maintenance is procured 7.4 is applicable	7.1 7.4.1	The organization shall plan and develop the processes needed for product realization. The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
d) Implement problem reporting and incident recording to guide diagnosis of individual events and histories to support future corrective, adaptive, perfective and preventive maintenance.	There is no clear requirement on maintenance in ISO 9001:2000.	None	None
e) Implement the procedures for correction of random faults and/or scheduled replacement of system elements.	There is no clear requirement on maintenance in ISO 9001:2000.	None	None
f) Initiate corrective action to remedy previously undetected design errors.	As a part of corrective action, this issue is covered (8.5.2).	8.5.2	The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure shall be established to define requirements for a) reviewing nonconformities (including customer complaints), b) determining the causes of nonconformities, c) evaluating the need for action to ensure that nonconformities do not recur, d) determining and implementing action needed, e) records of the results of action taken (see 4.2.4), and f) reviewing corrective action taken
g) Confirm that logistics actions satisfy the required replenishment levels so that stored system elements meet repair rates and planned schedules.	There is no clear requirement on maintenance in ISO 9001:2000. However personnel training is in 6.2.2	6.2.2	Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
h) Perform preventive maintenance by replacing or servicing system elements prior to failure, according to planned schedules and maintenance procedures.	This issue is treated partly in 8.2.3 process monitoring	8.2.3	The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product
	and in the generic concept of preventive action (8.5.3).	8.5.3	The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems. A documented procedure shall be established to define requirements for a) determining potential nonconformities and their causes, b) evaluating the need for action to prevent occurrence of nonconformities, c) determining and implementing action needed, d) records of results of action taken (see 4.2.4), and e) reviewing preventive action taken.
i) Perform failure identification actions when a non-compliance has occurred in the system.	Monitoring of processes (8.2.3)	8.2.3	The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
	and Corrective action may be relevant to this requirement (8.5.2).	8.5.2	The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure shall be established to define requirements for a) reviewing nonconformities (including customer complaints), b) determining the causes of nonconformities , c) evaluating the need for action to ensure that nonconformities do not recur, d) determining and implementing action needed, e) records of the results of action taken (see 4.2.4), and f) reviewing corrective action taken
j) Maintain a history of problem reports, corrective actions and trends to inform operations and maintenance personnel, and other projects that are creating or utilizing similar system entities.	Collection of data is in 8.4 of ISO 9001:2000.	8.4	The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources. The analysis of data shall provide information relating to a) customer satisfaction (see 8.2.1), b) conformity to product requirements (see 7.2.1), c) characteristics and trends of processes and products including opportunities for preventive action, and d) suppliers.

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
5.5.12 Disposal Process			
5.5.12.1 Purpose of the Disposal Process	The purpose of the Disposal Process is to end the existence of a system entity.		
5.5.12.3 Disposal Process Activities			
The project shall implement the following activities in accordance with applicable organization policies and procedures with respect to the Disposal Process.	No Comment	N/A	N/A
a) Define a disposal strategy for the system, to include each system element and any resulting waste products.	ISO 9001:2000 does not include the concept of disposal.	None	None
b) Unavoidable constraints on the system design arising from the disposal strategy are communicated.	ISO 9001:2000 does not include the concept of disposal.	None	None
c) Acquire the enabling systems or services to be used during disposal of a system.	ISO 9001:2000 does not include the concept of disposal.	None	None
d) Deactivate the system to prepare it for removal from operation.	ISO 9001:2000 does not include the concept of disposal.	None	None
e) Withdraw operating staff from the system and record relevant operating knowledge.	ISO 9001:2000 does not include the concept of disposal.	None	None
f) Disassemble the system into manageable elements to facilitate its removal for reuse, recycling, reconditioning, overhaul, archiving or destruction.	ISO 9001:2000 does not include the concept of disposal.	None	None
g) Remove the system from the operational environment for reuse, recycling, reconditioning, overhaul or destruction.	ISO 9001:2000 does not include the concept of disposal.	None	None
h) Specify containment facilities, storage locations, inspection criteria and storage periods if the system is to be stored.	ISO 9001:2000 does not include the concept of disposal.	None	None
i) Conduct destruction of the system, as necessary, to reduce the amount of waste treatment or to make the waste easier to handle.	ISO 9001:2000 does not include the concept of disposal.	None	None
j) Confirm that no detrimental health, safety, security and environmental factors exist following disposal.	ISO 9001:2000 does not include the concept of disposal.	None	None

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale
© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
© ISO/IEC 2008 – All rights reserved
Not for Resale

ISO/IEC 15288 text	Rationale / Explanation	ISO 9001 para.	ISO 9001 text
k) Archive information gathered through the lifetime of the system to permit audits and reviews in the event of long-term hazards to health, safety, security and the environment, and to permit future system creators and users to build a knowledge base from past experiences.	ISO 9001:2000 does not include the concept of disposal.	None	None

4 ISO 9001 Sections not yet invoked in Table 5

ISO 9001 text	Rationale/ Explanation	ISO/IEC 15288 para.	ISO/IEC 15288 text
4.2.2 Quality manual The organization shall establish and maintain a quality manual that includes a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2), b) the documented procedures established for the quality management system, or reference to them, and c) a description of the interaction between the processes of the quality management system.	This is an organisation level issue not addressed by ISO/IEC 15288, although definition of policy, objectives and procedures is requested.	None	None
5.5.2 a) b) Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes a) ensuring that processes needed for the quality management system are established, implemented and maintained, b) reporting to top management on the performance of the quality management system and any need for improvement, and	Not included as a concept in ISO/IEC 15288.	None	None

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS

ISO 9001 text	Rationale/ Explanation	ISO/IEC 15288 para.	ISO/IEC 15288 text
5.6.3 Review output The output from the management review shall include any decisions and actions related to a) improvement of the effectiveness of the quality management system and its processes, b) improvement of product related to customer requirements, and c) resource needs.	Improvement is catered for in ISO/IEC 15288, but there is no organization level review like ISO 9001.	None	None
7.5.4 Customer property The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 4.2.4). NOTE Customer property can include intellectual property.	Not included as a concept in ISO/IEC 15288.	None	None
8.1 a) b) The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed a) to demonstrate conformity of the product, b) to ensure conformity of the quality management system, and...	Not included as a concept in ISO/IEC 15288.	None	None

Not for Resale

© ISO/IEC 2008 – All rights reserved

Bibliography

[1] ISO 9000:2005, *Quality management systems — Fundamentals and vocabulary*

[2] ISO 9001:2000, *Quality management systems — Requirements*

[3] ISO/IEC 12207:2008, *Systems and software engineering — Software life cycle processes*

[4] ISO/IEC 15288:2002 [1)], *Systems engineering — System life cycle processes*

[5] ISO/IEC 90003:2004, *Software engineering — Guidelines for the application of ISO 9001:2000 to computer sofware*

1) ISO/IEC 15288:2002 has been cancelled and replaced by ISO/IEC 15288:2008, *Systems and software engineering — System life cycle processes*

© ISO/IEC 2008 – All rights reserved

Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale

ICS 03.120.10; 35.080

Price based on 135 pages

© ISO/IEC 2008 – All rights reserved
Copyright International Organization for Standardization
Provided by IHS under license with ISO
No reproduction or networking permitted without license from IHS
Not for Resale