

ISO IEC 9003 2014 TRANSLATED INTO PLAIN ENGLISH

7. REALIZATION REQUIREMENTS AND GUIDELINES

7.1 PLANNING REQUIREMENTS AND GUIDELINES

1	SHL	Establish a product realization planning process.	TODO	DONE	N/A	A product starts out as an idea. The idea is <i>realized</i> by following a set of product realization processes. <i>Product realization</i> refers to all of the processes that are used to bring products into being. (When ISO uses the term <i>product</i> , they're also talking about <i>service</i> .)
2	SHL	Plan the realization of your organization's products.	TODO	DONE	N/A	
3	SHL	Use your planning process to set your product quality objectives.	TODO	DONE	N/A	
4	SHL	Use your planning process to specify product quality requirements.	TODO	DONE	N/A	
5	SHL	Use your planning process to identify your product realization needs.	TODO	DONE	N/A	A document that describes the QMS processes and resources that will be applied to a specific product, project, or contract is called a <i>quality plan</i> .
6	SHL	Determine the documents that you will need in order to realize products.	TODO	DONE	N/A	
7	SHL	Determine the records that you will need in order to realize products.	TODO	DONE	N/A	Section 7 requirements may be <i>excluded</i> if doing so does not undermine your ability or willingness to meet product requirements. That's why we've added an N/A column.
8	SHL	Select the records needed to prove that products meet requirements.	TODO	DONE	N/A	
9	SHL	Select the records needed to prove that processes meet requirements.	TODO	DONE	N/A	
10	SHL	Establish records to support your product realization processes.	TODO	DONE	N/A	
11	SHL	Determine the criteria that you will need to decide if products are acceptable.	TODO	DONE	N/A	
12	SHL	Clarify and establish your organization's product acceptance criteria.	TODO	DONE	N/A	
13	SHL	Determine the processes that you will need in order to realize products.	TODO	DONE	N/A	
14	SHL	Ensure that these processes are integrated with other QMS processes.	TODO	DONE	N/A	
15	SHL	Determine the methods that you will need to control product quality.	TODO	DONE	N/A	<i>Verification</i> uses objective evidence to confirm that requirements are met. <i>Validation</i> uses objective evidence to confirm that the requirements which define an intended use or application have been met.
16	SHL	Identify the verification methods that you will need to control product quality.	TODO	DONE	N/A	
17	SHL	Identify the validation methods that you will need to control product quality.	TODO	DONE	N/A	<i>Inspections</i> use observation, measurement, testing and judgment to evaluate conformity.
18	SHL	Identify the monitoring methods that you will need to control product quality.	TODO	DONE	N/A	
19	SHL	Identify the measurement methods that you will need to control product quality.	TODO	DONE	N/A	
20	SHL	Identify the inspection methods that you will need to control product quality.	TODO	DONE	N/A	<i>To test</i> means to use a procedure to determine or to identify the characteristics of something.
21	SHL	Identify the testing methods that you will need to control product quality.	TODO	DONE	N/A	

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22	SHL	Determine the resources that you will need to realize products.	TODO	DONE	N/A	
23	SHL	Produce product realization planning outputs.	TODO	DONE	N/A	A note to section 7.1 says that you may use the approach described in section 7.3 to develop your product realization processes (if you find it helpful).
24	SHL	Prepare outputs that are suitable and consistent with your organization's methods.	TODO	DONE	N/A	
25	SHL	Develop your product realization processes.	TODO	DONE	N/A	

7.1.1 USE LIFE CYCLE MODELS TO PLAN WORK

26	SHD	Select suitable life cycle models to manage software design and development.	TODO	DONE	N/A	Section 7.1.1 says: "ISO 9001:2008 is intended for application irrespective of the life cycle models used and is not intended to indicate a specific life cycle model or process sequence." ISO 9001:2008 does not force you to use a particular software life cycle model or expect you to follow a particular process sequence. You may use any suitable approach. Section 7.1.1 says: "Design and development can be an evolutionary process and procedures may therefore need to be changed or updated as the project progresses, after consideration of changes to related activities and tasks."
27	SHD	Consider the nature of your project when you select models and methods.	TODO	DONE	N/A	
28	SHD	Consider project size and complexity when you select models and methods.	TODO	DONE	N/A	
29	SHD	Consider tasks and activities when you select models and methods.	TODO	DONE	N/A	
30	SHD	Consider the nature of your product when you select models and methods.	TODO	DONE	N/A	
31	SHD	Consider risks and safety concerns when you select models and methods.	TODO	DONE	N/A	
32	SHD	Consider software products that could cause injury, damage, or destruction.	TODO	DONE	N/A	
33	SHD	Make sure that design specifications address potential software failure conditions.	TODO	DONE	N/A	
34	SHD	Specify requirements that expect immunity from potential failure conditions.	TODO	DONE	N/A	
35	SHD	Specify requirements that expect a response to potential failure conditions.	TODO	DONE	N/A	
36	SHD	Use suitable life cycle models to plan and perform software design and development.	TODO	DONE	N/A	
37	SHD	Use suitable life cycle models to plan your processes, activities, and tasks.	TODO	DONE	N/A	
38	SHD	Use your life cycle models to develop software development plans.	TODO	DONE	N/A	
39	SHD	Use your plans to describe the software products that will be developed.	TODO	DONE	N/A	
40	SHD	Specify who will develop them and when this work will be done.	TODO	DONE	N/A	
41	SHD	Use your plans to describe how software products will be developed.	TODO	DONE	N/A	
42	SHD	Use your plans to describe how products will be assessed.	TODO	DONE	N/A	

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43	SHD	Use your plans to describe how products will be maintained.	TODO	DONE	N/A	
44	SHD	Use suitable life cycle models to perform processes, activities, and tasks.	TODO	DONE	N/A	
7.1.2 CARRY OUT SOFTWARE QUALITY PLANNING						
45	SHD	Plan software projects, products, and contracts.	TODO	DONE	N/A	<p>The purpose of your quality planning should be to figure out how to apply your quality management system to your software projects, products, and contracts.</p> <p>Your quality planning activities will generate a quality plan. Your plan could be a single document, several documents, or part of another larger document.</p> <p>Also see ISO/IEC 12207 section 6.3.1 on project planning and section 7.2 on software support. ISO/IEC 12207 treats quality planning and product development planning as a single planning activity which results in the creation of a project management plan.</p>
46	SHD	Clarify quality needs and requirements.	TODO	DONE	N/A	
47	SHD	Clarify product oriented quality needs and requirements.	TODO	DONE	N/A	
48	SHD	Clarify process oriented quality needs and requirements.	TODO	DONE	N/A	
49	SHD	Figure out how QMS should be tailored.	TODO	DONE	N/A	
50	SHD	Figure out how QMS can be applied to projects, products, and contracts.	TODO	DONE	N/A	
51	SHD	Address quality needs and requirements.	TODO	DONE	N/A	
52	SHD	Address the need to have suitable procedures.	TODO	DONE	N/A	
53	SHD	Address the need to have appropriate QMS procedures and instructions.	TODO	DONE	N/A	
54	SHD	Use procedures and instructions that respect the scope of your quality manual.	TODO	DONE	N/A	
55	SHD	Use procedures and instructions that acknowledge any official exclusions.	TODO	DONE	N/A	
56	SHD	Address the need to have project-specific procedures and instructions.	TODO	DONE	N/A	
57	SHD	Address the need to have project-specific software test specifications.	TODO	DONE	N/A	
58	SHD	Use suitable project-specific test plans, designs, cases, and procedures.	TODO	DONE	N/A	
59	SHD	Use suitable unit, integration, system, and acceptance testing procedures.	TODO	DONE	N/A	
60	SHD	Address the need to have effective configuration management procedures.	TODO	DONE	N/A	See section 7.5.3, below.
61	SHD	Address the need to employ reusable assets.	TODO	DONE	N/A	
62	SHD	Employ reusable tools, methods, and life cycle models.	TODO	DONE	N/A	
63	SHD	Employ reusable programming language conventions.	TODO	DONE	N/A	

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64	SHD	Employ reusable software libraries and frameworks.	TODO	DONE	N/A	
65	SHD	Address the need to perform monitoring activities.	TODO	DONE	N/A	
66	SHD	Address the need to carry out suitable measurement activities.	TODO	DONE	N/A	
67	SHD	Address the need to approve process outputs.	TODO	DONE	N/A	
68	SHD	Make people responsible for approving outputs for subsequent use.	TODO	DONE	N/A	
69	SHD	Address the need to use competent personnel.	TODO	DONE	N/A	
70	SHD	Clarify your software training needs and requirements.	TODO	DONE	N/A	
71	SHD	Schedule suitable training before skills are needed.	TODO	DONE	N/A	
72	SHD	Teach people how to use tools and techniques.	TODO	DONE	N/A	
73	SHD	Address the need to control software quality.	TODO	DONE	N/A	
74	SHD	Establish specific software review methods and procedures.	TODO	DONE	N/A	See section 7.3.4, below.
75	SHD	Establish specific software verification methods and procedures.	TODO	DONE	N/A	See section 7.3.5, below.
76	SHD	Establish specific software validation methods and procedures.	TODO	DONE	N/A	See section 7.3.6, below.
77	SHD	Address the need to manage and control changes.	TODO	DONE	N/A	
78	SHD	Address the need to manage and control resource changes.	TODO	DONE	N/A	
79	SHD	Address the need to manage and control schedule changes.	TODO	DONE	N/A	
80	SHD	Address the need to manage and control contractual changes.	TODO	DONE	N/A	
81	SHD	Address the need to maintain suitable records.	TODO	DONE	N/A	See section 4.2.4, below.
82	SHD	Establish software quality objectives.	TODO	DONE	N/A	
83	SHD	Clarify limited quality objectives for limited-purpose software.	TODO	DONE	N/A	
84	SHD	Plan the testing of this software to ensure that it fulfils its limited purpose.	TODO	DONE	N/A	
85	SHD	Define each software development stage.	TODO	DONE	N/A	
86	SHD	Define each design and development stage before you begin work on that stage.	TODO	DONE	N/A	

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87	SHD	Establish criteria that determines when each project stage starts and finishes.	TODO	DONE	N/A	
88	SHD	Include all related plans and procedures.	TODO	DONE	N/A	For more information, see ISO/IEC 25010:2011 on systems and software quality requirements and evaluation (SQuaRE), and system and software quality models; ISO/IEC 25001:2007 on systems and software quality requirements and evaluation (SQuaRE), and planning and management; and ISO/IEC 16326:2009 on life cycle processes, and project management.
89	MAY	Include or refer to generic or project, product, or contract-specific procedures.	TODO	DONE	N/A	
90	SHD	Include or refer to your product development plans, procedures, and policies.	TODO	DONE	N/A	
91	MAY	Review plans for projects, products, and contracts.	TODO	DONE	N/A	
92	MAY	Ask all participating organizations to review your software quality plans.	TODO	DONE	N/A	
93	MAY	Approve plans for projects, products, and contracts.	TODO	DONE	N/A	
94	MAY	Ask all participating organizations to agree before work is carried out.	TODO	DONE	N/A	

7.2 CUSTOMER REQUIREMENTS AND GUIDELINES

7.2.1 DETERMINE REQUIREMENTS RELATED TO PRODUCTS

95	SHL	Determine your customers' requirements.	TODO	DONE	N/A	
96	SHL	Identify your customers' product requirements.	TODO	DONE	N/A	
97	SHL	Identify your customers' delivery requirements.	TODO	DONE	N/A	
98	SHL	Identify your customers' post-delivery requirements.	TODO	DONE	N/A	
99	SHL	Identify customers' warranty requirements.	TODO	DONE	N/A	
100	SHL	Identify customers' maintenance requirements.	TODO	DONE	N/A	
101	SHL	Identify customers' contractual requirements.	TODO	DONE	N/A	
102	SHL	Identify supplementary service requirements.	TODO	DONE	N/A	
103	SHL	Identify customers' recycling requirements.	TODO	DONE	N/A	
104	SHL	Identify customers' final disposal requirements.	TODO	DONE	N/A	
105	SHL	Determine your intended use requirements.	TODO	DONE	N/A	
106	SHL	Determine your legal product requirements.	TODO	DONE	N/A	

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107	SHL	Identify product requirements imposed by regulators.	TODO	DONE	N/A	
108	SHL	Identify product requirements imposed by statute.	TODO	DONE	N/A	
109	SHL	Determine your organization's requirements.	TODO	DONE	N/A	

7.2.1.1 DETERMINE CUSTOMER-RELATED REQUIREMENTS

110	MAY	Establish methods for managing software requirements.	TODO	DONE	N/A	
111	MAY	Establish methods for developing software requirements.	TODO	DONE	N/A	
112	MAY	Establish methods for identifying software requirements.	TODO	DONE	N/A	
113	MAY	Establish methods for identifying your customer's software requirements.	TODO	DONE	N/A	
114	MAY	Establish methods for clarifying the customer's operational environment.	TODO	DONE	N/A	
115	MAY	Establish methods for identifying your organization's software requirements.	TODO	DONE	N/A	
116	MAY	Establish methods for clarifying your organization's operational environment.	TODO	DONE	N/A	
117	MAY	Establish methods for allocating software requirements.	TODO	DONE	N/A	
118	MAY	Establish methods for allocating requirements for system specifications.	TODO	DONE	N/A	
119	MAY	Establish methods for allocating requirements between software and hardware.	TODO	DONE	N/A	
120	MAY	Establish methods for ensuring that interface specifications are formulated.	TODO	DONE	N/A	
121	MAY	Establish methods for formulating software requirements.	TODO	DONE	N/A	
122	MAY	Establish methods for ensuring that requirements are clearly specified.	TODO	DONE	N/A	
123	MAY	Establish methods for ensuring that misunderstandings are avoided.	TODO	DONE	N/A	
124	MAY	Establish methods for defining terms and providing background information.	TODO	DONE	N/A	
125	MAY	Establish methods for ensuring that specifications facilitate product acceptance.	TODO	DONE	N/A	
126	MAY	Establish methods for evaluating software requirements.	TODO	DONE	N/A	
127	MAY	Establish methods for evaluating software prototypes or demonstrations.	TODO	DONE	N/A	

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128	MAY	Establish methods for reviewing software requirements.	TODO	DONE	N/A	
129	MAY	Establish methods for reviewing requirements and recording results.	TODO	DONE	N/A	
130	MAY	Establish methods for approving software requirements.	TODO	DONE	N/A	
131	MAY	Establish methods for agreeing on software requirements.	TODO	DONE	N/A	
132	MAY	Establish methods for obtaining official customer approval.	TODO	DONE	N/A	
133	MAY	Establish methods for authorizing changes in requirements.	TODO	DONE	N/A	
134	MAY	Establish methods for tracking changes in software requirements.	TODO	DONE	N/A	
135	MAY	Establish methods for tracking changes during iterative development.	TODO	DONE	N/A	
136	MAY	Establish methods for controlling software requirements.	TODO	DONE	N/A	
137	MAY	Establish methods for controlling changes to software requirements.	TODO	DONE	N/A	
138	MAY	Establish methods for controlling changes during development projects.	TODO	DONE	N/A	
139	MAY	Establish methods for amending contracts whenever requirements change.	TODO	DONE	N/A	
140	MAY	Establish methods for tracing software requirements.	TODO	DONE	N/A	
141	MAY	Establish methods for tracing requirements throughout development life cycle.	TODO	DONE	N/A	See section 7.5.3, below.
142	MAY	Establish methods for tracing software requirements to final software products.	TODO	DONE	N/A	
143	MAY	Manage your organization's software requirements.	TODO	DONE	N/A	
144	MAY	Clarify requirements for your software.	TODO	DONE	N/A	
145	MAY	Clarify relevant operational environments.	TODO	DONE	N/A	
146	MAY	Clarify legal obligations for your software.	TODO	DONE	N/A	
147	MAY	Clarify regulatory and statutory requirements.	TODO	DONE	N/A	
148	MAY	Clarify required software characteristics.	TODO	DONE	N/A	
149	MAY	Clarify software reliability requirements.	TODO	DONE	N/A	
150	MAY	Clarify software efficiency requirements.	TODO	DONE	N/A	

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151	MAY	Clarify software functionality requirements.	TODO	DONE	N/A	
152	MAY	Clarify software maintainability requirements.	TODO	DONE	N/A	
153	MAY	Clarify software traceability requirements.	TODO	DONE	N/A	
154	MAY	Clarify software portability requirements.	TODO	DONE	N/A	
155	MAY	Clarify software usability requirements.	TODO	DONE	N/A	
156	MAY	Clarify software security requirements.	TODO	DONE	N/A	
157	MAY	Clarify software safety requirements.	TODO	DONE	N/A	
158	MAY	Specify requirements for your software.	TODO	DONE	N/A	
159	MAY	Specify requirements for software that will be developed as part of a contract.	TODO	DONE	N/A	
160	MAY	Specify requirements for software that will be produced for a market sector.	TODO	DONE	N/A	
161	MAY	Specify requirements for software that will be used to support processes.	TODO	DONE	N/A	
162	MAY	Specify requirements for software that will be embedded in a system.	TODO	DONE	N/A	
163	MAY	Approve requirements for your software.	TODO	DONE	N/A	
164	MAY	Control requirements for your software.	TODO	DONE	N/A	

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