

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: <i>"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."</i> 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: <i>"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."</i> |
| 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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