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| **PART** | **TABLE OF CONTENTS** | **PAGE** |
| **A** | **Introduction to Framework** | **3** |
| **B** | **Overview of Framework** | **6** |
|  | **THE FRAMEWORK** |  |
| **1** | **Develop Process** | **11** |
| **2** | **Implement Process** | **45** |
| **3** | **Operate Process** | **58** |
| **4** | **Maintain Process** | **81** |
| **5** | **Measure Process** | **91** |
| **6** | **Monitor Process** | **107** |
| **7** | **Control Process** | **127** |
| **8** | **Evaluate Process** | **155** |
| **9** | **Modify Process** | **166** |
| License agreement and contact information | | |

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|  | **INTRODUCTION TO PROCESS MANAGEMENT FRAMEWORK** | |
|  | **PROCESS APPROACH** | Almost all ISO management standards now expect organizations to use a process approach. These include the following:   * ISO 9001 Quality Management Standard * ISO 14001 Environmental Management Standard * ISO 45001 Occupational Health and Safety Standard * ISO 27001 Information Security Management Standard * ISO 13485 Quality Management Standard for Medical Devices * AS9100 Quality Management Standard for Aerospace and Defense * IATF 16949 Quality Management Standard for Automotive Sector * ISO 17025 Standard for Testing and Calibration Laboratories * ISO 22301 Business Continuity Management Standard * ISO 50001 Energy Management Standard * ISO 31000 Risk Management Standard |
|  |  | Even though many ISO standards now expect organizations to use a process approach, ISO has failed to explain how they are supposed to meet this important requirement. That's why we developed our Plain English Process Management Framework. Our Process Management Framework is based on, is derived from, and is entirely consistent and compatible with the above management standards. |
|  |  | If you use a process approach or you want to learn how to use a process approach or you'd like to teach others how to use a process approach, our Plain English Process Management Framework is for you. |
|  | **BRIEF OUTLINE OF PROCESS MANAGEMENT FRAMEWORK** | |
|  | **1. DEVELOP PROCESS** | 1.1 Study the context of your process  1.2 Clarify the purpose of your process  1.3 Consider your process requirements  1.4 Plan process design and development  1.5 Design process support programmes  1.6 Identify process documents and records  1.7 Establish process roles and responsibilities |
|  | **2. IMPLEMENT PROCESS** | 2.1 Provide resources needed to implement process  2.2 Create the environment that your process needs  2.3 Verify that process can produce required outputs  2.4 Establish plans to achieve your process objectives  2.5 Explain process policies, procedures, and objectives  2.6 Communicate process management expectations  2.7 Expect all process managers to be accountable  2.8 Establish process management programmes  2.9 Retain implementation documentation |
|  | **3. OPERATE PROCESS** | 3.1 Provide resources to facilitate process operations  3.2 Ask process owners to manage process operations  3.3 Expect personnel to carry out process operations |
|  | **4. MAINTAIN PROCESS** | 4.1 Provide the resources needed to maintain process  4.2 Use authorized methods to maintain your process |
| **5. MEASURE PROCESS** | 5.1 Plan how you're going to measure your process  5.2 Qualify the resources needed to measure process  5.3 Provide the resources needed to measure process  5.4 Use authorized methods to measure your process  5.5 Control the resources needed to measure process |
| **6. MONITOR PROCESS** | 6.1 Plan how you're going to monitor your process  6.2 Qualify the resources needed to monitor process  6.3 Provide the resources needed to monitor process  6.4 Use authorized methods to monitor your process  6.5 Control the resources needed to monitor process |
| **7. CONTROL PROCESS** | 7.1 Plan how you're going to control process  7.2 Develop ways of controlling your process  7.3 Provide resources needed to control process  7.4 Use authorized methods to control process |
|  | **8. EVALUATE PROCESS** | 8.1 Plan how you're going to evaluate process  8.2 Provide resources needed to evaluate process  8.3 Use authorized methods to evaluate process  8.4 Record the results of process evaluations |
|  | **9. MODIFY PROCESS** | 9.1 Establish your process modification methods  9.2 Identify opportunities to modify your process  9.3 Plan how you're going to modify your process  9.4 Use authorized methods to modify your process  9.5 Review and evaluate process modifications |
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|  | **1. DEVELOP PROCESS** | 1.1 Study the context of your process  1.1.1 Consider process participants  1.1.2 Consider process environment  1.1.3 Consider process risks and threats  1.1.4 Consider process opportunities  1.2 Clarify the purpose of your process  1.2.1 Define process scope and boundaries  1.2.2 Establish your process objectives  1.3 Consider your process requirements  1.3.1 Clarify process output requirements  1.3.2 Clarify process knowledge requirements  1.3.3 Clarify process competence requirements  1.3.4 Clarify process management requirements  1.3.5 Clarify process communication requirements  1.3.6 Clarify process infrastructure requirements  1.3.7 Clarify process environment requirements  1.3.8 Clarify process resource requirements  1.4 Plan process design and development  1.4.1 Carry out output planning  1.4.2 Carry out process planning  1.4.3 Carry out input planning  1.5 Design process support programmes  1.5.1 Design risk management programme  1.5.2 Design safety management programme  1.5.3 Design quality management programme  1.5.4 Design security management programme  1.5.5 Design supplier management programme  1.5.6 Design environmental management programme  1.5.7 Design business continuity management programme  1.6 Identify process documents and records  1.6.1 Evaluate documentation requirements  1.6.2 Select process documents and records  1.6.3 Develop process documents and records  1.7 Establish process roles and responsibilities  1.7.1 Assign process responsibilities and authorities  1.7.2 Document process responsibilities and authorities |
|  | **2. IMPLEMENT PROCESS** | 2.1 Provide resources needed to implement process  2.2 Create the environment that your process needs  2.3 Verify that process can produce required outputs  2.4 Establish plans to achieve your process objectives  2.5 Explain process policies, procedures, and objectives  2.6 Communicate process management expectations  2.7 Expect all process managers to be accountable  2.8 Establish process management programmes  2.9 Retain implementation documentation |
|  | **3. OPERATE PROCESS** | 3.1 Provide resources to facilitate process operations  3.1.1 Provide the expertise needed to operate your process  3.1.2 Provide the technology needed to operate your process  3.1.3 Provide the infrastructure needed to operate your process  3.2 Ask process owners to manage process operations  3.2.1 Expect process managers to address risks and opportunities  3.2.2 Expect process managers to implement policies and procedures  3.2.3 Expect process managers to specify output requirements and capabilities  3.2.4 Expect process managers to communicate with their process customers  3.2.5 Expect process managers to evaluate and select their external providers  3.2.6 Expect process managers to supervise and control all process activities  3.2.7 Expect process managers to measure conformance and performance  3.2.8 Expect process managers to meet expectations and requirements  3.2.9 Expect process managers to be accountable for their process  3.3 Expect personnel to carry out process operations  3.3.1 Expect personnel to focus on process customers  3.3.2 Expect personnel to handle risks and opportunities  3.3.3 Expect personnel to implement policies and procedures  3.3.4 Expect personnel to comply with all relevant requirements  3.3.5 Expect personnel to take appropriate action when necessary  3.3.6 Expect personnel to control process documents and records |
|  | **4. MAINTAIN PROCESS** | 4.1 Provide the resources needed to maintain process  4.1.1 Provide the expertise needed to maintain your process  4.1.2 Provide the technology needed to maintain your process  4.1.3 Provide the infrastructure needed to maintain your process  4.2 Use authorized methods to maintain your process  4.2.1 Use authorized methods to maintain process documents  4.2.2 Use authorized methods to maintain process records  4.2.3 Use authorized methods to maintain process property  4.2.4 Use authorized methods to maintain process procedures  4.2.5 Use authorized methods to maintain process programmes  4.2.6 Use authorized methods to maintain process competence  4.2.7 Use authorized methods to maintain process technologies  4.2.8 Use authorized methods to maintain process infrastructure  4.2.9 Use authorized methods to maintain process communications |
| **5. MEASURE PROCESS** | 5.1 Plan how you're going to measure your process  5.1.1 Figure out what needs to be measured  5.1.2 Figure out how measurements will be done  5.1.3 Figure out who will perform measurement tasks  5.2 Qualify the resources needed to measure process  5.3 Provide the resources needed to measure process  5.3.1 Provide the expertise needed to measure your process  5.3.2 Provide the technology needed to measure your process  5.3.3 Provide the infrastructure needed to measure your process  5.4 Use authorized methods to measure your process  5.4.1 Use authorized methods to measure process elements  5.4.2 Use authorized methods to measure process performance  5.5 Control the resources needed to measure process  5.5.1 Control the documents needed to measure your process  5.5.2 Control the technology needed to measure your process  5.5.3 Control the records needed to measure your process |
|  | **6. MONITOR PROCESS** | 6.1 Plan how you're going to monitor your process  6.1.1 Figure out what needs to be monitored  6.1.2 Figure out how monitoring will be done  6.1.3 Figure out who will perform monitoring tasks  6.2 Qualify the resources needed to monitor process  6.3 Provide the resources needed to monitor process  6.3.1 Provide the expertise needed to monitor your process  6.3.2 Provide the technology needed to monitor your process  6.3.3 Provide the infrastructure needed to monitor your process  6.4 Use authorized methods to monitor your process  6.4.1 Use authorized methods to monitor process activities  6.4.2 Use authorized methods to monitor process outputs  6.4.3 Use authorized methods to monitor process inputs  6.4.4 Use authorized methods to monitor process documents  6.4.5 Use authorized methods to monitor process records  6.4.6 Use authorized methods to monitor process property  6.4.7 Use authorized methods to monitor process participants  6.4.8 Use authorized methods to monitor process technologies  6.4.9 Use authorized methods to monitor process environment  6.4.10 Use authorized methods to monitor process infrastructure  6.5 Control the resources needed to monitor process |
| **7. CONTROL PROCESS** | 7.1 Plan how you're going to control process  7.1.1 Consider how to control your process outputs  7.1.2 Consider how to control your process inputs  7.1.3 Consider how to control your process activities  7.1.4 Consider how to control your process providers  7.2 Develop ways of controlling your process  7.2.1 Develop ways of controlling process elements  7.2.2 Develop ways of controlling process providers  7.3 Provide resources needed to control process  7.4 Use authorized methods to control process  7.4.1 Use authorized methods to control process inputs  7.4.2 Use authorized methods to control process outputs  7.4.3 Use authorized methods to control process activities  7.4.4 Use authorized methods to control process technology  7.4.5 Use authorized methods to control process programmes  7.4.6 Use authorized methods to control process performance  7.4.7 Use authorized methods to control process documentation |
|  | **8. EVALUATE PROCESS** | 8.1 Plan how you're going to evaluate process  8.1.1 Plan how you're going to audit your process  8.1.2 Plan how you're going to analyze your process  8.1.3 Plan how you're going to review your process  8.2 Provide resources needed to evaluate process  8.2.1 Provide the people that you need to evaluate your process  8.2.2 Provide the knowledge that you need to evaluate your process  8.2.3 Provide the technology that you need to evaluate your process  8.2.4 Provide the infrastructure that you need to evaluate your process  8.3 Use authorized methods to evaluate process  8.3.1 Use authorized methods to audit your process  8.3.2 Use authorized methods to analyze your process  8.3.3 Use authorized methods to review your process  8.4 Record the results of process evaluations |
|  | **9. MODIFY PROCESS** | 9.1 Establish your process modification methods  9.1.1 Establish methods for correcting process and outputs  9.1.2 Establish methods for improving process and outputs  9.2 Identify opportunities to modify your process  9.2.1 Discover opportunities to modify process and outputs  9.2.2 Define opportunities to modify your process and outputs  9.2.3 Confirm that process and output modifications are needed  9.2.4 Approve opportunities to modify your process and outputs  9.3 Plan how you're going to modify your process  9.3.1 Plan how you're going to correct process and its outputs  9.3.2 Plan how you're going to improve process and its outputs  9.4 Use authorized methods to modify your process  9.4.1 Use authorized methods to correct process and outputs  9.4.2 Use authorized methods to improve process and outputs  9.5 Review and evaluate process modifications  9.5.1 Review and evaluate process and output corrections  9.5.2 Review and evaluate process and output improvements |
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| 1.1 STUDY THE CONTEXT OF YOUR PROCESS | | | | | | | | | | | | | |
| 1.1.1 CONSIDER PROCESS PARTICIPANTS | | | | | | | | | | | | | |
|  | Identify the parties that have an interest in your process. | | | | | | | | | DO | DN | NA |  |
|  |  | Identify the internal parties that have an interest in your process. | | | | | | | | DO | DN | NA |  |
|  |  | | Identify the internal parties that could influence your process. | | | | | | | DO | DN | NA |  |
|  |  | | | Clarify the needs and expectations of interested internal parties. | | | | | | DO | DN | NA |  |
|  |  | | | Clarify the issues and concerns that interested internal parties have. | | | | | | DO | DN | NA |  |
|  |  | Identify the external parties that have an interest in your process. | | | | | | | | DO | DN | NA |  |
|  |  | | Identify the external parties that could influence your process. | | | | | | | DO | DN | NA |  |
|  |  | | | Clarify the needs and expectations of interested external parties. | | | | | | DO | DN | NA |  |
|  |  | | | Clarify the issues and concerns that interested external parties have. | | | | | | DO | DN | NA |  |
| 1.1.2 consider process environment | | | | | | | | | | | | | |
|  | Consider your internal process environment. | | | | | | | | | DO | DN | NA |  |
|  |  | Consider the impact it could have on process performance. | | | | | | | | DO | DN | NA |  |
|  |  | | Consider the impact your organization's culture could have. | | | | | | | DO | DN | NA |  |
|  |  | | Consider the impact your organization's expertise could have. | | | | | | | DO | DN | NA |  |
|  |  | | Consider the impact your organization's technology could have. | | | | | | | DO | DN | NA |  |
|  |  | | Consider the impact your organization's infrastructure could have. | | | | | | | DO | DN | NA |  |
|  | Consider your external process environment. | | | | | | | | | DO | DN | NA |  |
|  |  | Consider the impact it could have on process performance. | | | | | | | | DO | DN | NA |  |
|  |  | | Consider the impact your legal environment could have. | | | | | | | DO | DN | NA |  |
|  |  | | | Identify statutory process output requirements. | | | | | | DO | DN | NA |  |
|  |  | | | Identify regulatory process output requirements. | | | | | | DO | DN | NA |  |
|  |  | | Consider the impact your social environment could have. | | | | | | | DO | DN | NA |  |
|  |  | | Consider the impact your market environment could have. | | | | | | | DO | DN | NA |  |
|  |  | | | Identify your customers' process output requirements. | | | | | | DO | DN | NA |  |
|  |  | | Consider the impact your economic environment could have. | | | | | | | DO | DN | NA |  |
|  |  | | Consider the impact your competitive environment could have. | | | | | | | DO | DN | NA |  |
|  |  | | Consider the impact your technological environment could have. | | | | | | | DO | DN | NA |  |
| 1.1.3 CONSIDER PROCESS RISKS AND THREATS | | | | | | | | | | | | | |
|  | Consider how your context could weaken process performance. | | | | | | | | | DO | DN | NA |  |
|  |  | Consider how interested parties could threaten  process performance or disrupt operations. | | | | | | | | DO | DN | NA |  |
|  |  | | Consider how interested parties could weaken your ability  to provide outputs that meet customer requirements. | | | | | | | DO | DN | NA |  |
|  |  | | Consider how interested parties could weaken your ability  to provide outputs that meet legal requirements. | | | | | | | DO | DN | NA |  |
|  |  | Consider how potential problems could threaten process performance or disrupt operations. | | | | | | | | DO | DN | NA |  |
|  |  | | Consider how internal problems could weaken your ability to achieve process objectives. | | | | | | | DO | DN | NA |  |
|  |  | | | Consider how your values could weaken your ability to achieve process objectives. | | | | | | DO | DN | NA |  |
|  |  | | | Consider how your culture could weaken your ability to achieve process objectives. | | | | | | DO | DN | NA |  |
|  |  | | | Consider how your knowledge could weaken your ability to achieve process objectives. | | | | | | DO | DN | NA |  |
|  |  | | | Consider how your infrastructure could weaken your ability to achieve process objectives. | | | | | | DO | DN | NA |  |
|  |  | | | Consider how your performance could weaken your ability to achieve process objectives. | | | | | | DO | DN | NA |  |
|  |  | | Consider how external problems could weaken your ability to achieve process objectives. | | | | | | | DO | DN | NA |  |
|  |  | | | Consider how legal problems could weaken your ability to achieve objectives. | | | | | | DO | DN | NA |  |
|  |  | | | Consider how social problems could weaken your ability to achieve objectives. | | | | | | DO | DN | NA |  |
|  |  | | | Consider how cultural problems could weaken your ability to achieve objectives. | | | | | | DO | DN | NA |  |
|  |  | | | Consider how market problems could weaken your ability to achieve objectives. | | | | | | DO | DN | NA |  |
|  |  | | | Consider how economic problems could weaken your ability to achieve objectives. | | | | | | DO | DN | NA |  |
|  |  | | | Consider how competitive problems could weaken your ability to achieve objectives. | | | | | | DO | DN | NA |  |
|  |  | | | Consider how technological problems could weaken your ability to achieve objectives. | | | | | | DO | DN | NA |  |
|  | Consider how to address the risks that could weaken process performance. | | | | | | | | | DO | DN | NA |  |
|  |  | Figure out what you need to do to ensure that your process achieves process objectives. | | | | | | | | DO | DN | NA |  |
|  |  | | Figure out how to prevent or reduce undesired affects that your process could cause. | | | | | | | DO | DN | NA |  |
| 1.1.4 CONSIDER PROCESS OPPORTUNITIES | | | | | | | | | | | | | |
|  | Consider opportunities to enhance process operations. | | | | | | | | | DO | DN | NA |  |
|  |  | Consider how your organization's context could reveal  opportunities to enhance process operations. | | | | | | | | DO | DN | NA |  |
|  |  | | Consider how interested parties could represent  opportunities to enhance process performance. | | | | | | | DO | DN | NA |  |
|  |  | | | Consider how interested parties could represent opportunities to enhance  your ability to provide outputs that meet customer requirements. | | | | | | DO | DN | NA |  |
|  |  | | | Consider how interested parties could represent opportunities to  enhance your ability to provide outputs that meet legal requirements. | | | | | | DO | DN | NA |  |
|  |  | | Consider how potential challenges could represent  opportunities to enhance process performance. | | | | | | | DO | DN | NA |  |
|  |  | | | Consider how internal challenges could create opportunities  to improve your ability to achieve process objectives. | | | | | | DO | DN | NA |  |
|  |  | | | | Consider how your values could generate opportunities  to enhance your ability to achieve process objectives. | | | | | DO | DN | NA |  |
|  |  | | | | Consider how your culture could generate opportunities  to enhance your ability to achieve process objectives. | | | | | DO | DN | NA |  |
|  |  | | | | Consider how your knowledge could generate opportunities  to enhance your ability to achieve process objectives. | | | | | DO | DN | NA |  |
|  |  | | | | Consider how your infrastructure could generate opportunities  to enhance your ability to achieve process objectives. | | | | | DO | DN | NA |  |
|  |  | | | | Consider how your performance could generate opportunities  to enhance your ability to achieve process objectives. | | | | | DO | DN | NA |  |
|  |  | | | Consider how external challenges could create opportunities  to improve your ability to achieve process objectives. | | | | | | DO | DN | NA |  |
|  |  | | | | Consider how your legal environment could create opportunities  to enhance your ability to achieve process objectives. | | | | | DO | DN | NA |  |
|  |  | | | | Consider how your social environment could create opportunities  to enhance your ability to achieve process objectives. | | | | | DO | DN | NA |  |
|  |  | | | | Consider how your cultural environment could create opportunities  to enhance your ability to achieve process objectives. | | | | | DO | DN | NA |  |
|  |  | | | | Consider how your market environment could create opportunities  to enhance your ability to achieve process objectives. | | | | | DO | DN | NA |  |
|  |  | | | | Consider how your economic environment could create opportunities  to enhance your ability to achieve process objectives. | | | | | DO | DN | NA |  |
|  |  | | | | Consider how your competitive environment could create opportunities  to enhance your ability to achieve process objectives. | | | | | DO | DN | NA |  |
|  |  | | | | Consider how your technological environment could create opportunities  to enhance your ability to achieve process objectives. | | | | | DO | DN | NA |  |
|  | Figure out what you could do to exploit process opportunities. | | | | | | | | | DO | DN | NA |  |
|  |  | Figure out what you could do to improve process performance. | | | | | | | | DO | DN | NA |  |
| 1.2 CLARIFY THE PURPOSE OF YOUR PROCESS | | | | | | | | | | | | | |
| 1.2.1 DEFINE PROCESS SCOPE AND BOUNDARIES | | | | | | | | | | | | | |
|  | Clarify the scope and boundaries of your process. | | | | | | | | | DO | DN | NA |  |
|  |  | Consider how your context could influence your process. | | | | | | | | DO | DN | NA |  |
|  |  | | Consider how internal issues could influence your process. | | | | | | | DO | DN | NA |  |
|  |  | | | Consider the impact your organization's values could have. | | | | | | DO | DN | NA |  |
|  |  | | | Consider the impact your organization's culture could have. | | | | | | DO | DN | NA |  |
|  |  | | | Consider the impact your organization's services could have. | | | | | | DO | DN | NA |  |
|  |  | | | Consider the impact your organization's products could have. | | | | | | DO | DN | NA |  |
|  |  | | | Consider the impact your organization's knowledge could have. | | | | | | DO | DN | NA |  |
|  |  | | | Consider the impact your organization's infrastructure could have. | | | | | | DO | DN | NA |  |
|  |  | | | Consider the impact your organization's performance could have. | | | | | | DO | DN | NA |  |
|  |  | | Consider how external issues could influence your process. | | | | | | | DO | DN | NA |  |
|  |  | | | Consider the impact legal issues and factors could have. | | | | | | DO | DN | NA |  |
|  |  | | | Consider the impact social issues and factors could have. | | | | | | DO | DN | NA |  |
|  |  | | | Consider the impact cultural issues and factors could have. | | | | | | DO | DN | NA |  |
|  |  | | | Consider the impact market issues and factors could have. | | | | | | DO | DN | NA |  |
|  |  | | | Consider the impact economic issues and factors could have. | | | | | | DO | DN | NA |  |
|  |  | | | Consider the impact competitive issues and factors could have. | | | | | | DO | DN | NA |  |
|  |  | | | Consider the impact technological issues and factors could have. | | | | | | DO | DN | NA |  |
|  | Document the scope and boundaries of your process. | | | | | | | | | DO | DN | NA |  |
|  |  | Retain the documents that describe the scope and boundaries of your process. | | | | | | | | DO | DN | NA |  |
|  |  | Control the documents that describe the scope and boundaries of your process. | | | | | | | | DO | DN | NA |  |
| 1.2.2 establish your process objectives | | | | | | | | | | | | | |
|  | Establish business objectives for your process. | | | | | | | | | DO | DN | NA |  |
|  | Establish technical objectives for your process. | | | | | | | | | DO | DN | NA |  |
|  | Establish safety objectives for your process. | | | | | | | | | DO | DN | NA |  |
|  | Establish quality objectives for your process. | | | | | | | | | DO | DN | NA |  |
|  | Establish security objectives for your process. | | | | | | | | | DO | DN | NA |  |
|  | Establish continuity objectives for your process. | | | | | | | | | DO | DN | NA |  |
|  | Establish environmental objectives for your process. | | | | | | | | | DO | DN | NA |  |
| 1.3 CONSIDER YOUR PROCESS REQUIREMENTS | | | | | | | | | | | | | |
| 1.3.1 CLARIFY PROCESS OUTPUT REQUIREMENTS | | | | | | | | | | | | | |
|  | Consider output quality requirements. | | | | | | | | | DO | DN | NA |  |
|  |  | Consider output reliability requirements. | | | | | | | | DO | DN | NA |  |
|  |  | Consider output consistency requirements. | | | | | | | | DO | DN | NA |  |
|  |  | Consider output availability requirements. | | | | | | | | DO | DN | NA |  |
|  |  | Consider output suitability requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Consider suitability requirements for parts and materials to be used in outputs. | | | | | | | DO | DN | NA |  |
|  |  | | Consider suitability requirements for software to be embedded in outputs. | | | | | | | DO | DN | NA |  |
|  |  | | | Consider suitability requirements for software that you plan to purchase. | | | | | | DO | DN | NA |  |
|  |  | | | Consider suitability requirements for software that you plan to develop. | | | | | | DO | DN | NA |  |
|  |  | Consider output purity requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Consider the need to control foreign objects. | | | | | | | DO | DN | NA |  |
|  |  | | Consider the need to detect foreign objects. | | | | | | | DO | DN | NA |  |
|  |  | | Consider the need to remove foreign objects. | | | | | | | DO | DN | NA |  |
|  |  | | Consider the need to prevent foreign objects. | | | | | | | DO | DN | NA |  |
|  |  | Consider output verification requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Consider how to verify that output requirements are being met. | | | | | | | DO | DN | NA |  |
|  |  | | | Consider how verifications will be done at all appropriate stages. | | | | | | DO | DN | NA |  |
|  |  | Consider output validation requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Consider how to confirm that intended use requirements are being met. | | | | | | | DO | DN | NA |  |
|  |  | | | Consider how validations will be done at all appropriate stages. | | | | | | DO | DN | NA |  |
|  |  | Consider output control requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Consider how nonconforming outputs will be controlled. | | | | | | | DO | DN | NA |  |
|  | Consider output safety requirements. | | | | | | | | | DO | DN | NA |  |
|  |  | Consider personal safety requirements. | | | | | | | | DO | DN | NA |  |
|  | Consider output security requirements. | | | | | | | | | DO | DN | NA |  |
|  |  | Consider personnel security requirements. | | | | | | | | DO | DN | NA |  |
|  |  | Consider information security requirements. | | | | | | | | DO | DN | NA |  |
|  | Consider output production requirements. | | | | | | | | | DO | DN | NA |  |
|  |  | Consider output producibility requirements. | | | | | | | | DO | DN | NA |  |
|  |  | Consider output inspectability requirements. | | | | | | | | DO | DN | NA |  |
|  | Consider output maintenance requirements. | | | | | | | | | DO | DN | NA |  |
|  |  | Consider output maintainability requirements. | | | | | | | | DO | DN | NA |  |
|  | Consider output handling requirements. | | | | | | | | | DO | DN | NA |  |
|  | Consider output packaging requirements. | | | | | | | | | DO | DN | NA |  |
|  | Consider output preservation requirements. | | | | | | | | | DO | DN | NA |  |
|  | Consider output obsolescence requirements. | | | | | | | | | DO | DN | NA |  |
|  |  | Consider output recycling requirements. | | | | | | | | DO | DN | NA |  |
|  |  | Consider output disposal requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Consider final disposal requirements. | | | | | | | DO | DN | NA |  |
| 1.3.2 clarify process knowledge requirements | | | | | | | | | | | | | |
|  | Determine the knowledge that process personnel need to have. | | | | | | | | | DO | DN | NA |  |
|  |  | Determine the knowledge that process personnel need in order  to support process operations and achieve conformity of outputs. | | | | | | | | DO | DN | NA |  |
|  |  | | Consider internal sources of process knowledge. | | | | | | | DO | DN | NA |  |
|  |  | | | Consider the need to learn from failures and successes. | | | | | | DO | DN | NA |  |
|  |  | | | Consider the need to gather knowledge about processes. | | | | | | DO | DN | NA |  |
|  |  | | | | Consider the need to gather knowledge about process outputs. | | | | | DO | DN | NA |  |
|  |  | | | Consider the need to capture undocumented knowledge. | | | | | | DO | DN | NA |  |
|  |  | | | | Consider the need to capture the knowledge, expertise,  and experience that your own people have accumulated. | | | | | DO | DN | NA |  |
|  |  | | Consider external sources of process knowledge. | | | | | | | DO | DN | NA |  |
|  |  | | | Consider the knowledge that suppliers can provide. | | | | | | DO | DN | NA |  |
|  |  | | | Consider the knowledge that customers can share with you. | | | | | | DO | DN | NA |  |
|  |  | | | Consider the knowledge that can be gathered at conferences. | | | | | | DO | DN | NA |  |
|  |  | | | Consider the knowledge that can be acquired from academia. | | | | | | DO | DN | NA |  |
| 1.3.3 clarify process competence requirements | | | | | | | | | | | | | |
|  | Identify the people under your control who have an impact  on the performance and effectiveness of your process. | | | | | | | | | DO | DN | NA |  |
|  |  | Establish competence requirements for your process. | | | | | | | | DO | DN | NA |  |
|  |  | | Make sure that process personnel have the appropriate training. | | | | | | | DO | DN | NA |  |
|  |  | | Make sure that process personnel have the appropriate education. | | | | | | | DO | DN | NA |  |
|  |  | | Make sure that process personnel have the appropriate experience. | | | | | | | DO | DN | NA |  |
|  |  | | Make sure that process personnel have the appropriate knowledge. | | | | | | | DO | DN | NA |  |
|  |  | Implement competence requirements for your process. | | | | | | | | DO | DN | NA |  |
|  |  | | Define the knowledge and skill required to implement this process. | | | | | | | DO | DN | NA |  |
|  |  | | Define the knowledge and skill required to operate this process. | | | | | | | DO | DN | NA |  |
|  |  | | Define the knowledge and skill required to maintain this process. | | | | | | | DO | DN | NA |  |
|  |  | | Define the knowledge and skill required to monitor this process. | | | | | | | DO | DN | NA |  |
|  |  | | Define the knowledge and skill required to measure this process. | | | | | | | DO | DN | NA |  |
|  |  | | Define the knowledge and skill required to control this process. | | | | | | | DO | DN | NA |  |
|  |  | | Define the knowledge and skill required to evaluate this process. | | | | | | | DO | DN | NA |  |
|  |  | | | Define the knowledge and skill required to audit this process. | | | | | | DO | DN | NA |  |
|  |  | | | Define the knowledge and skill required to review this process. | | | | | | DO | DN | NA |  |
|  |  | | Define the knowledge and skill required to modify this process. | | | | | | | DO | DN | NA |  |
|  |  | | | Define the knowledge and skill required to correct this process. | | | | | | DO | DN | NA |  |
|  |  | | | Define the knowledge and skill required to improve this process. | | | | | | DO | DN | NA |  |
| 1.3.4 clarify process MANAGEMENT requirements | | | | | | | | | | | | | |
|  | Specify risk management requirements for your process. | | | | | | | | | DO | DN | NA |  |
|  | Specify legal management requirements for your process. | | | | | | | | | DO | DN | NA |  |
|  |  | Specify legal management requirements for process outputs. | | | | | | | | DO | DN | NA |  |
|  |  | | Specify statutory management requirements for process outputs. | | | | | | | DO | DN | NA |  |
|  |  | | Specify regulatory management requirements for process outputs. | | | | | | | DO | DN | NA |  |
|  | Specify business management requirements for your process. | | | | | | | | | DO | DN | NA |  |
|  | Specify technical management requirements for your process. | | | | | | | | | DO | DN | NA |  |
|  | Specify quality management requirements for your process. | | | | | | | | | DO | DN | NA |  |
|  |  | Derive quality requirements from your quality policy. | | | | | | | | DO | DN | NA |  |
|  |  | Derive quality requirements from customer expectations. | | | | | | | | DO | DN | NA |  |
|  | Specify safety management requirements for your process. | | | | | | | | | DO | DN | NA |  |
|  |  | Specify safety management requirements for process personnel. | | | | | | | | DO | DN | NA |  |
|  | Specify security management requirements for your process. | | | | | | | | | DO | DN | NA |  |
|  |  | Specify personnel security management requirements. | | | | | | | | DO | DN | NA |  |
|  |  | Specify information security management requirements. | | | | | | | | DO | DN | NA |  |
|  |  | Specify component security management requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Specify counterfeit parts management requirements. | | | | | | | DO | DN | NA |  |
|  | Specify supplier management requirements for your process. | | | | | | | | | DO | DN | NA |  |
|  | Specify configuration management requirements for your process. | | | | | | | | | DO | DN | NA |  |
|  | Specify environmental management requirements for your process. | | | | | | | | | DO | DN | NA |  |
|  | Specify business continuity management requirements for your process. | | | | | | | | | DO | DN | NA |  |
| 1.3.5 clarify process communication requirements | | | | | | | | | | | | | |
|  | Figure out how internal process communications will be handled. | | | | | | | | | DO | DN | NA |  |
|  |  | Figure out what internal process communications need to say. | | | | | | | | DO | DN | NA |  |
|  |  | Figure out when internal process communications should be done. | | | | | | | | DO | DN | NA |  |
|  |  | Figure out who should carry out internal process communications. | | | | | | | | DO | DN | NA |  |
|  |  | | Figure out who should receive internal process communications. | | | | | | | DO | DN | NA |  |
|  | Figure out how external process communications will be handled. | | | | | | | | | DO | DN | NA |  |
|  |  | Figure out what external process communications need to say. | | | | | | | | DO | DN | NA |  |
|  |  | Figure out when external process communications should be done. | | | | | | | | DO | DN | NA |  |
|  |  | Figure out who should carry out external process communications. | | | | | | | | DO | DN | NA |  |
| 1.3.6 clarify process INFRASTRUCTURE requirements | | | | | | | | | | | | | |
|  | Identify the infrastructure that your process needs in order  to support operations and achieve conformity of outputs. | | | | | | | | | DO | DN | NA |  |
|  |  | Consider the buildings that your process needs. | | | | | | | | DO | DN | NA |  |
|  |  | Consider the utilities that your process needs. | | | | | | | | DO | DN | NA |  |
|  |  | Consider the equipment that your process needs. | | | | | | | | DO | DN | NA |  |
|  |  | | Consider the hardware that your process needs. | | | | | | | DO | DN | NA |  |
|  |  | | Consider the software that your process needs. | | | | | | | DO | DN | NA |  |
|  |  | Consider the technology that your process need. | | | | | | | | DO | DN | NA |  |
|  |  | | Consider your information technology needs. | | | | | | | DO | DN | NA |  |
|  |  | | Consider your communication technology needs. | | | | | | | DO | DN | NA |  |
|  |  | | Consider your transportation technology needs. | | | | | | | DO | DN | NA |  |
| 1.3.7 clarify process ENVIRONMENT requirements | | | | | | | | | | | | | |
|  | Identify the environment that your process needs  in order to achieve conformity of outputs. | | | | | | | | | DO | DN | NA |  |
|  |  | Consider the social factors that could affect your process. | | | | | | | | DO | DN | NA |  |
|  |  | Consider the cultural factors that could affect your process. | | | | | | | | DO | DN | NA |  |
|  |  | Consider the psychological factors that could affect your process. | | | | | | | | DO | DN | NA |  |
|  |  | Consider the ergonomic factors that could affect your process. | | | | | | | | DO | DN | NA |  |
|  |  | Consider the climatic factors that could affect your process. | | | | | | | | DO | DN | NA |  |
|  |  | | Consider whether humidity could affect process. | | | | | | | DO | DN | NA |  |
|  |  | | Consider whether temperature could affect process. | | | | | | | DO | DN | NA |  |
|  |  | | Consider whether pollution could affect your process. | | | | | | | DO | DN | NA |  |
|  |  | Consider the physical factors that could affect your process. | | | | | | | | DO | DN | NA |  |
|  |  | | Consider the sanitation factors that could affect your process. | | | | | | | DO | DN | NA |  |
|  |  | | | Consider whether cleanliness is an important factor. | | | | | | DO | DN | NA |  |
| 1.3.8 clarify process RESOURCE requirements | | | | | | | | | | | | | |
|  | Consider internal capabilities and external sources. | | | | | | | | | DO | DN | NA |  |
|  |  | Consider your organization's internal capabilities and constraints. | | | | | | | | DO | DN | NA |  |
|  |  | Consider what needs to be obtained from external resource providers. | | | | | | | | DO | DN | NA |  |
|  | Determine the resources that your process needs. | | | | | | | | | DO | DN | NA |  |
|  |  | Identify the resources needed to implement your process. | | | | | | | | DO | DN | NA |  |
|  |  | Identify the resources needed to operate your process. | | | | | | | | DO | DN | NA |  |
|  |  | Identify the resources needed to monitor your process. | | | | | | | | DO | DN | NA |  |
|  |  | Identify the resources needed to measure your process. | | | | | | | | DO | DN | NA |  |
|  |  | Identify the resources needed to control your process. | | | | | | | | DO | DN | NA |  |
|  |  | Identify the resources needed to maintain your process. | | | | | | | | DO | DN | NA |  |
|  |  | Identify the resources needed to evaluate your process. | | | | | | | | DO | DN | NA |  |
|  |  | | Identify the resources needed to audit your process. | | | | | | | DO | DN | NA |  |
|  |  | | Identify the resources needed to review your process. | | | | | | | DO | DN | NA |  |
|  |  | Identify the resources needed to modify your process. | | | | | | | | DO | DN | NA |  |
|  |  | | Identify the resources needed to correct your process. | | | | | | | DO | DN | NA |  |
|  |  | | Identify the resources needed to improve your process. | | | | | | | DO | DN | NA |  |
| 1.4 PLAN PROCESS DESIGN AND DEVELOPMENT | | | | | | | | | | | | | |
| 1.4.1 CARRY OUT OUTPUT PLANNING | | | | | | | | | | | | | |
|  | Determine criteria for your outputs. | | | | | | | | | DO | DN | NA |  |
|  |  | Establish acceptance criteria for outputs. | | | | | | | | DO | DN | NA |  |
|  |  | | Use statistical techniques to support outputs. | | | | | | | DO | DN | NA |  |
|  |  | | | Use statistical techniques to verify output designs. | | | | | | DO | DN | NA |  |
|  |  | | | | Use statistical techniques to verify output safety. | | | | | DO | DN | NA |  |
|  |  | | | | Use statistical techniques to verify output quality. | | | | | DO | DN | NA |  |
|  | Determine the outputs that are needed. | | | | | | | | | DO | DN | NA |  |
|  |  | Plan output design and development activities. | | | | | | | | DO | DN | NA |  |
|  |  | | Consider your output needs and complexities. | | | | | | | DO | DN | NA |  |
|  |  | | | Consider your ability to meet output requirements. | | | | | | DO | DN | NA |  |
|  |  | | | | Consider how you're going to meet output safety requirements. | | | | | DO | DN | NA |  |
|  |  | | | | Consider how you're going to meet output quality requirements. | | | | | DO | DN | NA |  |
|  |  | | | | Consider how you're going to meet output control requirements. | | | | | DO | DN | NA |  |
|  |  | | | | Consider how you're going to meet output testing requirements. | | | | | DO | DN | NA |  |
|  |  | | | | Consider how you're going to meet output suitability requirements. | | | | | DO | DN | NA |  |
|  |  | | | | Consider how you're going to meet output availability requirements. | | | | | DO | DN | NA |  |
|  |  | | | | Consider how you're going to meet output reliability requirements. | | | | | DO | DN | NA |  |
|  |  | | | | Consider how you're going to meet output monitoring requirements. | | | | | DO | DN | NA |  |
|  |  | | | | Consider how you're going to meet output measurement requirements. | | | | | DO | DN | NA |  |
|  |  | | | | Consider how you're going to meet output production requirements. | | | | | DO | DN | NA |  |
|  |  | | | | Consider how you're going to meet output preservation requirements. | | | | | DO | DN | NA |  |
|  |  | | | | Consider how you're going to meet output maintenance requirements. | | | | | DO | DN | NA |  |
|  |  | | | | Consider how you're going to meet output obsolescence requirements. | | | | | DO | DN | NA |  |
|  |  | | | | Consider how you're going to meet output delivery requirements. | | | | | DO | DN | NA |  |
|  |  | | Consider output design and development complexities. | | | | | | | DO | DN | NA |  |
|  |  | | | Consider your output design and development activities. | | | | | | DO | DN | NA |  |
|  |  | | | | Consider dividing output design and development into distinct activities. | | | | | DO | DN | NA |  |
|  |  | | | | | Define content for each set of output design and development activities. | | | | DO | DN | NA |  |
|  |  | | | | | Define tasks for each set of output design and development activities. | | | | DO | DN | NA |  |
|  |  | | | | | Define inputs for each set of output design and development activities. | | | | DO | DN | NA |  |
|  |  | | | | | Define outputs for each set of output design and development activities. | | | | DO | DN | NA |  |
|  |  | | | | | Define resources for each set of output design and development activities. | | | | DO | DN | NA |  |
|  |  | | | | | Define responsibilities for each set of output design and development activities. | | | | DO | DN | NA |  |
|  |  | | | Consider output design and development requirements. | | | | | | DO | DN | NA |  |
|  |  | | | | Consider your output evaluation requirements. | | | | | DO | DN | NA |  |
|  |  | | | | | Consider output review requirements. | | | | DO | DN | NA |  |
|  |  | | | | | Consider output verification requirements. | | | | DO | DN | NA |  |
|  |  | | | | | Consider output validation requirements. | | | | DO | DN | NA |  |
|  |  | | | | Consider design and development output requirements. | | | | | DO | DN | NA |  |
|  |  | | | Consider output design and development expectations. | | | | | | DO | DN | NA |  |
|  |  | | | | Consider output control expectations. | | | | | DO | DN | NA |  |
|  |  | | | | | Consider the level of control expected by your customers. | | | | DO | DN | NA |  |
|  |  | | | | | Consider the level of control expected by interested parties. | | | | DO | DN | NA |  |
|  |  | | | Consider output design and development relationships. | | | | | | DO | DN | NA |  |
|  |  | | | | Consider the need to control interactions between people. | | | | | DO | DN | NA |  |
|  |  | | | | Consider the need to control interactions between groups. | | | | | DO | DN | NA |  |
|  |  | | | Consider output design and development responsibilities. | | | | | | DO | DN | NA |  |
|  |  | | | | Consider design and development authorities. | | | | | DO | DN | NA |  |
|  |  | | | Consider output design and development documentation. | | | | | | DO | DN | NA |  |
|  |  | | | | Consider the need to control and maintain documentation. | | | | | DO | DN | NA |  |
|  |  | | | | | Consider the need to confirm that requirements are being met. | | | | DO | DN | NA |  |
|  |  | | | Consider output design and development resources. | | | | | | DO | DN | NA |  |
|  |  | | | | Consider internal design and development resource needs. | | | | | DO | DN | NA |  |
|  |  | | | | Consider external design and development resource needs. | | | | | DO | DN | NA |  |
|  |  | | Consider output verification and validation activities. | | | | | | | DO | DN | NA |  |
|  |  | | | Plan your design verification and validation testing activities. | | | | | | DO | DN | NA |  |
|  |  | | | | Make sure that test plans and specifications specify test items. | | | | | DO | DN | NA |  |
|  |  | | | | Make sure that test plans and specifications specify test requirements. | | | | | DO | DN | NA |  |
|  |  | | | | | Make sure that plans and specifications specify testing objectives. | | | | DO | DN | NA |  |
|  |  | | | | | Make sure that plans and specifications specify testing conditions. | | | | DO | DN | NA |  |
|  |  | | | | | Make sure that plans and specifications specify testing parameters. | | | | DO | DN | NA |  |
|  |  | | | | | Make sure that plans and specifications specify testing resources. | | | | DO | DN | NA |  |
|  |  | | | | Make sure that plans and specifications specify acceptance criteria. | | | | | DO | DN | NA |  |
|  |  | | | Control your design verification and validation testing activities. | | | | | | DO | DN | NA |  |
|  |  | | | | Make sure that your test procedures describe how testing is performed. | | | | | DO | DN | NA |  |
|  |  | | | | | Make sure that test procedures describe testing methods and techniques. | | | | DO | DN | NA |  |
|  |  | | | | Make sure that your test procedures describe how testing results are recorded. | | | | | DO | DN | NA |  |
|  |  | | | Review your design verification and validation testing activities. | | | | | | DO | DN | NA |  |
|  |  | | | | Make sure that the correct items were used for testing. | | | | | DO | DN | NA |  |
|  |  | | | | | Make sure that the right configuration was submitted. | | | | DO | DN | NA |  |
|  |  | | | | Make sure that your testing procedures were followed. | | | | | DO | DN | NA |  |
|  |  | | | | Make sure that all testing objectives were achieved. | | | | | DO | DN | NA |  |
|  |  | | | | Make sure that test plan requirements were met. | | | | | DO | DN | NA |  |
|  |  | | | | Make sure that acceptance criteria were met. | | | | | DO | DN | NA |  |
|  |  | | | Document your design verification and validation testing activities. | | | | | | DO | DN | NA |  |
|  |  | | | | Make sure that records show that test items were identified. | | | | | DO | DN | NA |  |
|  |  | | | | Make sure that records show that test requirements were met. | | | | | DO | DN | NA |  |
|  |  | | | | | Make sure that your records show that testing objectives were set. | | | | DO | DN | NA |  |
|  |  | | | | | Make sure that your records show that testing resources were allocated. | | | | DO | DN | NA |  |
|  |  | | | | | Make sure that your records show that testing conditions were specified. | | | | DO | DN | NA |  |
|  |  | | | | | Make sure that your records show that testing procedures were followed. | | | | DO | DN | NA |  |
|  |  | | | | | Make sure that your records show that testing parameters were recorded. | | | | DO | DN | NA |  |
|  |  | | | | | Make sure that your records show that testing reviews were carried out. | | | | DO | DN | NA |  |
|  |  | | | | | Make sure that your records show that acceptance criteria were used. | | | | DO | DN | NA |  |
|  |  | | | | Make sure that records show that operational conditions were examined. | | | | | DO | DN | NA |  |
|  |  | | | | | Make sure that reports show that the design for your output meets specification requirements for all identified operational conditions. | | | | DO | DN | NA |  |
|  |  | | | | | Make sure that calculations show that the design for your output meets specification requirements for all identified operational conditions. | | | | DO | DN | NA |  |
|  |  | | | | | Make sure that test results show that the design for your output meets specification requirements for all identified operational conditions. | | | | DO | DN | NA |  |
|  | Determine how outputs will be controlled. | | | | | | | | | DO | DN | NA |  |
|  |  | Define your configuration management requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Make sure that your configuration management methods can be used to identify  and control physical and functional attributes throughout the lifecycle of your outputs. | | | | | | | DO | DN | NA |  |
|  |  | | | Make sure that your configuration management methods are  appropriate for your organization and the outputs it produces. | | | | | | DO | DN | NA |  |
|  |  | Define how you intend to control nonconforming outputs. | | | | | | | | DO | DN | NA |  |
|  |  | | Document your output nonconformity control methods. | | | | | | | DO | DN | NA |  |
|  |  | | | Define responsibility and authority for handling nonconforming outputs. | | | | | | DO | DN | NA |  |
|  |  | | | | Define responsibility and authority for review of nonconforming outputs. | | | | | DO | DN | NA |  |
|  |  | | | | | Define the process that will be used to approve personnel  who will make output nonconformity review decisions. | | | | DO | DN | NA |  |
|  |  | | | | Define responsibility and authority for disposition of nonconforming outputs. | | | | | DO | DN | NA |  |
|  |  | | | | | Define the process that will be used to approve personnel  who will make output nonconformity disposition decisions. | | | | DO | DN | NA |  |
|  |  | | | Define how you plan to manage and control your nonconforming outputs. | | | | | | DO | DN | NA |  |
|  |  | | | | Define how you're going to contain the impact of nonconformities. | | | | | DO | DN | NA |  |
|  |  | | | | | Define how you intend to contain the effect on other processes. | | | | DO | DN | NA |  |
|  |  | | | | | Define how you intend to contain the effect on other outputs. | | | | DO | DN | NA |  |
|  |  | | | | | Define how you intend to contain the effect on other parties. | | | | DO | DN | NA |  |
|  |  | | | | | | Define how you intend to contain the effect on customers. | | | DO | DN | NA |  |
|  |  | | | | Define how you intend to report your nonconforming outputs. | | | | | DO | DN | NA |  |
|  |  | | | | | Define how nonconformities affecting products and services are reported. | | | | DO | DN | NA |  |
|  |  | | | | | | Define how you intend to notify interested parties about nonconformities. | | | DO | DN | NA |  |
|  |  | | | | | | | Define how internal parties will be notified about nonconformities. | | DO | DN | NA |  |
|  |  | | | | | | | | Define how you plan to notify internal organizations about nonconformities. | DO | DN | NA |  |
|  |  | | | | | | | Define how external parties will be notified about nonconformities. | | DO | DN | NA |  |
|  |  | | | | | | | | Define how you plan to notify customers about nonconformities. | DO | DN | NA |  |
|  |  | | | | | | | | Define how you plan to notify distributors about nonconformities. | DO | DN | NA |  |
|  |  | | | | | | | | Define how you plan to notify regulators about nonconformities. | DO | DN | NA |  |
|  |  | | | | | | | | Define how you plan to notify suppliers about nonconformities. | DO | DN | NA |  |
|  |  | | | | Define how appropriate corrective actions will be implemented. | | | | | DO | DN | NA |  |
|  |  | | | | | Define how corrective action will be developed and taken  whenever nonconforming outputs are detected after delivery. | | | | DO | DN | NA |  |
|  |  | | | | | | Define how you intend to ensure that actions will deal with impacts. | | | DO | DN | NA |  |
| 1.4.2 CARRY OUT PROCESS PLANNING | | | | | | | | | | | | | |
|  | Select the people that should be involved in process planning. | | | | | | | | | DO | DN | NA |  |
|  |  | Ask people from affected organizational functions to participate. | | | | | | | | DO | DN | NA |  |
|  | Establish performance criteria that your process should meet. | | | | | | | | | DO | DN | NA |  |
|  |  | Establish performance criteria that process outputs should meet. | | | | | | | | DO | DN | NA |  |
|  | Determine the activities that should make up your process. | | | | | | | | | DO | DN | NA |  |
|  |  | Determine the activities needed to generate your outputs. | | | | | | | | DO | DN | NA |  |
|  |  | Determine the activities needed to control your “critical items”. | | | | | | | | DO | DN | NA |  |
|  |  | Determine the activities needed to prevent unintended deliveries. | | | | | | | | DO | DN | NA |  |
|  | Develop suitable process verification methods. | | | | | | | | | DO | DN | NA |  |
|  |  | Consider using risk assessments to help ensure that your  process is able to produce outputs that meet requirements. | | | | | | | | DO | DN | NA |  |
|  |  | Consider using capacity studies to help ensure that your  process is able to produce outputs that meet requirements. | | | | | | | | DO | DN | NA |  |
|  |  | Consider using capability studies to help ensure that your  process is able to produce outputs that meet requirements. | | | | | | | | DO | DN | NA |  |
|  |  | Consider using control plans to help ensure that your  process is able to produce outputs that meet requirements. | | | | | | | | DO | DN | NA |  |
|  | Clarify process interactions and interconnections. | | | | | | | | | DO | DN | NA |  |
|  |  | Identify downstream processes. | | | | | | | | DO | DN | NA |  |
|  |  | Identify upstream processes. | | | | | | | | DO | DN | NA |  |
|  | Allocate the resources needed to support process. | | | | | | | | | DO | DN | NA |  |
|  |  | Allocate the resources needed to manage process. | | | | | | | | DO | DN | NA |  |
|  |  | Allocate the resources needed to manage projects. | | | | | | | | DO | DN | NA |  |
|  |  | Allocate the resources needed to manage “critical items”. | | | | | | | | DO | DN | NA |  |
| 1.4.3 carry out input planning | | | | | | | | | | | | | |
|  | Identify your process input requirements. | | | | | | | | | DO | DN | NA |  |
|  |  | Identify the products that your process will need to have. | | | | | | | | DO | DN | NA |  |
|  |  | | Identify the product providers that will be needed. | | | | | | | DO | DN | NA |  |
|  |  | Identify the services that your process will need to have. | | | | | | | | DO | DN | NA |  |
|  |  | | Identify the service providers that will be needed. | | | | | | | DO | DN | NA |  |
|  |  | Identify the technologies that your process will need to have. | | | | | | | | DO | DN | NA |  |
|  |  | | Identify the hardware that your process will need to have. | | | | | | | DO | DN | NA |  |
|  |  | | Identify the software that your process will need to have. | | | | | | | DO | DN | NA |  |
|  |  | Identify the information that your process will need to have. | | | | | | | | DO | DN | NA |  |
|  |  | Identify the materials that your process will need to have. | | | | | | | | DO | DN | NA |  |
|  |  | Identify the supplies that your process will need to have. | | | | | | | | DO | DN | NA |  |
|  |  | Identify the parts that your process will need to have. | | | | | | | | DO | DN | NA |  |
|  | Document your process input requirements. | | | | | | | | | DO | DN | NA |  |
| 1.5 DESIGN PROCESS SUPPORT PROGRAMMES | | | | | | | | | | | | | |
| 1.5.1 design risk management programme | | | | | | | | | | | | | |
|  | Make sure that your risk management methods are  appropriate for your process and the outputs it generates. | | | | | | | | | DO | DN | NA |  |
|  |  | Plan the assignment of risk management responsibilities. | | | | | | | | DO | DN | NA |  |
|  |  | Clarify and define your operational risk assessment criteria. | | | | | | | | DO | DN | NA |  |
|  |  | | Figure out how you’re going to determine the likelihood of an occurrence. | | | | | | | DO | DN | NA |  |
|  |  | | Figure out how you’re going to evaluate potentially negative consequences. | | | | | | | DO | DN | NA |  |
|  |  | | Figure out how you’re going to make operational risk acceptance decisions. | | | | | | | DO | DN | NA |  |
|  |  | Describe how you intend to manage operational risks. | | | | | | | | DO | DN | NA |  |
|  |  | | Figure out how operational risks will be identified. | | | | | | | DO | DN | NA |  |
|  |  | | Figure out how operational risks will be assessed. | | | | | | | DO | DN | NA |  |
|  |  | | Figure out how operational risks will be communicated. | | | | | | | DO | DN | NA |  |
|  |  | Specify how risk management initiatives will be taken. | | | | | | | | DO | DN | NA |  |
|  |  | | Figure out how to manage the actions that must be taken to mitigate the  operational risks that exceed the limits set by your risk acceptance criteria. | | | | | | | DO | DN | NA |  |
|  |  | | | Figure out how you’re going to formulate the actions  that must be taken to mitigate operational risks. | | | | | | DO | DN | NA |  |
|  |  | | | Figure out how you’re going to implement the actions  that must be taken to mitigate operational risks. | | | | | | DO | DN | NA |  |
|  |  | Define how residual operational risks will be controlled. | | | | | | | | DO | DN | NA |  |
|  |  | | Figure out how you’re going to control the acceptable operational risks  that remain after you’ve taken action to mitigate unacceptable risks. | | | | | | | DO | DN | NA |  |
| 1.5.2 DESIGN SAFETY MANAGEMENT PROGRAMME | | | | | | | | | | | | | |
|  | Plan your safety management programme. | | | | | | | | | DO | DN | NA |  |
|  |  | Make sure that your safety programme is appropriate for your process. | | | | | | | | DO | DN | NA |  |
|  |  | | Make sure that safety programme is appropriate for your outputs. | | | | | | | DO | DN | NA |  |
|  |  | | | Ensure that your programme applies to the entire output life cycle. | | | | | | DO | DN | NA |  |
|  | Develop your safety management programme. | | | | | | | | | DO | DN | NA |  |
|  |  | Develop a way of managing safety hazards and threats. | | | | | | | | DO | DN | NA |  |
|  |  | | Develop a safety hazard and threat assessment process. | | | | | | | DO | DN | NA |  |
|  |  | | | Develop a suitable safety risk management process. | | | | | | DO | DN | NA |  |
|  |  | Develop a way of managing activities that affect safety. | | | | | | | | DO | DN | NA |  |
|  |  | | Develop a way of analyzing activities that affect safety. | | | | | | | DO | DN | NA |  |
|  |  | | Develop a way of reporting activities that affect safety. | | | | | | | DO | DN | NA |  |
|  |  | Develop a way of managing safety training services. | | | | | | | | DO | DN | NA |  |
|  |  | Develop a way of managing safety communications. | | | | | | | | DO | DN | NA |  |
| 1.5.3 DESIGN QUALITY MANAGEMENT PROGRAMME | | | | | | | | | | | | | |
|  | Establish quality expectations for your process. | | | | | | | | | DO | DN | NA |  |
|  |  | Define quality requirements for your process. | | | | | | | | DO | DN | NA |  |
|  |  | Formulate quality policies for your process. | | | | | | | | DO | DN | NA |  |
|  |  | Write quality procedures for your process. | | | | | | | | DO | DN | NA |  |
|  |  | Prepare quality criteria for your process. | | | | | | | | DO | DN | NA |  |
|  |  | Develop quality plans for your process. | | | | | | | | DO | DN | NA |  |
|  |  | Set quality objectives for your process. | | | | | | | | DO | DN | NA |  |
|  |  | | Clarify criteria for setting quality objectives. | | | | | | | DO | DN | NA |  |
|  |  | | | Make sure that quality objectives are measurable. | | | | | | DO | DN | NA |  |
|  |  | | | Make sure that quality objectives consider requirements. | | | | | | DO | DN | NA |  |
|  |  | | | Make sure that quality objectives support your strategic direction. | | | | | | DO | DN | NA |  |
|  |  | | | Make sure that quality objectives are compatible with your context. | | | | | | DO | DN | NA |  |
|  |  | | | Make sure that quality objectives are consistent with your quality policies. | | | | | | DO | DN | NA |  |
|  |  | | Define quality objectives for your process. | | | | | | | DO | DN | NA |  |
|  |  | | | Set quality objectives in all relevant areas of your process. | | | | | | DO | DN | NA |  |
|  |  | | | | Set quality objectives for all relevant process functions. | | | | | DO | DN | NA |  |
|  |  | | | | | Set objectives that address the need to provide compliant outputs. | | | | DO | DN | NA |  |
|  |  | | | | | Set objectives that address the need to enhance customer satisfaction. | | | | DO | DN | NA |  |
|  |  | Create quality controls for your process. | | | | | | | | DO | DN | NA |  |
|  |  | | Establish a configuration management system. | | | | | | | DO | DN | NA |  |
|  |  | | | Figure out how you're going to identify and control physical and  functional attributes throughout the lifecycle of your outputs. | | | | | | DO | DN | NA |  |
|  |  | | | | Develop configuration management methods that are  appropriate for your organization and the outputs it produces. | | | | | DO | DN | NA |  |
| 1.5.4 DESIGN SECURITY MANAGEMENT PROGRAMME | | | | | | | | | | | | | |
|  | Develop a personnel security management programme. | | | | | | | | | DO | DN | NA |  |
|  |  | Define personnel security requirements for your process. | | | | | | | | DO | DN | NA |  |
|  |  | Formulate personnel security policies for your process. | | | | | | | | DO | DN | NA |  |
|  |  | Write personnel security procedures for your process. | | | | | | | | DO | DN | NA |  |
|  |  | Prepare personnel security criteria for your process. | | | | | | | | DO | DN | NA |  |
|  |  | Develop personnel security plans for your process. | | | | | | | | DO | DN | NA |  |
|  |  | Set personnel security objectives for your process. | | | | | | | | DO | DN | NA |  |
|  | Develop an information security management programme. | | | | | | | | | DO | DN | NA |  |
|  |  | Define information security requirements for your process. | | | | | | | | DO | DN | NA |  |
|  |  | Formulate information security policies for your process. | | | | | | | | DO | DN | NA |  |
|  |  | Write information security procedures for your process. | | | | | | | | DO | DN | NA |  |
|  |  | Prepare information security criteria for your process. | | | | | | | | DO | DN | NA |  |
|  |  | Develop information security plans for your process. | | | | | | | | DO | DN | NA |  |
|  |  | Set information security objectives for your process. | | | | | | | | DO | DN | NA |  |
|  | Develop a component security management programme. | | | | | | | | | DO | DN | NA |  |
|  |  | Develop a counterfeit parts management programme. | | | | | | | | DO | DN | NA |  |
|  |  | | Plan your counterfeit part management programme. | | | | | | | DO | DN | NA |  |
|  |  | | | Ensure that counterfeit part management programme is designed to prevent the use and inclusion of suspicious or counterfeit parts in outputs delivered to customers. | | | | | | DO | DN | NA |  |
|  |  | | | | Make sure that your counterfeit part management programme is  appropriate for your process and the outputs it provides to its customers. | | | | | DO | DN | NA |  |
|  |  | | Develop your counterfeit part management programme. | | | | | | | DO | DN | NA |  |
|  |  | | | Develop a process to teach people about counterfeit parts. | | | | | | DO | DN | NA |  |
|  |  | | | Develop a process to monitor counterfeit parts and components. | | | | | | DO | DN | NA |  |
|  |  | | | | Develop a process to monitor obsolete parts and components. | | | | | DO | DN | NA |  |
|  |  | | | Develop a process to control the acquisition of parts and components. | | | | | | DO | DN | NA |  |
|  |  | | | | Develop a process to detect suspicious and counterfeit parts and components. | | | | | DO | DN | NA |  |
|  |  | | | | | Develop methodologies to test and to verify your parts and components. | | | | DO | DN | NA |  |
|  |  | | | | | | Develop methodologies to detect counterfeit parts and components. | | | DO | DN | NA |  |
|  |  | | | | Develop a process to quarantine suspicious or counterfeit parts and components. | | | | | DO | DN | NA |  |
|  |  | | | | Develop a process to report suspicious or counterfeit parts and components. | | | | | DO | DN | NA |  |
|  |  | | | Develop a process to trace parts and components back to suppliers. | | | | | | DO | DN | NA |  |
|  |  | | | | Ensure that you can trace them back to original or authorized manufacturers. | | | | | DO | DN | NA |  |
| 1.5.5 DESIGN SUPPLIER MANAGEMENT PROGRAMME | | | | | | | | | | | | | |
|  | Develop a programme to manage, monitor, and control the use of external providers. | | | | | | | | | DO | DN | NA |  |
|  |  | Clarify what you expect from external process, product, and service providers. | | | | | | | | DO | DN | NA |  |
|  |  | | Specify your external document and record keeping requirements. | | | | | | | DO | DN | NA |  |
|  | Develop and maintain a register of external provider performance and status. | | | | | | | | | DO | DN | NA |  |
| 1.5.6 DESIGN environmental MANAGEMENT PROGRAMME | | | | | | | | | | | | | |
|  | Plan your environmental management programme. | | | | | | | | | DO | DN | NA |  |
|  |  | Make sure that your environmental programme is appropriate for your process. | | | | | | | | DO | DN | NA |  |
|  |  | | Make sure that your environmental programme is appropriate for your outputs. | | | | | | | DO | DN | NA |  |
|  |  | | | Ensure that your environmental programme applies to the entire output life cycle. | | | | | | DO | DN | NA |  |
|  | Develop your environmental management programme. | | | | | | | | | DO | DN | NA |  |
|  |  | Develop ways of analyzing environmental aspects and impacts. | | | | | | | | DO | DN | NA |  |
|  |  | Develop a way of managing environmental aspects and impacts. | | | | | | | | DO | DN | NA |  |
| 1.5.7 DESIGN BUSINESS CONTINUITY MANAGEMENT PROGRAMME | | | | | | | | | | | | | |
|  | Plan your business continuity management programme. | | | | | | | | | DO | DN | NA |  |
|  |  | Make sure that your continuity programme is appropriate for your process. | | | | | | | | DO | DN | NA |  |
|  |  | | Make sure that continuity programme is appropriate for your outputs. | | | | | | | DO | DN | NA |  |
|  |  | | | Ensure that your continuity programme applies to the entire output life cycle. | | | | | | DO | DN | NA |  |
|  | Develop your continuity management programme. | | | | | | | | | DO | DN | NA |  |
|  |  | Ensure that operations continue at specified levels. | | | | | | | | DO | DN | NA |  |
|  |  | | Develop ways of identifying potential threats. | | | | | | | DO | DN | NA |  |
|  |  | | Develop ways of analyzing all possible impacts. | | | | | | | DO | DN | NA |  |
|  |  | | Develop ways of responding to disruptive incidents. | | | | | | | DO | DN | NA |  |
|  |  | | Develop ways of resuming prioritized process activities. | | | | | | | DO | DN | NA |  |
|  |  | | Develop ways of restoring operations to acceptable levels. | | | | | | | DO | DN | NA |  |
| 1.6 IDENTIFY PROCESS DOCUMENTS AND RECORDS | | | | | | | | | | | | | |
| 1.6.1 EVALUATE DOCUMENTATION REQUIREMENTS | | | | | | | | | | | | | |
|  | Figure out how extensive documented process information should be. | | | | | | | | | DO | DN | NA |  |
|  |  | Consider process activities when you establish documents and records. | | | | | | | | DO | DN | NA |  |
|  |  | Consider your process outputs when you establish documents and records. | | | | | | | | DO | DN | NA |  |
|  |  | Consider process personnel when you establish documents and records. | | | | | | | | DO | DN | NA |  |
|  |  | | Consider the competence and expertise of your process personnel. | | | | | | | DO | DN | NA |  |
|  |  | Consider your process obligations when you establish documents and records. | | | | | | | | DO | DN | NA |  |
|  |  | | Consider process property and information provided by your customers. | | | | | | | DO | DN | NA |  |
|  |  | | Consider process property and information provided by external providers. | | | | | | | DO | DN | NA |  |
| 1.6.2 SELECT PROCESS DOCUMENTS AND RECORDS | | | | | | | | | | | | | |
|  | Select all the documents and records that your process needs. | | | | | | | | | DO | DN | NA |  |
|  |  | Select all the internal documents and records that your process needs. | | | | | | | | DO | DN | NA |  |
|  |  | | Include documented information that your process needs to be effective. | | | | | | | DO | DN | NA |  |
|  |  | | | Include all the documents and records that you need in order  to be sure that your process is being carried out as planned. | | | | | | DO | DN | NA |  |
|  |  | | Include documented information required by external standards. | | | | | | | DO | DN | NA |  |
|  |  | | | Include information that documents the scope of your process. | | | | | | DO | DN | NA |  |
|  |  | | | Include information that documents your process goals and objectives. | | | | | | DO | DN | NA |  |
|  |  | | | Include information that documents your process policies and procedures. | | | | | | DO | DN | NA |  |
|  |  | | | Include information that documents your monitoring and measuring resources. | | | | | | DO | DN | NA |  |
|  |  | | | | Include documented information that can prove that your  monitoring and measuring resources are fit for purpose. | | | | | DO | DN | NA |  |
|  |  | | | | | Include documented information describing your verification and  calibration methods whenever traceability is required and whenever  national or international measurement standards do not exist. | | | | DO | DN | NA |  |
|  |  | | | | Include information that documents your process  monitoring and measuring activities and results. | | | | | DO | DN | NA |  |
|  |  | | | Include information that documents the competence of process personnel. | | | | | | DO | DN | NA |  |
|  |  | | | | Include documented information that can prove that the people under  your control who do work that affects quality are, in fact, competent. | | | | | DO | DN | NA |  |
|  |  | | | Include information that documents process activities and results. | | | | | | DO | DN | NA |  |
|  |  | | | | Include documented information that can prove  that your process is being carried out as planned. | | | | | DO | DN | NA |  |
|  |  | | | | Include documented information that facilitates the traceability  of process outputs whenever traceability is a requirement. | | | | | DO | DN | NA |  |
|  |  | | | Include information that documents your output characteristics. | | | | | | DO | DN | NA |  |
|  |  | | | Include information that documents your output requirements. | | | | | | DO | DN | NA |  |
|  |  | | | | Include information that documents changes in requirements. | | | | | DO | DN | NA |  |
|  |  | | | Include information that documents your output compliance. | | | | | | DO | DN | NA |  |
|  |  | | | Include information that documents your output reviews. | | | | | | DO | DN | NA |  |
|  |  | | | | Include information that documents results  whenever you review output requirements. | | | | | DO | DN | NA |  |
|  |  | | | Include information that documents process development activities. | | | | | | DO | DN | NA |  |
|  |  | | | | Include information that documents process development inputs. | | | | | DO | DN | NA |  |
|  |  | | | | | Include documented information that describes changes in inputs. | | | | DO | DN | NA |  |
|  |  | | | | Include information that documents process development outputs. | | | | | DO | DN | NA |  |
|  |  | | | | | Include documented information that describes changes in outputs. | | | | DO | DN | NA |  |
|  |  | | | | Include information that documents process development changes. | | | | | DO | DN | NA |  |
|  |  | | | | | Include documents that authorize changes in process development. | | | | DO | DN | NA |  |
|  |  | | | | | Include documents that record reviews of all relevant changes. | | | | DO | DN | NA |  |
|  |  | | | | Include information that records actions taken to prevent adverse impacts. | | | | | DO | DN | NA |  |
|  |  | | | | Include information that records process development requirements. | | | | | DO | DN | NA |  |
|  |  | | | | | Include documents that confirm that requirements were met. | | | | DO | DN | NA |  |
|  |  | | | Include information that documents external provider performance. | | | | | | DO | DN | NA |  |
|  |  | | | | Include documented information that describes the  results of your evaluation of external providers. | | | | | DO | DN | NA |  |
|  |  | | | | | Include information that describes your re-evaluation results. | | | | DO | DN | NA |  |
|  |  | | | | | | Include information that describes your monitoring results. | | | DO | DN | NA |  |
|  |  | | | Include information that documents other people’s property and information. | | | | | | DO | DN | NA |  |
|  |  | | | | Include information that documents the status of property and information supplied by customers and external providers that is lost, damaged, or unsuitable. | | | | | DO | DN | NA |  |
|  |  | | | Include information that documents your process operations and outputs. | | | | | | DO | DN | NA |  |
|  |  | | | | Include documented information that describes the process  activities to be performed and the results to be achieved. | | | | | DO | DN | NA |  |
|  |  | | | | | Include information that documents unplanned changes in process activities. | | | | DO | DN | NA |  |
|  |  | | | | | | Include documented information that describes who authorized changes,  the actions that were taken, and the results of your review of these changes. | | | DO | DN | NA |  |
|  |  | | | | Include documented information that describes output delivery and  post-delivery activities to be performed and the results to be achieved. | | | | | DO | DN | NA |  |
|  |  | | | Include information that documents the release of process outputs. | | | | | | DO | DN | NA |  |
|  |  | | | Include information that documents your process nonconformities. | | | | | | DO | DN | NA |  |
|  |  | | | | Include documented information that describes the  corrective actions taken and the results achieved. | | | | | DO | DN | NA |  |
|  |  | | | | | Include documented information that describes the actions that  are taken whenever nonconforming process outputs are produced. | | | | DO | DN | NA |  |
|  |  | | | Include information that documents your internal process audit results. | | | | | | DO | DN | NA |  |
|  |  | | | | Include documented information that can demonstrate that  you have implemented an internal process audit programme. | | | | | DO | DN | NA |  |
|  |  | | | Include information that documents your management review outputs. | | | | | | DO | DN | NA |  |
|  |  | Select all the external documents and records that your process needs. | | | | | | | | DO | DN | NA |  |
|  |  | | Include all documented information of external origin  that you need in order to plan your process. | | | | | | | DO | DN | NA |  |
|  |  | | Include all documented information of external origin that you need in order to operate your process. | | | | | | | DO | DN | NA |  |
|  |  | | Include all documented information of external origin that you need in order to maintain your process. | | | | | | | DO | DN | NA |  |
|  |  | | Include all documented information of external origin that you need in order to monitor your process. | | | | | | | DO | DN | NA |  |
|  |  | | Include all documented information of external origin that you need in order to measure your process. | | | | | | | DO | DN | NA |  |
|  |  | | Include all documented information of external origin  that you need in order to control your process. | | | | | | | DO | DN | NA |  |
|  |  | | Include all documented information of external origin that you need in order to evaluate your process. | | | | | | | DO | DN | NA |  |
|  |  | | | Include all documented information of external origin that you need in order to audit your process. | | | | | | DO | DN | NA |  |
|  |  | | | Include all documented information of external origin that you need in order to review your process. | | | | | | DO | DN | NA |  |
|  |  | | Include all documented information of external origin that you need in order to modify your process. | | | | | | | DO | DN | NA |  |
|  |  | | | Include all documented information of external origin that you need in order to correct your process. | | | | | | DO | DN | NA |  |
|  |  | | | Include all documented information of external origin  that you need in order to improve your process. | | | | | | DO | DN | NA |  |
| 1.6.3 DEVELOP PROCESS DOCUMENTS AND RECORDS | | | | | | | | | | | | | |
|  | Document process participants. | | | | | | | | | DO | DN | NA |  |
|  |  | Document the parties that have an interest in your process. | | | | | | | | DO | DN | NA |  |
|  | Document the scope of process. | | | | | | | | | DO | DN | NA |  |
|  |  | Consider interested party requirements when you document the scope of your process. | | | | | | | | DO | DN | NA |  |
|  |  | Consider your process environment when you document the scope of your process. | | | | | | | | DO | DN | NA |  |
|  |  | Consider your process outputs when you document the scope of your process. | | | | | | | | DO | DN | NA |  |
|  | Document your process outputs. | | | | | | | | | DO | DN | NA |  |
|  |  | Develop documents defining expected output results. | | | | | | | | DO | DN | NA |  |
|  |  | Document characteristics of outputs you plan to produce. | | | | | | | | DO | DN | NA |  |
|  |  | | Develop and document your output definition data. | | | | | | | DO | DN | NA |  |
|  | Document your process activities. | | | | | | | | | DO | DN | NA |  |
|  |  | Document characteristics of process activities to be performed. | | | | | | | | DO | DN | NA |  |
|  |  | Document performance criteria that your process should meet. | | | | | | | | DO | DN | NA |  |
|  |  | | Document performance criteria that process outputs should meet. | | | | | | | DO | DN | NA |  |
|  |  | Document the activities that should make up your process. | | | | | | | | DO | DN | NA |  |
|  |  | | Document the activities needed to generate your outputs. | | | | | | | DO | DN | NA |  |
|  |  | | Document the activities needed to control your “critical items”. | | | | | | | DO | DN | NA |  |
|  |  | | Document the activities needed to prevent unintended deliveries. | | | | | | | DO | DN | NA |  |
|  |  | Document suitable process verification methods. | | | | | | | | DO | DN | NA |  |
|  |  | Document process interactions and interconnections. | | | | | | | | DO | DN | NA |  |
|  |  | | Document your downstream processes. | | | | | | | DO | DN | NA |  |
|  |  | | Document your upstream processes. | | | | | | | DO | DN | NA |  |
|  |  | Document the resources needed to support process. | | | | | | | | DO | DN | NA |  |
|  |  | | Document the resources needed to manage process. | | | | | | | DO | DN | NA |  |
|  |  | | Document the resources needed to manage projects. | | | | | | | DO | DN | NA |  |
|  |  | | Document the resources needed to manage “critical items”. | | | | | | | DO | DN | NA |  |
|  | Document process inputs. | | | | | | | | | DO | DN | NA |  |
|  |  | Document the products that your process will need to have. | | | | | | | | DO | DN | NA |  |
|  |  | | Document the product providers that will be needed. | | | | | | | DO | DN | NA |  |
|  |  | Document the services that your process will need to have. | | | | | | | | DO | DN | NA |  |
|  |  | | Document the service providers that will be needed. | | | | | | | DO | DN | NA |  |
|  |  | Document the technologies that your process will need to have. | | | | | | | | DO | DN | NA |  |
|  |  | | Document the hardware that your process will need to have. | | | | | | | DO | DN | NA |  |
|  |  | | Document the software that your process will need to have. | | | | | | | DO | DN | NA |  |
|  |  | Document the information that your process will need to have. | | | | | | | | DO | DN | NA |  |
|  |  | Document the materials that your process will need to have. | | | | | | | | DO | DN | NA |  |
|  |  | Document the supplies that your process will need to have. | | | | | | | | DO | DN | NA |  |
|  |  | Document the parts that your process will need to have. | | | | | | | | DO | DN | NA |  |
|  | Document process assignments. | | | | | | | | | DO | DN | NA |  |
|  |  | Document process authorities. | | | | | | | | DO | DN | NA |  |
|  |  | Document process responsibilities. | | | | | | | | DO | DN | NA |  |
|  | Document the objectives that your process must achieve. | | | | | | | | | DO | DN | NA |  |
|  |  | Control documents that specify process objectives. | | | | | | | | DO | DN | NA |  |
|  |  | | Retain documents that specify process objectives. | | | | | | | DO | DN | NA |  |
|  | Document process policies, procedures, and work instructions. | | | | | | | | | DO | DN | NA |  |
|  |  | Make sure that policies and procedures support your strategic direction. | | | | | | | | DO | DN | NA |  |
| 1.7 ESTABLISH PROCESS ROLES AND RESPONSIBILITIES | | | | | | | | | | | | | |
| 1.7.1 ASSIGN PROCESS RESPONSIBILITIES AND AUTHORITIES | | | | | | | | | | | | | |
|  | Assign responsibility and authority for managing this process. | | | | | | | | | DO | DN | NA |  |
|  |  | Assign responsibility and authority for applying your quality policy and procedures. | | | | | | | | DO | DN | NA |  |
|  |  | Assign responsibility and authority for complying with regulations and standards. | | | | | | | | DO | DN | NA |  |
|  |  | Assign responsibility and authority for maintaining a focus on process customers. | | | | | | | | DO | DN | NA |  |
|  |  | | Assign responsibility and authority for meeting customer requirements. | | | | | | | DO | DN | NA |  |
|  |  | | Assign responsibility and authority for enhancing customer satisfaction. | | | | | | | DO | DN | NA |  |
|  |  | Assign responsibility and authority for interacting with your external parties. | | | | | | | | DO | DN | NA |  |
|  |  | | Assign responsibility and authority for interacting with  external parties that have an interest in this process. | | | | | | | DO | DN | NA |  |
|  |  | | Assign responsibility and authority for interacting with  external providers that support this process. | | | | | | | DO | DN | NA |  |
|  |  | | | Assign responsibility and authority for deciding when external providers are used. | | | | | | DO | DN | NA |  |
|  |  | | | | Assign responsibility and authority for granting an approval status to providers. | | | | | DO | DN | NA |  |
|  |  | | | | | Allocate responsibility and authority for changing a provider's approval status. | | | | DO | DN | NA |  |
|  | Assign responsibility and authority for operating this process. | | | | | | | | | DO | DN | NA |  |
|  |  | Assign responsibility and authority for ensuring that process is efficient and effective. | | | | | | | | DO | DN | NA |  |
|  |  | | Make managers accountable for ensuring that process produces intended outputs. | | | | | | | DO | DN | NA |  |
|  | Assign responsibility and authority for maintaining this process. | | | | | | | | | DO | DN | NA |  |
|  | Assign responsibility and authority for monitoring this process. | | | | | | | | | DO | DN | NA |  |
|  | Assign responsibility and authority for measuring this process. | | | | | | | | | DO | DN | NA |  |
|  | Assign responsibility and authority for controlling this process. | | | | | | | | | DO | DN | NA |  |
|  |  | Assign responsibility and authority for controlling process modifications. | | | | | | | | DO | DN | NA |  |
|  |  | | Make managers accountable for protecting process integrity when changes occur. | | | | | | | DO | DN | NA |  |
|  | Assign responsibility and authority for evaluating this process. | | | | | | | | | DO | DN | NA |  |
|  |  | Assign responsibility and authority for auditing process. | | | | | | | | DO | DN | NA |  |
|  |  | | Assign responsibility and authority for preparing audit reports. | | | | | | | DO | DN | NA |  |
|  |  | Assign responsibility and authority for reviewing process. | | | | | | | | DO | DN | NA |  |
|  |  | | Assign responsibility and authority for preparing review reports. | | | | | | | DO | DN | NA |  |
|  |  | | | Assign responsibility and authority for submitting process performance reports. | | | | | | DO | DN | NA |  |
|  |  | | | Assign responsibility and authority for reporting process improvement opportunities. | | | | | | DO | DN | NA |  |
|  | Assign responsibility and authority for modifying this process. | | | | | | | | | DO | DN | NA |  |
|  |  | Assign responsibility and authority for correcting this process. | | | | | | | | DO | DN | NA |  |
|  |  | Assign responsibility and authority for improving this process. | | | | | | | | DO | DN | NA |  |
| 1.7.2 DOCUMENT PROCESS RESPONSIBILITIES AND AUTHORITIES | | | | | | | | | | | | | |
|  | Document responsibility and authority for managing this process. | | | | | | | | | DO | DN | NA |  |
|  | Document responsibility and authority for operating this process. | | | | | | | | | DO | DN | NA |  |
|  | Document responsibility and authority for maintaining this process. | | | | | | | | | DO | DN | NA |  |
|  | Document responsibility and authority for monitoring this process. | | | | | | | | | DO | DN | NA |  |
|  | Document responsibility and authority for measuring this process. | | | | | | | | | DO | DN | NA |  |
|  | Document responsibility and authority for controlling this process. | | | | | | | | | DO | DN | NA |  |
|  | Document responsibility and authority for evaluating this process. | | | | | | | | | DO | DN | NA |  |
|  |  | Document responsibility and authority for auditing this process. | | | | | | | | DO | DN | NA |  |
|  |  | Document responsibility and authority for reviewing this process. | | | | | | | | DO | DN | NA |  |
|  | Document responsibility and authority for modifying this process. | | | | | | | | | DO | DN | NA |  |
|  |  | Document responsibility and authority for correcting this process. | | | | | | | | DO | DN | NA |  |
|  |  | Document responsibility and authority for improving this process. | | | | | | | | DO | DN | NA |  |
|  | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | |
| Consider each task and select a response. If you haven’t done it and it needs to be done, select DO. If you’ve already done it, select DN. If the task is not applicable in your situation and you can justify and explain why it should be ignored or excluded, select NA.  In the spaces below, please enter the name and location of your organization, who completed this page, who reviewed it, and the dates. | | | | | | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 2.1 PROVIDE RESOURCES NEEDED TO IMPLEMENT PROCESS | | | | | | | | | | | |
|  | Provide the expertise needed to implement your process. | | | | | | | DO | DN | NA |  |
|  |  | Acquire the knowledge needed to implement your process. | | | | | | DO | DN | NA |  |
|  |  | | Consider internal sources of knowledge about process implementation. | | | | | DO | DN | NA |  |
|  |  | | Consider external sources of knowledge about process implementation. | | | | | DO | DN | NA |  |
|  |  | | | Consider the implementation knowledge that suppliers can provide. | | | | DO | DN | NA |  |
|  |  | | | Consider the implementation knowledge that customers can share with you. | | | | DO | DN | NA |  |
|  |  | | | Consider the implementation knowledge that can be gathered at conferences. | | | | DO | DN | NA |  |
|  |  | | | Consider the implementation knowledge that can be gained from training courses. | | | | DO | DN | NA |  |
|  |  | | | Consider the implementation knowledge that can be acquired from published materials. | | | | DO | DN | NA |  |
|  |  | Share the knowledge needed to implement your process. | | | | | | DO | DN | NA |  |
|  |  | | Share implementation knowledge with managers. | | | | | DO | DN | NA |  |
|  |  | | | Teach managers how to implement your process. | | | | DO | DN | NA |  |
|  |  | | Share implementation knowledge with personnel. | | | | | DO | DN | NA |  |
|  |  | | | Teach personnel how to implement your process. | | | | DO | DN | NA |  |
|  | Provide the technology needed to implement your process. | | | | | | | DO | DN | NA |  |
|  |  | Provide the software needed to implement your process. | | | | | | DO | DN | NA |  |
|  |  | Provide the hardware needed to implement your process. | | | | | | DO | DN | NA |  |
|  |  | | Provide the tools needed to implement your process. | | | | | DO | DN | NA |  |
|  |  | | Provide the equipment needed to implement your process. | | | | | DO | DN | NA |  |
|  | Provide the infrastructure needed to implement your process. | | | | | | | DO | DN | NA |  |
| 2.2 CREATE THE ENVIRONMENT THAT YOUR PROCESS NEEDS | | | | | | | | | | | |
|  | Establish the environment that your process needs in order to achieve conformity of outputs. | | | | | | | DO | DN | NA |  |
|  |  | Create the culture that your process needs in order to achieve conformity of outputs. | | | | | | DO | DN | NA |  |
|  |  | Get the technology that your process needs in order to achieve conformity of outputs. | | | | | | DO | DN | NA |  |
|  |  | Acquire the knowledge that your process needs in order to achieve conformity of outputs. | | | | | | DO | DN | NA |  |
|  |  | | Acquire the knowledge that process managers need to achieve conformity of outputs. | | | | | DO | DN | NA |  |
|  |  | | Acquire the knowledge that process personnel need to achieve conformity of outputs. | | | | | DO | DN | NA |  |
|  |  | Develop the expertise that your process needs in order to achieve conformity of outputs. | | | | | | DO | DN | NA |  |
|  |  | | Develop the management expertise that your process will need. | | | | | DO | DN | NA |  |
|  |  | | | Deliver training and awareness programmes to managers. | | | | DO | DN | NA |  |
|  |  | | | | Teach process managers how to operate your process. | | | DO | DN | NA |  |
|  |  | | | | Teach process managers how to maintain your process. | | | DO | DN | NA |  |
|  |  | | | | Teach process managers how to monitor your process. | | | DO | DN | NA |  |
|  |  | | | | Teach process managers how to measure your process. | | | DO | DN | NA |  |
|  |  | | | | Teach process managers how to control your process. | | | DO | DN | NA |  |
|  |  | | Develop the process expertise that process personnel will need. | | | | | DO | DN | NA |  |
|  |  | | | Deliver training and awareness programmes to personnel. | | | | DO | DN | NA |  |
|  |  | | | | Teach process personnel how to operate your process. | | | DO | DN | NA |  |
|  |  | | | | Teach process personnel how to maintain your process. | | | DO | DN | NA |  |
|  |  | | | | Teach process personnel how to monitor your process. | | | DO | DN | NA |  |
|  |  | | | | Teach process personnel how to measure your process. | | | DO | DN | NA |  |
|  |  | | | | Teach process personnel how to control your process. | | | DO | DN | NA |  |
| 2.3 VERIFY THAT PROCESS CAN PRODUCE REQUIRED OUTPUTS | | | | | | | | | | | |
|  | Verify that process can produce outputs that meet requirements. | | | | | | | DO | DN | NA |  |
|  |  | Verify that process documentation can produce the required results. | | | | | | DO | DN | NA |  |
|  |  | Verify that your process resources can produce the required results. | | | | | | DO | DN | NA |  |
|  |  | | Validate resources that will be used to perform process. | | | | | DO | DN | NA |  |
|  |  | | | Validate tools before they are used to perform process. | | | | DO | DN | NA |  |
|  |  | | | Validate equipment before it is used to perform process. | | | | DO | DN | NA |  |
|  |  | | | Validate software before it is used to perform process. | | | | DO | DN | NA |  |
|  |  | | Validate resources that will be used to automate process. | | | | | DO | DN | NA |  |
|  |  | | | Validate tools before they are used to automate process. | | | | DO | DN | NA |  |
|  |  | | | Validate equipment before it is used to automate process. | | | | DO | DN | NA |  |
|  |  | | | Validate software before it is used to automate process. | | | | DO | DN | NA |  |
|  |  | | Validate resources that will be used to monitor process. | | | | | DO | DN | NA |  |
|  |  | | | Validate tools before they are used to monitor process. | | | | DO | DN | NA |  |
|  |  | | | Validate equipment before it is used to monitor process. | | | | DO | DN | NA |  |
|  |  | | | Validate software before it is used to monitor process. | | | | DO | DN | NA |  |
|  |  | | Validate resources that will be used to measure process. | | | | | DO | DN | NA |  |
|  |  | | | Validate tools before they are used to measure process. | | | | DO | DN | NA |  |
|  |  | | | Validate equipment before it is used to measure process. | | | | DO | DN | NA |  |
|  |  | | | Validate software before it is used to measure process. | | | | DO | DN | NA |  |
|  |  | | Validate resources that will be used to control process. | | | | | DO | DN | NA |  |
|  |  | | | Validate tools before they are used to control process. | | | | DO | DN | NA |  |
|  |  | | | Validate equipment before it is used to control process. | | | | DO | DN | NA |  |
|  |  | | | Validate software before it is used to control process. | | | | DO | DN | NA |  |
| 2.4 ESTABLISH PLANS TO ACHIEVE YOUR PROCESS OBJECTIVES | | | | | | | | | | | |
|  | Figure out what must be done to achieve process objectives. | | | | | | | DO | DN | NA |  |
|  |  | Figure out what must be done to achieve business objectives. | | | | | | DO | DN | NA |  |
|  |  | Figure out what must be done to achieve technical objectives. | | | | | | DO | DN | NA |  |
|  |  | Figure out what must be done to achieve quality objectives. | | | | | | DO | DN | NA |  |
|  |  | Figure out what must be done to achieve safety objectives. | | | | | | DO | DN | NA |  |
|  |  | Figure out what must be done to achieve security objectives. | | | | | | DO | DN | NA |  |
|  |  | Figure out what must be done to achieve continuity objectives. | | | | | | DO | DN | NA |  |
|  |  | Figure out what must be done to achieve environmental objectives. | | | | | | DO | DN | NA |  |
|  | Figure out who will be responsible for achieving process objectives. | | | | | | | DO | DN | NA |  |
|  |  | Figure out who will be responsible for achieving business objectives. | | | | | | DO | DN | NA |  |
|  |  | Figure out who will be responsible for achieving technical objectives. | | | | | | DO | DN | NA |  |
|  |  | Figure out who will be responsible for achieving quality objectives. | | | | | | DO | DN | NA |  |
|  |  | Figure out who will be responsible for achieving safety objectives. | | | | | | DO | DN | NA |  |
|  |  | Figure out who will be responsible for achieving security objectives. | | | | | | DO | DN | NA |  |
|  |  | Figure out who will be responsible for achieving continuity objectives. | | | | | | DO | DN | NA |  |
|  |  | Figure out who will be responsible for achieving environmental objectives. | | | | | | DO | DN | NA |  |
|  | Figure out what resources will be needed to achieve process objectives. | | | | | | | DO | DN | NA |  |
|  |  | Figure out what resources will be needed to achieve business objectives. | | | | | | DO | DN | NA |  |
|  |  | Figure out what resources will be needed to achieve technical objectives. | | | | | | DO | DN | NA |  |
|  |  | Figure out what resources will be needed to achieve quality objectives. | | | | | | DO | DN | NA |  |
|  |  | Figure out what resources will be needed to achieve safety objectives. | | | | | | DO | DN | NA |  |
|  |  | Figure out what resources will be needed to achieve security objectives. | | | | | | DO | DN | NA |  |
|  |  | Figure out what resources will be needed to achieve continuity objectives. | | | | | | DO | DN | NA |  |
|  |  | Figure out what resources will be needed to achieve environmental objectives. | | | | | | DO | DN | NA |  |
| 2.5 EXPLAIN PROCESS POLICIES, PROCEDURES, AND OBJECTIVES | | | | | | | | | | | |
|  | Ensure that managers understand policies, procedures, and objectives. | | | | | | | DO | DN | NA |  |
|  |  | Make sure that process managers understand your process policies. | | | | | | DO | DN | NA |  |
|  |  | | Make sure that process managers know how to apply process policies. | | | | | DO | DN | NA |  |
|  |  | Make sure that process managers understand your process procedures. | | | | | | DO | DN | NA |  |
|  |  | | Make sure that process managers know how to follow process procedures. | | | | | DO | DN | NA |  |
|  |  | Make sure that process managers understand their process objectives. | | | | | | DO | DN | NA |  |
|  |  | | Make sure that process managers know how to achieve process objectives. | | | | | DO | DN | NA |  |
|  |  | | | Make sure that managers know who is responsible for achieving objectives. | | | | DO | DN | NA |  |
|  | Ensure that personnel understand policies, procedures, and objectives. | | | | | | | DO | DN | NA |  |
|  |  | Make sure that process personnel understand your process policies. | | | | | | DO | DN | NA |  |
|  |  | | Make sure that process personnel know how to apply process policies. | | | | | DO | DN | NA |  |
|  |  | Make sure that process personnel understand your process procedures. | | | | | | DO | DN | NA |  |
|  |  | | Make sure that process personnel know how to follow process procedures. | | | | | DO | DN | NA |  |
|  |  | Make sure that process personnel understand their process objectives. | | | | | | DO | DN | NA |  |
|  |  | | Make sure that process personnel know how to achieve process objectives. | | | | | DO | DN | NA |  |
|  |  | | | Make sure that personnel know who is responsible for achieving objectives. | | | | DO | DN | NA |  |
| 2.6 COMMUNICATE PROCESS MANAGEMENT EXPECTATIONS | | | | | | | | | | | |
|  | Explain why process policies must be applied. | | | | | | | DO | DN | NA |  |
|  | Explain why process procedures must be used. | | | | | | | DO | DN | NA |  |
|  | Explain why process objectives must be achieved. | | | | | | | DO | DN | NA |  |
|  | Explain why process requirements must be met. | | | | | | | DO | DN | NA |  |
|  |  | Explain why output requirements must be met. | | | | | | DO | DN | NA |  |
|  | Explain why process methods must be followed. | | | | | | | DO | DN | NA |  |
|  |  | Explain why the process approach is important. | | | | | | DO | DN | NA |  |
|  |  | Explain why management programmes are important. | | | | | | DO | DN | NA |  |
|  |  | | Explain why risk management is important. | | | | | DO | DN | NA |  |
|  |  | | Explain why safety management is important. | | | | | DO | DN | NA |  |
|  |  | | | Explain why safety policies must be implemented. | | | | DO | DN | NA |  |
|  |  | | | Explain why safety objectives must be achieved. | | | | DO | DN | NA |  |
|  |  | | | Explain why safety requirements must be met. | | | | DO | DN | NA |  |
|  |  | | Explain why quality management is important. | | | | | DO | DN | NA |  |
|  |  | | | Explain why quality policies must be implemented. | | | | DO | DN | NA |  |
|  |  | | | Explain why quality objectives must be achieved. | | | | DO | DN | NA |  |
|  |  | | | Explain why quality requirements must be met. | | | | DO | DN | NA |  |
|  |  | | Explain why environmental management is important. | | | | | DO | DN | NA |  |
|  |  | | | Explain why environmental policies must be implemented. | | | | DO | DN | NA |  |
|  |  | | | Explain why environmental objectives must be achieved. | | | | DO | DN | NA |  |
|  |  | | | Explain why environmental requirements must be met. | | | | DO | DN | NA |  |
|  |  | | Explain why continuity management is important. | | | | | DO | DN | NA |  |
|  |  | | | Explain why business continuity policies must be implemented. | | | | DO | DN | NA |  |
|  |  | | | Explain why business continuity objectives must be achieved. | | | | DO | DN | NA |  |
|  |  | | | Explain why business continuity requirements must be met. | | | | DO | DN | NA |  |
|  |  | | Explain why security management is important. | | | | | DO | DN | NA |  |
|  |  | | | Explain why personnel security is important. | | | | DO | DN | NA |  |
|  |  | | | | Explain why personnel security policies must be implemented. | | | DO | DN | NA |  |
|  |  | | | | Explain why personnel security objectives must be achieved. | | | DO | DN | NA |  |
|  |  | | | | Explain why personnel security requirements must be met. | | | DO | DN | NA |  |
|  |  | | | Explain why information security is important. | | | | DO | DN | NA |  |
|  |  | | | | Explain why information security policies must be implemented. | | | DO | DN | NA |  |
|  |  | | | | Explain why information security objectives must be achieved. | | | DO | DN | NA |  |
|  |  | | | | Explain why information security requirements must be met. | | | DO | DN | NA |  |
|  |  | | | Explain why component security is important. | | | | DO | DN | NA |  |
|  |  | | | | Explain why counterfeit parts management is important. | | | DO | DN | NA |  |
|  |  | | | | | Explain why counterfeit parts policies must be implemented. | | DO | DN | NA |  |
|  |  | | | | | Explain why counterfeit parts objectives must be achieved. | | DO | DN | NA |  |
|  |  | | | | | Explain why counterfeit parts requirements must be met. | | DO | DN | NA |  |
| 2.7 EXPECT ALL PROCESS MANAGERS TO BE ACCOUNTABLE | | | | | | | | | | | |
|  | Ask managers to accept responsibility for their process. | | | | | | | DO | DN | NA |  |
|  |  | Ask managers to be accountable for ensuring that process is effective. | | | | | | DO | DN | NA |  |
|  |  | | Ask them to be accountable for ensuring that process produces intended outputs. | | | | | DO | DN | NA |  |
|  |  | Ask managers to be accountable for ensuring that process meets requirements. | | | | | | DO | DN | NA |  |
|  |  | | Ask them to be accountable for ensuring that process meets customer requirements. | | | | | DO | DN | NA |  |
|  |  | | Ask them to be accountable for ensuring that process meets technical requirements. | | | | | DO | DN | NA |  |
|  |  | | Ask them to be accountable for ensuring that process meets business requirements. | | | | | DO | DN | NA |  |
|  |  | | Ask them to be accountable for ensuring that process meets security requirements. | | | | | DO | DN | NA |  |
|  |  | | Ask them to be accountable for ensuring that process meets quality requirements. | | | | | DO | DN | NA |  |
|  |  | | Ask them to be accountable for ensuring that process meets safety requirements. | | | | | DO | DN | NA |  |
|  |  | | Ask them to be accountable for ensuring that process meets legal requirements. | | | | | DO | DN | NA |  |
|  |  | | Ask them to be accountable for ensuring that process meets environmental requirements. | | | | | DO | DN | NA |  |
|  |  | Ask managers to be accountable for ensuring that process complies with standards. | | | | | | DO | DN | NA |  |
|  |  | | Ask them to be accountable for ensuring that process complies with audit standards. | | | | | DO | DN | NA |  |
|  |  | | Ask them to be accountable for ensuring that process complies with safety standards. | | | | | DO | DN | NA |  |
|  |  | | Ask them to be accountable for ensuring that process complies with quality standards. | | | | | DO | DN | NA |  |
|  |  | | Ask them to be accountable for ensuring that process complies with service standards. | | | | | DO | DN | NA |  |
|  |  | | Ask them to be accountable for ensuring that process complies with product standards. | | | | | DO | DN | NA |  |
|  |  | | Ask them to be accountable for ensuring that process complies with security standards. | | | | | DO | DN | NA |  |
|  |  | | Ask them to be accountable for ensuring that process complies with environmental standards. | | | | | DO | DN | NA |  |
|  |  | Ask managers to be accountable for ensuring that process implements policies. | | | | | | DO | DN | NA |  |
|  |  | | Ask them to be accountable for ensuring that process implements audit policies. | | | | | DO | DN | NA |  |
|  |  | | Ask them to be accountable for ensuring that process implements safety policies. | | | | | DO | DN | NA |  |
|  |  | | Ask them to be accountable for ensuring that process implements quality policies. | | | | | DO | DN | NA |  |
|  |  | | Ask them to be accountable for ensuring that process implements service policies. | | | | | DO | DN | NA |  |
|  |  | | Ask them to be accountable for ensuring that process implements product policies. | | | | | DO | DN | NA |  |
|  |  | | Ask them to be accountable for ensuring that process implements security policies. | | | | | DO | DN | NA |  |
|  |  | | Ask them to be accountable for ensuring that process implements environmental policies. | | | | | DO | DN | NA |  |
|  |  | Ask managers to be accountable for ensuring that process follows procedures. | | | | | | DO | DN | NA |  |
|  |  | | Ask them to be accountable for ensuring that process follows safety procedures. | | | | | DO | DN | NA |  |
|  |  | | Ask them to be accountable for ensuring that process follows quality procedures. | | | | | DO | DN | NA |  |
|  |  | | Ask them to be accountable for ensuring that process follows service procedures. | | | | | DO | DN | NA |  |
|  |  | | Ask them to be accountable for ensuring that process follows product procedures. | | | | | DO | DN | NA |  |
|  |  | | Ask them to be accountable for ensuring that process follows security procedures. | | | | | DO | DN | NA |  |
|  |  | | Ask them to be accountable for ensuring that process follows environmental procedures. | | | | | DO | DN | NA |  |
| 2.8 ESTABLISH PROCESS MANAGEMENT PROGRAMMES | | | | | | | | | | | |
|  | Establish your quality management programme. | | | | | | | DO | DN | NA |  |
|  |  | Formulate quality management requirements. | | | | | | DO | DN | NA |  |
|  |  | Allocate quality management goals and objectives. | | | | | | DO | DN | NA |  |
|  |  | Assign quality management responsibilities and authorities. | | | | | | DO | DN | NA |  |
|  |  | Implement quality management plans, policies, and procedures. | | | | | | DO | DN | NA |  |
|  |  | Identify suitable quality control points and apply quality controls. | | | | | | DO | DN | NA |  |
|  |  | | Establish your configuration management programme. | | | | | DO | DN | NA |  |
|  |  | | | Establish a programme to identify and control the attributes of process outputs. | | | | DO | DN | NA |  |
|  |  | | | | Establish a programme to identify and control output identities and characteristics. | | | DO | DN | NA |  |
|  |  | | | | Establish a programme to identify and control output traceability to requirements. | | | DO | DN | NA |  |
|  |  | | | | Establish a programme to identify and control output changes and modifications. | | | DO | DN | NA |  |
|  |  | | | | Establish a programme to identify and control output documents and records. | | | DO | DN | NA |  |
|  |  | | | | | Make sure that your output documents and records are  consistent with the actual attributes of your outputs. | | DO | DN | NA |  |
|  |  | | | | | | Ensure that requirements documentation is consistent with actual attributes. | DO | DN | NA |  |
|  |  | | | | | | Ensure that your design documentation is consistent with actual attributes. | DO | DN | NA |  |
|  |  | | | | | | Ensure that your validation documentation is consistent with actual attributes. | DO | DN | NA |  |
|  |  | | | | | | Ensure that your verification documentation is consistent with actual attributes. | DO | DN | NA |  |
|  |  | | | | | | Ensure that your acceptance documentation is consistent with actual attributes. | DO | DN | NA |  |
|  |  | | | Assign responsibility for identifying and controlling the attributes of process outputs. | | | | DO | DN | NA |  |
|  | Establish your supplier management programme. | | | | | | | DO | DN | NA |  |
|  |  | Establish a programme to manage and control external providers. | | | | | | DO | DN | NA |  |
|  |  | | Allocate supplier management goals and objectives. | | | | | DO | DN | NA |  |
|  |  | | Assign supplier management responsibilities and authorities. | | | | | DO | DN | NA |  |
|  |  | | Implement supplier management plans, policies, and procedures. | | | | | DO | DN | NA |  |
|  |  | | Identify suitable supplier control points and apply supplier controls. | | | | | DO | DN | NA |  |
|  |  | Establish a register of external provider performance and status. | | | | | | DO | DN | NA |  |
|  | Establish your risk management programme. | | | | | | | DO | DN | NA |  |
|  |  | Assign risk management responsibilities. | | | | | | DO | DN | NA |  |
|  |  | | Assign operational risk management tasks. | | | | | DO | DN | NA |  |
|  |  | Manage risks related to process outputs. | | | | | | DO | DN | NA |  |
|  |  | | Identify risks related to process outputs. | | | | | DO | DN | NA |  |
|  |  | | Assess risks related to process outputs. | | | | | DO | DN | NA |  |
|  |  | | | Determine the likelihood that events will occur. | | | | DO | DN | NA |  |
|  |  | | | | Determine the likelihood or probability that an undesirable  occurrence or outcome will actually occur in the future. | | | DO | DN | NA |  |
|  |  | | | Evaluate potentially severe consequences. | | | | DO | DN | NA |  |
|  |  | | | Make operational risk acceptance decisions. | | | | DO | DN | NA |  |
|  |  | | Communicate risks related to process outputs. | | | | | DO | DN | NA |  |
|  |  | Apply the actions that must be taken to mitigate the operational  risks that exceed the limits set by your risk acceptance criteria. | | | | | | DO | DN | NA |  |
|  |  | | Identify the actions that must be taken to mitigate operational risks. | | | | | DO | DN | NA |  |
|  |  | | Implement actions that must be taken to mitigate operational risks. | | | | | DO | DN | NA |  |
|  |  | Control the risks that remain after you’ve implemented  actions to mitigate unacceptable operational risks. | | | | | | DO | DN | NA |  |
|  | Establish your security management programme. | | | | | | | DO | DN | NA |  |
|  |  | Establish your component security management programme. | | | | | | DO | DN | NA |  |
|  |  | | Set up a counterfeit parts management programme. | | | | | DO | DN | NA |  |
|  |  | | | Assign responsibility and authority for counterfeit parts. | | | | DO | DN | NA |  |
|  |  | | | Implement policies and procedures for counterfeit parts. | | | | DO | DN | NA |  |
|  |  | | | Identify counterfeit control points and apply controls. | | | | DO | DN | NA |  |
|  |  | | | Teach people about counterfeit parts and components. | | | | DO | DN | NA |  |
|  |  | | | | Explain how counterfeit parts can be prevented. | | | DO | DN | NA |  |
|  |  | | | | | Explain how suspicious parts can be detected. | | DO | DN | NA |  |
|  |  | | | Monitor counterfeit parts reported by external sources. | | | | DO | DN | NA |  |
|  |  | | | | Monitor suspicious and obsolete parts and components. | | | DO | DN | NA |  |
|  |  | | | Control the acquisition and use of parts and components. | | | | DO | DN | NA |  |
|  |  | | | | Acquire parts and components from original or authorized manufacturers. | | | DO | DN | NA |  |
|  |  | | | | | Acquire items from authorized distributors or other approved sources. | | DO | DN | NA |  |
|  |  | | | | Test and verify parts and components and detect all counterfeit items. | | | DO | DN | NA |  |
|  |  | | | | Quarantine and report suspicious or counterfeit parts and components. | | | DO | DN | NA |  |
|  |  | | | Maintain a parts and components traceability programme. | | | | DO | DN | NA |  |
|  |  | Establish your information security management programme. | | | | | | DO | DN | NA |  |
|  |  | | Allocate goals and objectives for information security. | | | | | DO | DN | NA |  |
|  |  | | Assign responsibility and authority for information security. | | | | | DO | DN | NA |  |
|  |  | | Implement plans, policies, and procedures for information security. | | | | | DO | DN | NA |  |
|  |  | | Identify suitable infosec control points and apply infosec controls. | | | | | DO | DN | NA |  |
|  |  | Establish your personnel security management programme. | | | | | | DO | DN | NA |  |
|  |  | | Allocate goals and objectives for personnel security. | | | | | DO | DN | NA |  |
|  |  | | Assign responsibility and authority for personnel security. | | | | | DO | DN | NA |  |
|  |  | | Implement plans, policies, and procedures for personnel security. | | | | | DO | DN | NA |  |
|  |  | | Identify suitable personnel control points and apply personnel controls. | | | | | DO | DN | NA |  |
|  | Establish your safety management programme. | | | | | | | DO | DN | NA |  |
|  |  | Formulate safety management requirements. | | | | | | DO | DN | NA |  |
|  |  | Allocate safety management goals and objectives. | | | | | | DO | DN | NA |  |
|  |  | Assign safety management responsibilities and authorities. | | | | | | DO | DN | NA |  |
|  |  | Implement safety management plans, policies, and procedures. | | | | | | DO | DN | NA |  |
|  |  | Identify suitable safety control points and apply safety controls. | | | | | | DO | DN | NA |  |
|  | Establish your environmental management programme. | | | | | | | DO | DN | NA |  |
|  |  | Formulate environmental management requirements. | | | | | | DO | DN | NA |  |
|  |  | Allocate environmental management goals and objectives. | | | | | | DO | DN | NA |  |
|  |  | Assign environmental management responsibilities and authorities. | | | | | | DO | DN | NA |  |
|  |  | Implement environmental management plans, policies, and procedures. | | | | | | DO | DN | NA |  |
|  | Establish your business continuity management programme. | | | | | | | DO | DN | NA |  |
|  |  | Formulate business continuity management requirements. | | | | | | DO | DN | NA |  |
|  |  | Allocate business continuity management goals and objectives. | | | | | | DO | DN | NA |  |
|  |  | Assign business continuity management responsibilities and authorities. | | | | | | DO | DN | NA |  |
|  |  | Implement business continuity management plans, policies, and procedures. | | | | | | DO | DN | NA |  |
| 2.9 RETAIN IMPLEMENTATION DOCUMENTATION | | | | | | | | | | | |
|  | Retain a record of implementation responsibilities. | | | | | | | DO | DN | NA |  |
|  | Retain a record of implementation plans and procedures. | | | | | | | DO | DN | NA |  |
|  | Retain a record of implementation results and achievements. | | | | | | | DO | DN | NA |  |
|  | Retain a record of process verification and validation activities. | | | | | | | DO | DN | NA |  |
|  |  | Retain a record of process verification and validation results. | | | | | | DO | DN | NA |  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| 3.1 PROVIDE RESOURCES TO FACILITATE PROCESS OPERATIONS | | | | | | | | | | | | | |
| 3.1.1 Provide the expertise needed to operate your process | | | | | | | | | | | | | |
|  | Provide the managers needed to manage process operations. | | | | | | | | | DO | DN | NA |  |
|  |  | Acquire the knowledge that managers need to manage  process operations and achieve conformity of outputs. | | | | | | | | DO | DN | NA |  |
|  |  | | Consider internal sources of knowledge about managing processes. | | | | | | | DO | DN | NA |  |
|  |  | | Consider external sources of knowledge about managing processes. | | | | | | | DO | DN | NA |  |
|  |  | Share the knowledge that managers need to manage  process operations and achieve conformity of outputs. | | | | | | | | DO | DN | NA |  |
|  |  | | Deliver suitable process management training and  awareness programmes to process managers. | | | | | | | DO | DN | NA |  |
|  | Provide the personnel needed to operate your process. | | | | | | | | | DO | DN | NA |  |
|  |  | Acquire the knowledge that personnel need to operate  your process and achieve conformity of outputs. | | | | | | | | DO | DN | NA |  |
|  |  | | Consider internal sources of knowledge about process operations. | | | | | | | DO | DN | NA |  |
|  |  | | Consider external sources of knowledge about process operations. | | | | | | | DO | DN | NA |  |
|  |  | Share the knowledge that personnel need to operate  your process and achieve conformity of outputs. | | | | | | | | DO | DN | NA |  |
|  |  | | Deliver suitable process training and awareness  programmes to support process operations. | | | | | | | DO | DN | NA |  |
| 3.1.2 Provide the technology needed to operate your process | | | | | | | | | | | | | |
|  | Provide the software needed to operate your process. | | | | | | | | | DO | DN | NA |  |
|  |  | Provide software needed to support operations and achieve conformity of outputs. | | | | | | | | DO | DN | NA |  |
|  | Provide the hardware needed to operate your process. | | | | | | | | | DO | DN | NA |  |
|  |  | Provide hardware needed to support operations and achieve conformity of outputs. | | | | | | | | DO | DN | NA |  |
| 3.1.3 Provide the infrastructure needed to operate your process | | | | | | | | | | | | | |
|  | Provide the infrastructure needed to support process  operations and achieve conformity of outputs. | | | | | | | | | DO | DN | NA |  |
|  |  | Provide the physical infrastructure needed to support  process operations and achieve conformity of outputs. | | | | | | | | DO | DN | NA |  |
|  |  | Provide the electrical infrastructure needed to support  process operations and achieve conformity of outputs. | | | | | | | | DO | DN | NA |  |
|  |  | Provide the transportation infrastructure needed to support  process operations and achieve conformity of outputs. | | | | | | | | DO | DN | NA |  |
|  |  | Provide the communications infrastructure needed to support  process operations and achieve conformity of outputs. | | | | | | | | DO | DN | NA |  |
| 3.2 ASK PROCESS OWNERS TO MANAGE PROCESS OPERATIONS | | | | | | | | | | | | | |
| 3.2.1 Expect process managers to address risks and opportunities | | | | | | | | | | | | | |
|  | Expect process managers to identify the operational risks  that could affect their ability to meet requirements. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to identify risks and opportunities. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to consider whether they have the  capacity or are capable of meeting requirements. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to consider whether output  delivery time frames can be accommodated. | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to consider whether the use of  new technologies could influence performance. | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to identify the opportunities  that could improve their ability to meet requirements. | | | | | | | | DO | DN | NA |  |
|  | Expect process managers to cope with process risks and opportunities. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to manage and control process risks. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to consider all of their risk treatment options. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to consider avoiding or reducing their risk. | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to consider eliminating the source of their risk. | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to consider retaining the risk or sharing it with others. | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to consider modifying the probabilities or consequences. | | | | | | DO | DN | NA |  |
|  |  | | Expect process managers to define actions to address risks and opportunities. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to define actions that they can take to address the risks that could weaken the performance of their process or disrupt or damage operations. | | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to consider the potential impact on outputs when  they define the actions they plan to take to address process risks. | | | | | DO | DN | NA |  |
|  |  | | | | | Expect them to figure out how they're going to implement these  actions and how they're going to make them part of their process. | | | | DO | DN | NA |  |
|  |  | | | | | Expect them to figure out how they're going to evaluate the  effectiveness of the actions they take to address process risks. | | | | DO | DN | NA |  |
|  |  | Expect process managers to exploit process improvement opportunities. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect managers to define actions to exploit process improvement opportunities. | | | | | | | DO | DN | NA |  |
| 3.2.2 Expect process managers to implement policies and procedures | | | | | | | | | | | | | |
|  | Expect process managers to implement process policies. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect managers to implement business policies. | | | | | | | | DO | DN | NA |  |
|  |  | Expect managers to implement quality policies. | | | | | | | | DO | DN | NA |  |
|  |  | Expect managers to implement safety policies. | | | | | | | | DO | DN | NA |  |
|  |  | Expect managers to implement security policies. | | | | | | | | DO | DN | NA |  |
|  |  | Expect managers to implement continuity policies. | | | | | | | | DO | DN | NA |  |
|  |  | Expect managers to implement environmental policies. | | | | | | | | DO | DN | NA |  |
|  | Expect process managers to implement process procedures. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect managers to implement business procedures. | | | | | | | | DO | DN | NA |  |
|  |  | Expect managers to implement quality procedures. | | | | | | | | DO | DN | NA |  |
|  |  | Expect managers to implement safety procedures. | | | | | | | | DO | DN | NA |  |
|  |  | Expect managers to implement security procedures. | | | | | | | | DO | DN | NA |  |
|  |  | Expect managers to implement continuity procedures. | | | | | | | | DO | DN | NA |  |
|  |  | Expect managers to implement environmental procedures. | | | | | | | | DO | DN | NA |  |
| 3.2.3 Expect process managers to specify output requirements and cabilities | | | | | | | | | | | | | |
|  | Expect process managers to determine requirements for outputs offered to customers. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect managers to determine statutory and regulatory requirements for outputs. | | | | | | | | DO | DN | NA |  |
|  |  | Expect managers to determine your organization's own requirements for outputs. | | | | | | | | DO | DN | NA |  |
|  |  | Expect managers to determine any additional “special requirements” for outputs. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect managers to identify requirements that may be especially difficult to meet. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to identify requirements that force them  to operate at the limit of their technical capability. | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to identify requirements that force them  to operate at the limit of their process capability. | | | | | | DO | DN | NA |  |
|  | Expect process managers to review output requirements before accepting an order. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect managers to review output requirements before  making a commitment to supply outputs to customers. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect managers to coordinate reviews with  applicable functions within your organization. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to review all documented requirements before accepting an order. | | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to review output requirements specified by customers. | | | | | DO | DN | NA |  |
|  |  | | | | | Expect them to review delivery and post-delivery requirements before proceeding. | | | | DO | DN | NA |  |
|  |  | | | | Expect them to review output requirements specified by regulatory bodies. | | | | | DO | DN | NA |  |
|  |  | | | | | Expect them to review applicable statutory and regulatory requirements. | | | | DO | DN | NA |  |
|  |  | | | | Expect them to review output requirements specified by interested parties. | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to review output requirements specified by your organization. | | | | | DO | DN | NA |  |
|  |  | | | Expect them to review all undocumented requirements before accepting an order. | | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to review unstated requirements needed for specified or intended use. | | | | | DO | DN | NA |  |
|  | Expect process managers to clarify all differences  between the original proposal and the final order. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to review all orders and  contractual requirements that have been modified. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect process managers to coordinate the review  of contracts and orders that have been modified. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to resolve all differences between  the original proposal and the final order. | | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to negotiate mutually acceptable requirements with  customers whenever some customer requirements cannot be met. | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to amend all relevant documented information  to reflect changes in customers’ output requirements. | | | | | DO | DN | NA |  |
|  |  | | | | | Expect them to distribute amended information to all relevant people. | | | | DO | DN | NA |  |
|  | Expect process managers to confirm that they can meet output requirements. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to confirm that they can meet undocumented  customer requirements before making a commitment to supply outputs. | | | | | | | | DO | DN | NA |  |
|  | Expect process managers to document the review of output requirements. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to document the results of output requirement reviews. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect process managers to retain documents that record results of their reviews. | | | | | | | DO | DN | NA |  |
|  |  | | Expect process managers to control documents that record results of their reviews. | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to document any new or changed output requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect process managers to retain documents that record new or changed requirements. | | | | | | | DO | DN | NA |  |
|  |  | | Expect process managers to control documents that record new or changed requirements. | | | | | | | DO | DN | NA |  |
|  | Expect process managers to amend documents when output requirements change. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect managers to control documents that record changes in output requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect process managers to amend all relevant documented  information to reflect changes in customers' output requirements. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to retain documents and records  that describe new or modified output requirements. | | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to share amended information with relevant personnel. | | | | | DO | DN | NA |  |
| 3.2.4 Expect process managers to communicate with their process customers | | | | | | | | | | | | | |
|  | Expect process managers to provide information to customers. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to share information about process outputs. | | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to discuss contingency plans (when relevant). | | | | | | | | DO | DN | NA |  |
|  |  | | Expect process managers to clarify specific requirements for action. | | | | | | | DO | DN | NA |  |
|  | Expect process managers to obtain information from customers. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to obtain information about orders and contracts. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect process managers to receive information about changes to orders and contracts. | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to obtain information about process outputs. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect process managers to gather customer feedback about process outputs. | | | | | | | DO | DN | NA |  |
|  |  | | Expect process managers to gather complaints about their process outputs. | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to obtain information about property supplied by customers. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect process managers to manage and control property supplied by customers. | | | | | | | DO | DN | NA |  |
| 3.2.5 Expect process managers to evaluate and select their external providers | | | | | | | | | | | | | |
|  | Expect process managers to accept responsibility for  externally provided processes, products, and services. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect them to accept responsibility for conformity  of external processes, products, and services. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to accept responsibility for the conformity  of processes, products, and services that are defined by  customers and provided to them by external providers. | | | | | | | DO | DN | NA |  |
|  | Expect process managers to identify risks related to the  external provision of processes, products, and services. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect them to identify risks related to the selection  and use of external providers and external sources. | | | | | | | | DO | DN | NA |  |
|  | Expect process managers to define data and criteria to  manage external process, product, and service providers. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect them to use data and criteria to evaluate  external process, product, and service providers. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to use data from reliable external sources to evaluate external providers. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to use data from customer organizations to evaluate external providers. | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to use data from government authorities to evaluate external providers. | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to use data from accredited certification bodies to evaluate external providers. | | | | | | DO | DN | NA |  |
|  |  | | Expect them to use criteria to evaluate external process, product, and service providers. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to evaluate and re-evaluate their ability to meet specified requirements. | | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to document their external evaluation and re-evaluation activities. | | | | | DO | DN | NA |  |
|  |  | | | | | Expect them to retain and control a record of evaluation and re-evaluation activities. | | | | DO | DN | NA |  |
|  |  | Expect them to use data and criteria to select  external process, product, and service providers. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to use data from reliable external sources to select external providers. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to use data from customer organizations to select external providers. | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to use data from government authorities to select external providers. | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to use data from accredited certification bodies to select external providers. | | | | | | DO | DN | NA |  |
|  |  | | Expect them to use criteria to select providers that can meet specified requirements. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to document provider selection activities and retain these documents. | | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to control documents that describe provider selection activities. | | | | | DO | DN | NA |  |
|  |  | | | Expect them to record the approval status of each provider and to retain these records. | | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to record the scope of approvals and the work that has been authorized. | | | | | DO | DN | NA |  |
|  |  | | | | | Expect them to specify what types of products and services have been approved. | | | | DO | DN | NA |  |
|  | Expect process managers to specify what they expect  from external process, product, and service providers. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to identify process requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify external process approval requirements. | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to identify product requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify external product acceptance requirements. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to identify statistical techniques that must be used. | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to identify acceptance instructions that must be followed. | | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify external product approval requirements. | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify external product release requirements. | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to identify service requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify external service acceptance requirements. | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify external service approval requirements. | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify external service release requirements. | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to identify equipment requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify external equipment approval requirements. | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to identify “special requirements”. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify “critical items” and “key characteristics”. | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to identify information requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify technical data and information requirements. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to identify requirements for specifications and drawings. | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to identify procedural requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify any work practices that providers need to follow. | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify any work instructions that providers need to follow. | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to identify methodological requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify how external methods are approved. | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to identify interaction requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify how external providers interact with your process. | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to identify notification requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to specify supply chain notification requirements. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to ask external providers to notify them when changes are planned. | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to get approval whenever important changes are being considered. | | | | | | DO | DN | NA |  |
|  |  | | | | Ask process managers to get approval when process changes are being planned. | | | | | DO | DN | NA |  |
|  |  | | | | Ask process managers to get approval when product changes are being planned. | | | | | DO | DN | NA |  |
|  |  | | | | Ask process managers to get approval when service changes are being planned. | | | | | DO | DN | NA |  |
|  |  | | | | Ask process managers to get approval when provider changes are being planned. | | | | | DO | DN | NA |  |
|  |  | | | | Ask process managers to get approval when location changes are being planned. | | | | | DO | DN | NA |  |
|  |  | | | | | Ask them to get approval before changing manufacturing or assembly locations. | | | | DO | DN | NA |  |
|  |  | | Expect them to specify nonconformance notification requirements. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to specify nonconformance approval and disposition requirements. | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to identify design and development requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to specify design and development control requirements. | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to identify verification and validation requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify verification and validation activities to be done at external premises. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to identify verifications and validations that customers plan to perform. | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to identify verifications and validations that they intend to carry out. | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to identify production requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to specify production process verification requirements. | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to identify test and inspection requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Ask external providers to provide test specimens when required. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to provide test specimens for inspection purposes. | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to provide test specimens for verification purposes. | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to provide test specimens for investigative purposes. | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to provide test specimens for auditing purposes. | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to identify part and component requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect process managers to prohibit the use of counterfeit parts and components. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect managers to ask external providers to prevent the use of counterfeit parts. | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to identify outsourcing requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify any external providers that external providers must use. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to identify any special providers that customers have pre-approved. | | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to identify any special providers that customers expect you to use. | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify any specific processes that your external providers must use. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to identify any process sources that external providers must employ. | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to identify any "special process" requirements that must be met. | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to identify supply chain requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify your organization's supply chain access requirements. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to establish the right to access relevant areas throughout supply chain. | | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to establish your organization's right to access facilities and documents. | | | | | DO | DN | NA |  |
|  |  | | | | | Expect them to establish your customers’ right to access facilities and documents. | | | | DO | DN | NA |  |
|  |  | | Expect them to identify your organization's supply chain flowdown requirements. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to identify important requirements that must flow down the supply chain. | | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to identify customer requirements that must flow down to suppliers. | | | | | DO | DN | NA |  |
|  |  | Expect process managers to identify external staff awareness requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to ask external providers to emphasize the importance of safety. | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to ask external providers to emphasize the importance of security. | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to ask external providers to emphasize the importance of quality. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to ask external providers to emphasize the importance of conformity. | | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to ask external providers to make their personnel  aware of their contribution to product and service conformity. | | | | | DO | DN | NA |  |
|  |  | Expect process managers to identify external competence requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to specify external personnel qualification requirements. | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to identify monitoring and control requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to define how they plan to monitor the performance of external providers. | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to define how they plan to control the performance of external providers. | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to identify quality management requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify quality management system implementation requirements. | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to identify documentation requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to ask external providers to retain documented information. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to ask providers to specify retention periods and disposition requirements. | | | | | | DO | DN | NA |  |
| 3.2.6 Expect process managers to supervise and control all process activities | | | | | | | | | | | | | |
|  | Expect process managers to verify that resources can produce required results. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to validate resources that will be used to operate process. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect process managers to validate tools before they are used to operate process. | | | | | | | DO | DN | NA |  |
|  |  | | Expect process managers to validate equipment before it is used to operate process. | | | | | | | DO | DN | NA |  |
|  |  | | Expect process managers to validate software before it is used to operate process. | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to validate resources that will be used to automate process. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect process managers to validate tools before they are used to automate process. | | | | | | | DO | DN | NA |  |
|  |  | | Expect process managers to validate equipment before it is used to automate process. | | | | | | | DO | DN | NA |  |
|  |  | | Expect process managers to validate software before it is used to automate process. | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to validate resources that will be used to control process. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect process managers to validate tools before they are used to control process. | | | | | | | DO | DN | NA |  |
|  |  | | Expect process managers to validate equipment before it is used to control process. | | | | | | | DO | DN | NA |  |
|  |  | | Expect process managers to validate software before it is used to control process. | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to validate resources that will be used to monitor process. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect process managers to validate tools before they are used to monitor process. | | | | | | | DO | DN | NA |  |
|  |  | | Expect process managers to validate equipment before it is used to monitor process. | | | | | | | DO | DN | NA |  |
|  |  | | Expect process managers to validate software before it is used to monitor process. | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to validate resources that will be used to measure process. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect process managers to validate tools before they are used to measure process. | | | | | | | DO | DN | NA |  |
|  |  | | Expect process managers to validate equipment before it is used to measure process. | | | | | | | DO | DN | NA |  |
|  |  | | Expect process managers to validate software before it is used to measure process. | | | | | | | DO | DN | NA |  |
|  | Expect process managers to supervise and control all process personnel. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to plan and control all work transfer activities. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to ensure that risks are managed and requirements continue to be met. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to plan how they're going to manage and control the transfer of work. | | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to plan how they're going to transfer work within their own organization. | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to plan how they're going to transfer work to and from external providers. | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to plan how they're going to transfer work between external providers. | | | | | DO | DN | NA |  |
|  | Expect process managers to control process documents and record keeping. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect them to ensure that process documents  and records are properly reviewed and approved. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to ensure that authorized persons have  been identified for each type of document and record. | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to ensure that approval methods have  been identified for each type of document and record. | | | | | | | DO | DN | NA |  |
| 3.2.7 Expect process managers to measure conformance and performance | | | | | | | | | | | | | |
|  | Expect process managers to measure process performance and conformance. | | | | | | | | | DO | DN | NA |  |
|  | Expect process managers to measure output performance and conformance. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect process managers to measure output delivery performance and conformance. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect process managers to measure post-delivery performance and conformance. | | | | | | | DO | DN | NA |  |
| 3.2.8 Expect process managers to meet expectations and requirements | | | | | | | | | | | | | |
|  | Expect process managers to ensure that legal expectations and requirements are being met. | | | | | | | | | DO | DN | NA |  |
|  | Expect process managers to ensure that safety expectations and requirements are being met. | | | | | | | | | DO | DN | NA |  |
|  | Expect process managers to ensure that quality expectations and requirements are being met. | | | | | | | | | DO | DN | NA |  |
|  | Expect process managers to ensure that security expectations and requirements are being met. | | | | | | | | | DO | DN | NA |  |
|  | Expect process managers to ensure that business expectations and requirements are being met. | | | | | | | | | DO | DN | NA |  |
|  | Expect process managers to ensure that customer expectations and requirements are being met. | | | | | | | | | DO | DN | NA |  |
| 3.2.9 Expect process managers to be accountable for their process | | | | | | | | | | | | | |
|  | Expect managers to ensure that process produces intended outputs. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect managers to preserve outputs during process operations. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to figure out how to preserve outputs during process operations. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to consider using suitable identification methods to preserve outputs. | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to consider using suitable packaging methods to preserve outputs. | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to consider using suitable handling methods to preserve outputs. | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to consider using suitable storage methods to preserve outputs. | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to consider using suitable transmission methods to preserve outputs. | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to consider using suitable transportation methods to preserve outputs. | | | | | | DO | DN | NA |  |
|  |  | | Expect them to preserve outputs in accordance with official requirements. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to preserve outputs by establishing cleaning and sanitization practices. | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to preserve outputs by establishing arrangements to control foreign objects. | | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to make arrangements to detect, prevent, and remove foreign objects. | | | | | DO | DN | NA |  |
|  |  | | | | | Expect them to use arrangements to detect, prevent, and remove foreign objects. | | | | DO | DN | NA |  |
|  |  | | | Expect them to preserve outputs by establishing handling methods and storage facilities. | | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to use suitable methods and facilities to preserve sensitive products. | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to use suitable methods and facilities to manage hazardous materials. | | | | | DO | DN | NA |  |
|  |  | | | Expect them to preserve outputs by establishing marking methods and labeling practices. | | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to use safety warnings to preserve outputs during process operations. | | | | | DO | DN | NA |  |
|  |  | | | Expect them to preserve outputs by establishing shelf life controls and by rotating stock. | | | | | | DO | DN | NA |  |
|  | Expect managers to establish controlled conditions for output delivery. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect them to use documented information to control output delivery activities. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to document the characteristics of delivery activities to be provided. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to maintain and control documents defining delivery characteristics. | | | | | | DO | DN | NA |  |
|  |  | | Expect them to document the output delivery results that you expect to achieve. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to maintain and control documents defining expected delivery results. | | | | | | DO | DN | NA |  |
|  |  | Expect them to use suitable monitoring and measurement resources to control delivery. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to verify that output delivery process control criteria have been met. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to verify that your output delivery criteria have been met. | | | | | | DO | DN | NA |  |
|  |  | | Expect them to verify that acceptance criteria for delivery have been met. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to verify acceptance before outputs are released. | | | | | | DO | DN | NA |  |
|  |  | Expect them to use a suitable process environment to control output delivery process. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to use a suitable infrastructure to control output delivery activities. | | | | | | | DO | DN | NA |  |
|  |  | Expect them to use competent qualified personnel to control output delivery activities. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to take action to prevent human error during output delivery activities. | | | | | | | DO | DN | NA |  |
|  | Expect managers to address post-delivery requirements for outputs. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect managers to develop controlled conditions for post-delivery. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to consider post-delivery requirements and commitments. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to identify the activities that must be carried out after outputs are delivered. | | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to consider the output requirements that customers expect them to meet. | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to consider the nature and use of outputs and how long they could last. | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to consider the statutory and regulatory requirements affecting outputs. | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to consider the potential consequences that outputs could produce. | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to consider the feedback their customers provide about outputs. | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to consider the performance and reliability of their outputs. | | | | | DO | DN | NA |  |
|  |  | | | | | Expect them to consider collecting and analyzing in-service data about outputs. | | | | DO | DN | NA |  |
|  |  | | | | | Expect them to consider reviewing the lessons they have learned about outputs. | | | | DO | DN | NA |  |
|  |  | | | | Expect them to consider the technical documentation needed to support outputs. | | | | | DO | DN | NA |  |
|  |  | | Expect them to consider the need to provide, update, and control output documentation. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to consider the documentation needed in order to use their outputs. | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to consider the documentation needed in order to maintain their outputs. | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to consider the documentation needed in order to overhaul their outputs. | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to consider the documentation needed in order to repair their outputs. | | | | | | DO | DN | NA |  |
|  |  | | Expect them to consider the external work that must be done to support outputs. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to consider how external work should be carried out and controlled. | | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to consider the external resources that are needed to support outputs. | | | | | DO | DN | NA |  |
|  |  | | | | | Expect them to consider the agreements that they have made to support outputs. | | | | DO | DN | NA |  |
|  |  | | | | | | Expect them to consider the output warranty commitments that they have made. | | | DO | DN | NA |  |
|  |  | | | | | | | Expect them to consider the need to provide replacement parts and components. | | DO | DN | NA |  |
|  |  | | | | | | | Expect them to consider how, why, and when output will become obsolete. | | DO | DN | NA |  |
|  |  | | | | | | Expect them to consider the services that must be provided to support outputs. | | | DO | DN | NA |  |
|  |  | | | | | | | Expect them to consider the training that must be delivered to support outputs. | | DO | DN | NA |  |
|  |  | | | | | | | | Expect them to consider the follow-up queries that must be handled. | DO | DN | NA |  |
|  |  | | | | | | | Expect them to consider the maintenance that must be done to support outputs. | | DO | DN | NA |  |
|  |  | | | | | | | Expect them to consider the disposal services that must be provided. | | DO | DN | NA |  |
|  |  | | | | | | | | Expect them to consider the recycling services that must be provided. | DO | DN | NA |  |
|  |  | | Expect them to consider the actions that must be taken after outputs are delivered. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to consider the steps that must be taken when problems are detected. | | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to consider the investigations that must be carried out. | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to consider the reporting that must be carried out. | | | | | DO | DN | NA |  |
|  |  | Expect managers to implement controlled conditions for post-delivery of outputs. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to implement controlled conditions for post-delivery of process outputs. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to use documented information to control post-delivery activities. | | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to document characteristics of post-delivery activities to be provided. | | | | | DO | DN | NA |  |
|  |  | | | | | Expect them to maintain and control documents defining post-delivery characteristics. | | | | DO | DN | NA |  |
|  |  | | | Expect them to document the post-delivery results that they expect to achieve. | | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to maintain and control documents defining expected post-delivery results. | | | | | DO | DN | NA |  |
|  |  | | Expect them to use suitable monitoring and measurement resources to control post-delivery. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to verify that post-delivery process control criteria have been met. | | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to verify that post-delivery output criteria have been met. | | | | | DO | DN | NA |  |
|  |  | | | Expect them to verify that acceptance criteria for post-delivery have been met. | | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to verify acceptance before post-delivery outputs are released. | | | | | DO | DN | NA |  |
|  |  | | Expect them to use a suitable process environment to control post-delivery activities. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to use a suitable infrastructure to control post-delivery activities. | | | | | | DO | DN | NA |  |
|  |  | | Expect them to use competent qualified personnel to control post-delivery activities. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to take action to prevent human error during post-delivery activities. | | | | | | DO | DN | NA |  |
|  | Expect managers to identify and control nonconforming outputs. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect managers to evaluate nonconforming outputs. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to consider the nature of nonconforming output and to evaluate its effect. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to consider suspending or delaying the provision of products or services. | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to consider correcting, containing, or segregating nonconforming outputs. | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to consider scrapping, discarding, or destroying nonconforming outputs. | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to consider getting authorization to accept outputs under concession. | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to consider telling customers about your nonconforming outputs. | | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to consider asking for the return of nonconforming products. | | | | | DO | DN | NA |  |
|  |  | Expect managers to take action to control nonconforming outputs. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to prevent the unintended use or delivery of nonconforming outputs. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to control nonconforming outputs that occur before outputs are delivered. | | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to control nonconforming outputs by correcting or containing them. | | | | | DO | DN | NA |  |
|  |  | | | | | Expect them to verify conformity whenever nonconforming outputs are corrected. | | | | DO | DN | NA |  |
|  |  | | | | Expect them to control nonconforming outputs by getting approval to accept them. | | | | | DO | DN | NA |  |
|  |  | | | | | Expect them to get authorization from the customer or relevant authority. | | | | DO | DN | NA |  |
|  |  | | | | | | Expect them to accept the repair or use-as-is of nonconforming outputs  only after approval has been received from an authorized representative  of the organization responsible for designing the output and only after  the customer has authorized acceptance. | | | DO | DN | NA |  |
|  |  | | | | | | | Expect managers to ask the customer to accept the nonconformity whenever it results in a departure from contractual requirements. | | DO | DN | NA |  |
|  |  | | | | Expect them to control nonconforming outputs by scrapping or destroying them. | | | | | DO | DN | NA |  |
|  |  | | | | | Expect them to control nonconforming outputs that are “dispositioned for scrap”. | | | | DO | DN | NA |  |
|  |  | | | | | | Expect them to control scrapped outputs until they’re made physically unusable. | | | DO | DN | NA |  |
|  |  | | | | | | | Expect them to use output markings that are permanent and conspicuous. | | DO | DN | NA |  |
|  |  | | | | | Expect them to control nonconforming outputs that are or could be counterfeit. | | | | DO | DN | NA |  |
|  |  | | | | | | Expect them to prevent counterfeit parts from reentering the supply chain. | | | DO | DN | NA |  |
|  |  | | | Expect them to control nonconforming outputs that occur during output delivery. | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to control nonconforming outputs that occur after output delivery. | | | | | | DO | DN | NA |  |
|  |  | Expect managers to document nonconforming process outputs. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect managers to document the actions and decisions taken to  prevent the unintended use or delivery of nonconforming outputs. | | | | | | | DO | DN | NA |  |
|  |  | | | Expect them to identify the people who make the decisions and who  authorize remedial action (including any concessions that are obtained). | | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to retain documents describing nonconforming outputs and actions. | | | | | DO | DN | NA |  |
|  |  | | | | Expect them to control documents describing nonconforming outputs and actions. | | | | | DO | DN | NA |  |
|  | Expect managers to submit process performance reports. | | | | | | | | | DO | DN | NA |  |
| 3.3 EXPECT PERSONNEL TO CARRY OUT PROCESS OPERATIONS | | | | | | | | | | | | | |
| 3.3.1 Expect personnel to focus on process customers | | | | | | | | | | | | | |
|  | Expect personnel to identify customer needs and expectations. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect personnel to identify customer assumptions and perceptions. | | | | | | | | DO | DN | NA |  |
|  | Expect personnel to understand customer needs and expectations. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect personnel to understand customer assumptions and perceptions. | | | | | | | | DO | DN | NA |  |
|  | Expect personnel to meet relevant customer needs and expectations. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect personnel to focus on enhancing customer satisfaction. | | | | | | | | DO | DN | NA |  |
| 3.3.2 Expect personnel to handle risks and opportunities | | | | | | | | | | | | | |
|  | Expect personnel to identify their risks and opportunities. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect personnel to identify risks and opportunities related to outputs. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify the risks that could negatively influence  their ability to provide compliant outputs to process customers. | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify the opportunities that could possibly enhance  their ability to provide compliant outputs to process customers. | | | | | | | DO | DN | NA |  |
|  |  | Expect personnel to identify risks and opportunities related to customer satisfaction. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify risks that could influence their ability to satisfy customers. | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify opportunities that could enhance their ability to satisfy customers. | | | | | | | DO | DN | NA |  |
|  | Expect personnel to address their risks and opportunities. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect personnel to address risks and opportunities related to outputs. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to address the risks that could negatively influence  their ability to provide compliant outputs to process customers. | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to address the opportunities that could enhance  their ability to provide compliant outputs to process customers. | | | | | | | DO | DN | NA |  |
|  |  | Expect personnel to address risks and opportunities related to customer satisfaction. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to address risks that could influence their ability to satisfy customers. | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to address opportunities that could enhance their ability to satisfy customers. | | | | | | | DO | DN | NA |  |
| 3.3.3 Expect personnel to implement policies and procedures | | | | | | | | | | | | | |
|  | Expect personnel to apply process policies. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect them to apply safety policies. | | | | | | | | DO | DN | NA |  |
|  |  | Expect them to apply quality policies. | | | | | | | | DO | DN | NA |  |
|  |  | Expect them to apply security policies. | | | | | | | | DO | DN | NA |  |
|  |  | Expect them to apply business policies. | | | | | | | | DO | DN | NA |  |
|  |  | Expect them to apply continuity policies. | | | | | | | | DO | DN | NA |  |
|  |  | Expect them to apply environmental policies. | | | | | | | | DO | DN | NA |  |
|  | Expect personnel to apply process procedures. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect them to apply safety procedures. | | | | | | | | DO | DN | NA |  |
|  |  | Expect them to apply quality procedures. | | | | | | | | DO | DN | NA |  |
|  |  | Expect them to apply security procedures. | | | | | | | | DO | DN | NA |  |
|  |  | Expect them to apply business procedures. | | | | | | | | DO | DN | NA |  |
|  |  | Expect them to apply continuity procedures. | | | | | | | | DO | DN | NA |  |
|  |  | Expect them to apply environmental procedures. | | | | | | | | DO | DN | NA |  |
| 3.3.4 Expect personnel to comply with all relevant requirements | | | | | | | | | | | | | |
|  | Expect personnel to determine relevant requirements. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect them to identify customer requirements. | | | | | | | | DO | DN | NA |  |
|  |  | Expect them to identify legal requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify statutory requirements. | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify regulatory requirements. | | | | | | | DO | DN | NA |  |
|  | Expect personnel to meet all relevant requirements. | | | | | | | | | DO | DN | NA |  |
|  |  | Expect them to meet customer requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to provide products that meet customer requirements. | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to deliver services that meet customer requirements. | | | | | | | DO | DN | NA |  |
|  |  | Expect them to meet legal requirements. | | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to provide products that meet legal requirements. | | | | | | | DO | DN | NA |  |
|  |  | | Expect them to deliver services that meet legal requirements. | | | | | | | DO | DN | NA |  |
| 3.3.5 Expect personnel to take appropriate action when necessary | | | | | | | | | | | | | |
|  | Expect personnel to take action when planned results aren't being achieved. | | | | | | | | | DO | DN | NA |  |
|  | Expect personnel to take action when planned results won't be achieved. | | | | | | | | | DO | DN | NA |  |
| 3.3.6 Expect personnel to control process documents and records | | | | | | | | | | | | | |
|  | Expect personnel to retain and control process documents. | | | | | | | | | DO | DN | NA |  |
|  | Expect personnel to maintain and control process records. | | | | | | | | | DO | DN | NA |  |
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| Consider each task and select a response. If you haven’t done it and it needs to be done, select DO. If you’ve already done it, select DN. If the task is not applicable in your situation and you can justify and explain why it should be ignored or excluded, select NA.  In the spaces below, please enter the name and location of your organization, who completed this page, who reviewed it, and the dates. | | | | | | | | | | | | | |

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| 4.1 PROVIDE THE RESOURCES NEEDED TO MAINTAIN PROCESS | | | | | | | | | | | | |
| 4.1.1 Provide the expertise needed to maintain your process | | | | | | | | | | | | |
|  | Provide the managers needed to maintain your process. | | | | | | | | DO | DN | NA |  |
|  |  | Acquire the knowledge that managers need in order to  support process maintenance and achieve conformity of outputs. | | | | | | | DO | DN | NA |  |
|  |  | | Consider internal sources of knowledge about managing process maintenance. | | | | | | DO | DN | NA |  |
|  |  | | Consider external sources of knowledge about managing process maintenance. | | | | | | DO | DN | NA |  |
|  |  | Share the knowledge that managers need so that they can  support process maintenance and achieve conformity of outputs. | | | | | | | DO | DN | NA |  |
|  |  | | Deliver suitable training and awareness programmes to  the people that manage process maintenance activities. | | | | | | DO | DN | NA |  |
|  | Provide the personnel needed to maintain your process. | | | | | | | | DO | DN | NA |  |
|  |  | Acquire the knowledge that personnel need in order  to maintain process and achieve conformity of outputs. | | | | | | | DO | DN | NA |  |
|  |  | | Consider internal sources of knowledge about process maintenance. | | | | | | DO | DN | NA |  |
|  |  | | Consider external sources of knowledge about process maintenance. | | | | | | DO | DN | NA |  |
|  |  | Share the knowledge that personnel need in order to  maintain process and achieve conformity of outputs. | | | | | | | DO | DN | NA |  |
|  |  | | Deliver suitable training and awareness programmes  for your process maintenance personnel. | | | | | | DO | DN | NA |  |
| 4.1.2 Provide the technology needed to maintain your process | | | | | | | | | | | | |
|  | Provide the software needed to maintain your process. | | | | | | | | DO | DN | NA |  |
|  |  | Provide the software needed to support process  maintenance and achieve conformity of outputs. | | | | | | | DO | DN | NA |  |
|  | Provide the hardware needed to maintain your process. | | | | | | | | DO | DN | NA |  |
|  |  | Provide the hardware needed to support process  maintenance and achieve conformity of outputs. | | | | | | | DO | DN | NA |  |
| 4.1.3 Provide the infrastructure needed to maintain your process | | | | | | | | | | | | |
|  | Provide the infrastructure needed to support process  maintenance and achieve conformity of outputs. | | | | | | | | DO | DN | NA |  |
| 4.2 USE AUTHORIZED METHODS TO MAINTAIN YOUR PROCESS | | | | | | | | | | | | |
| 4.2.1 Use authorized methods to maintain process documents | | | | | | | | | | | | |
|  | Maintain documents that describe how your process should be carried out. | | | | | | | | DO | DN | NA |  |
|  |  | Maintain documents that show how process operations should be carried out. | | | | | | | DO | DN | NA |  |
|  |  | Maintain documents that show how process maintenance should be carried out. | | | | | | | DO | DN | NA |  |
|  |  | Maintain documents that show how process monitoring should be carried out. | | | | | | | DO | DN | NA |  |
|  |  | Maintain documents that show how process measurement should be carried out. | | | | | | | DO | DN | NA |  |
|  |  | Maintain documents that show how process control should be carried out. | | | | | | | DO | DN | NA |  |
|  |  | Maintain documents that show how process evaluation should be carried out. | | | | | | | DO | DN | NA |  |
|  |  | | Maintain documents that show how process audits should be carried out. | | | | | | DO | DN | NA |  |
|  |  | | Maintain documents that show how process reviews should be carried out. | | | | | | DO | DN | NA |  |
|  |  | Maintain documents that show how process modification should be carried out. | | | | | | | DO | DN | NA |  |
|  |  | | Maintain documents that show how process correction should be carried out. | | | | | | DO | DN | NA |  |
|  |  | | Maintain documents that show how process improvement should be carried out. | | | | | | DO | DN | NA |  |
| 4.2.2 Use authorized methods to maintain process records | | | | | | | | | | | | |
|  | Maintain a record that describes the scope of your process. | | | | | | | | DO | DN | NA |  |
|  | Maintain a record of process responsibilities and authorities. | | | | | | | | DO | DN | NA |  |
|  | Maintain a record of personnel performance and competence. | | | | | | | | DO | DN | NA |  |
|  |  | Retain your documentation and use it as evidence to show  that your process personnel are in fact competent. | | | | | | | DO | DN | NA |  |
|  | Maintain a record showing that process is performing as planned. | | | | | | | | DO | DN | NA |  |
|  |  | Maintain records that show that process operations are being carried out as planned. | | | | | | | DO | DN | NA |  |
|  |  | Maintain records that show that process maintenance is being carried out as planned. | | | | | | | DO | DN | NA |  |
|  |  | Maintain records that show that process monitoring is being carried out as planned. | | | | | | | DO | DN | NA |  |
|  |  | Maintain records that show that process measurement is being carried out as planned. | | | | | | | DO | DN | NA |  |
|  |  | Maintain records that show that process control is being carried out as planned. | | | | | | | DO | DN | NA |  |
|  |  | Maintain records that show that process evaluation is being carried out as planned. | | | | | | | DO | DN | NA |  |
|  |  | | Maintain records that show that process audits are being carried out as planned. | | | | | | DO | DN | NA |  |
|  |  | | Maintain records that show that process reviews are being carried out as planned. | | | | | | DO | DN | NA |  |
|  |  | Maintain records that show that process modification is being carried out as planned. | | | | | | | DO | DN | NA |  |
|  |  | | Maintain records that show that process corrections are being carried out as planned. | | | | | | DO | DN | NA |  |
|  |  | | Maintain records that show that process improvements are being carried out as planned. | | | | | | DO | DN | NA |  |
| 4.2.3 Use authorized methods to maintain process property | | | | | | | | | | | | |
|  | Maintain process property owned by your customers and  suppliers that is needed to achieve conformity of outputs. | | | | | | | | DO | DN | NA |  |
|  |  | Identify property belonging to customers and external providers. | | | | | | | DO | DN | NA |  |
|  |  | Verify property belonging to customers and external providers. | | | | | | | DO | DN | NA |  |
|  |  | Protect property belonging to customers and external providers. | | | | | | | DO | DN | NA |  |
|  |  | | Be careful with other people's property while it is being  used by your organization or while it is under its control. | | | | | | DO | DN | NA |  |
|  |  | | | Safeguard other people's property whenever your  process intends to use or incorporate it into its outputs. | | | | | DO | DN | NA |  |
|  |  | Report property belonging to your customers and external providers. | | | | | | | DO | DN | NA |  |
|  |  | | Report lost or damaged property to customers and external providers. | | | | | | DO | DN | NA |  |
|  |  | | Report unsuitable property to customers and external providers. | | | | | | DO | DN | NA |  |
|  |  | Document property belonging to your customers and external providers. | | | | | | | DO | DN | NA |  |
|  |  | | Document the status of external property that is lost, damaged, or unsuitable. | | | | | | DO | DN | NA |  |
|  |  | | | Control and retain records documenting lost, damaged, or unsuitable property. | | | | | DO | DN | NA |  |
|  | Maintain process property owned by your process that  is needed to achieve conformity of process outputs. | | | | | | | | DO | DN | NA |  |
|  |  | Maintain equipment that your process needs in order to achieve conformity of outputs. | | | | | | | DO | DN | NA |  |
|  |  | Maintain software that your process needs in order to achieve conformity of outputs. | | | | | | | DO | DN | NA |  |
|  |  | Maintain tools that your process needs in order to achieve conformity of outputs. | | | | | | | DO | DN | NA |  |
| 4.2.4 Use authorized methods to maintain process procedures | | | | | | | | | | | | |
|  | Use authorized methods to maintain process management procedures. | | | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to maintain process control procedures. | | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to maintain process operation procedures. | | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to maintain process maintenance procedures. | | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to maintain process monitoring procedures. | | | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to maintain process feedback procedures. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to maintain process measurement procedures. | | | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to maintain equipment calibration procedures. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to maintain process evaluation procedures. | | | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to maintain process audit procedures. | | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to maintain process review procedures. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to maintain process modification procedures. | | | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to maintain process correction procedures. | | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to maintain process improvement procedures. | | | | | | DO | DN | NA |  |
| 4.2.5 Use authorized methods to maintain process programmes | | | | | | | | | | | | |
|  | Use authorized methods to maintain process management programmes. | | | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to maintain risk management programme. | | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to maintain safety management programme. | | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to maintain quality management programme. | | | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to maintain configuration management programme. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to maintain security management programme. | | | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to maintain personnel security management programme. | | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to maintain information security management programme. | | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to maintain component security management programme. | | | | | | DO | DN | NA |  |
|  |  | | | Use authorized methods to maintain counterfeit parts management programme. | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to maintain supplier management programme. | | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to maintain environmental management programme. | | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to maintain business continuity management programme. | | | | | | | DO | DN | NA |  |
| 4.2.6 Use authorized methods to maintain process competence | | | | | | | | | | | | |
|  | Share information and knowledge with process personnel. | | | | | | | | DO | DN | NA |  |
|  |  | Make sure that they are aware of process policies. | | | | | | | DO | DN | NA |  |
|  |  | Make sure that they are aware of process objectives. | | | | | | | DO | DN | NA |  |
|  |  | Make sure that they are aware of process procedures. | | | | | | | DO | DN | NA |  |
|  |  | Make sure that they are aware of process documents and records. | | | | | | | DO | DN | NA |  |
|  |  | | Make sure that personnel stay abreast of all relevant changes. | | | | | | DO | DN | NA |  |
|  |  | Make sure that they are aware of the contribution they make. | | | | | | | DO | DN | NA |  |
|  |  | | Make sure that they understand how they affect process performance. | | | | | | DO | DN | NA |  |
|  |  | | Make sure that they understand how they influence process outputs. | | | | | | DO | DN | NA |  |
|  |  | | | Make sure that they understand how they affect output quality. | | | | | DO | DN | NA |  |
|  |  | | | Make sure that they understand how they affect output safety. | | | | | DO | DN | NA |  |
|  |  | | | Make sure that they understand how they affect output security. | | | | | DO | DN | NA |  |
|  |  | Make sure that they are aware of all relevant requirements. | | | | | | | DO | DN | NA |  |
|  |  | | Explain why compliance is important to your process. | | | | | | DO | DN | NA |  |
|  |  | | | Explain why they need to meet all relevant requirements. | | | | | DO | DN | NA |  |
|  |  | | | | Explain why they need to meet all output requirements. | | | | DO | DN | NA |  |
|  |  | | | | Explain why they need to meet all process requirements. | | | | DO | DN | NA |  |
|  |  | Make sure that they are aware of how they can help. | | | | | | | DO | DN | NA |  |
|  |  | | Explain how they can help enhance process effectiveness. | | | | | | DO | DN | NA |  |
|  |  | | | Explain why it's important to improve process performance. | | | | | DO | DN | NA |  |
|  | Acquire competence whenever shortcomings are discovered. | | | | | | | | DO | DN | NA |  |
|  |  | Acquire the necessary competence whenever process  personnel fail to meet process competence requirements. | | | | | | | DO | DN | NA |  |
|  |  | | Consider helping your personnel to improve. | | | | | | DO | DN | NA |  |
|  |  | | | Consider providing suitable training. | | | | | DO | DN | NA |  |
|  |  | | | Consider offering mentoring services. | | | | | DO | DN | NA |  |
|  |  | | Consider hiring competent people. | | | | | | DO | DN | NA |  |
|  |  | | | Consider hiring competent employees. | | | | | DO | DN | NA |  |
|  |  | | | Consider hiring competent contractors. | | | | | DO | DN | NA |  |
|  |  | | Consider reassigning unsuitable personnel. | | | | | | DO | DN | NA |  |
|  | Maintain the process knowledge that has been acquired. | | | | | | | | DO | DN | NA |  |
|  |  | Consider the need to protect and preserve lessons learned. | | | | | | | DO | DN | NA |  |
|  |  | Consider the need to protect and preserve intellectual property. | | | | | | | DO | DN | NA |  |
| 4.2.7 Use authorized methods to maintain process technologies | | | | | | | | | | | | |
|  | Maintain technology used to perform process operations. | | | | | | | | DO | DN | NA |  |
|  |  | Maintain tools used to perform process operations. | | | | | | | DO | DN | NA |  |
|  |  | | Define storage requirements for tools used for process operations. | | | | | | DO | DN | NA |  |
|  |  | | | Define how and when to check the status of tools used for process operations. | | | | | DO | DN | NA |  |
|  |  | Maintain equipment used to perform process operations. | | | | | | | DO | DN | NA |  |
|  |  | | Define storage requirements for equipment used for process operations. | | | | | | DO | DN | NA |  |
|  |  | | | Define how and when to check the status of equipment used for process operations. | | | | | DO | DN | NA |  |
|  |  | Maintain software used to perform process operations. | | | | | | | DO | DN | NA |  |
|  |  | | Define how and when to check the status of software used for process operations. | | | | | | DO | DN | NA |  |
|  | Maintain technology used to automate process operations. | | | | | | | | DO | DN | NA |  |
|  |  | Maintain tools used to automate process operations. | | | | | | | DO | DN | NA |  |
|  |  | | Define storage requirements for tools used to automate process operations. | | | | | | DO | DN | NA |  |
|  |  | | | Define how and when to check the status of tools used to automate process operations. | | | | | DO | DN | NA |  |
|  |  | Maintain equipment used to automate process operations. | | | | | | | DO | DN | NA |  |
|  |  | | Define storage requirements for equipment used to automate process operations. | | | | | | DO | DN | NA |  |
|  |  | | | Define how and when to check the status of equipment used for automation. | | | | | DO | DN | NA |  |
|  |  | Maintain software used to automate process operations. | | | | | | | DO | DN | NA |  |
|  |  | | Define how and when to check the status of software used for automation. | | | | | | DO | DN | NA |  |
|  | Maintain technology used to control process operations. | | | | | | | | DO | DN | NA |  |
|  |  | Maintain tools used to control process operations. | | | | | | | DO | DN | NA |  |
|  |  | | Define storage requirements for tools used to control process operations. | | | | | | DO | DN | NA |  |
|  |  | | | Define how and when to check the status of tools used to control process operations. | | | | | DO | DN | NA |  |
|  |  | Maintain equipment used to control process operations. | | | | | | | DO | DN | NA |  |
|  |  | | Define storage requirements for equipment used to control process operations. | | | | | | DO | DN | NA |  |
|  |  | | | Define how and when to check the status of process control equipment. | | | | | DO | DN | NA |  |
|  |  | Maintain software used to control process operations. | | | | | | | DO | DN | NA |  |
|  |  | | Define how and when to check the status of software used to control process operations. | | | | | | DO | DN | NA |  |
|  | Maintain technology used to monitor process operations. | | | | | | | | DO | DN | NA |  |
|  |  | Maintain tools used to monitor process operations. | | | | | | | DO | DN | NA |  |
|  |  | | Define storage requirements for tools used to monitor process operations. | | | | | | DO | DN | NA |  |
|  |  | | | Define how and when to check the status of tools used to monitor process operations. | | | | | DO | DN | NA |  |
|  |  | Maintain equipment used to monitor process operations. | | | | | | | DO | DN | NA |  |
|  |  | | Define storage requirements for equipment used to monitor process operations. | | | | | | DO | DN | NA |  |
|  |  | | | Define how and when to check the status of process monitoring equipment. | | | | | DO | DN | NA |  |
|  |  | Maintain software used to monitor process operations. | | | | | | | DO | DN | NA |  |
|  |  | | Define how and when to check the status of software used to monitor process operations. | | | | | | DO | DN | NA |  |
|  | Maintain technology used to measure process operations. | | | | | | | | DO | DN | NA |  |
|  |  | Maintain software used to measure process operations. | | | | | | | DO | DN | NA |  |
|  |  | | Define how and when to check the status of software used to measure process operations. | | | | | | DO | DN | NA |  |
|  |  | Maintain tools used to measure process operations. | | | | | | | DO | DN | NA |  |
|  |  | | Define storage requirements for tools used to measure process operations. | | | | | | DO | DN | NA |  |
|  |  | | | Define how and when to check the status of tools used to measure process operations. | | | | | DO | DN | NA |  |
|  |  | Maintain equipment used to measure process operations. | | | | | | | DO | DN | NA |  |
|  |  | | Define storage requirements for equipment used to measure process operations. | | | | | | DO | DN | NA |  |
|  |  | | | Define how and when to check the status of process measuring equipment. | | | | | DO | DN | NA |  |
|  |  | | Establish an identification system for measurement equipment. | | | | | | DO | DN | NA |  |
|  |  | | | Use it to ensure that your equipment calibration status is always clear. | | | | | DO | DN | NA |  |
|  |  | | Verify or calibrate your process measurement equipment. | | | | | | DO | DN | NA |  |
|  |  | | | Verify or calibrate equipment under suitable conditions. | | | | | DO | DN | NA |  |
|  |  | | | | Verify or calibrate your equipment at planned intervals or prior to use. | | | | DO | DN | NA |  |
|  |  | | | | | Verify or calibrate your equipment against measurement standards  that are traceable to national or international measurement standards. | | | DO | DN | NA |  |
|  |  | | | | | | Document your verification and calibration methods whenever  national or international measurement standards do not exist. | | DO | DN | NA |  |
|  |  | | | | | | | Control your verification and calibration documents. | DO | DN | NA |  |
|  |  | | | | | | | Retain your verification and calibration documents. | DO | DN | NA |  |
|  |  | | Safeguard your process measurement equipment. | | | | | | DO | DN | NA |  |
|  |  | | | Protect your calibration status and measurement results. | | | | | DO | DN | NA |  |
|  |  | | | | Protect measurement equipment from damage or deterioration. | | | | DO | DN | NA |  |
|  |  | | | | Protect measurement equipment from unauthorized adjustment. | | | | DO | DN | NA |  |
|  |  | | | Evaluate the validity of previous measurement results whenever you  discover that measurement equipment is unfit for its intended purpose. | | | | | DO | DN | NA |  |
|  |  | | | | Take corrective action whenever you discover that your  measurement equipment is unfit for its intended purpose. | | | | DO | DN | NA |  |
| 4.2.8 Use authorized methods to maintain process infrastructure | | | | | | | | | | | | |
|  | Maintain the infrastructure that your process needs in order to achieve conformity of outputs. | | | | | | | | DO | DN | NA |  |
|  |  | Maintain the facilities that your process needs in order to achieve conformity of outputs. | | | | | | | DO | DN | NA |  |
|  |  | Maintain the utilities that your process needs in order to achieve conformity of outputs. | | | | | | | DO | DN | NA |  |
|  |  | Maintain the services that your process needs in order to achieve conformity of outputs. | | | | | | | DO | DN | NA |  |
|  |  | Maintain the technologies that your process needs in order to achieve conformity of outputs. | | | | | | | DO | DN | NA |  |
|  |  | | Maintain the hardware that your process needs in order to achieve conformity of outputs. | | | | | | DO | DN | NA |  |
|  |  | | Maintain the software that your process needs in order to achieve conformity of outputs. | | | | | | DO | DN | NA |  |
| 4.2.9 Use authorized methods to maintain process communications | | | | | | | | | | | | |
|  | Use authorized methods to maintain internal process communications. | | | | | | | | DO | DN | NA |  |
|  | Use authorized methods to maintain external process communications. | | | | | | | | DO | DN | NA |  |
|  | | | | | | | | | | | | |
|  | | | | | | | | | | | | |
|  | | | | | | | | | | | | |
|  | | | | | | | | | | | | |
| Consider each task and select a response. If you haven’t done it and it needs to be done, select DO. If you’ve already done it, select DN. If the task is not applicable in your situation and you can justify and explain why it should be ignored or excluded, select NA.  In the spaces below, please enter the name and location of your organization, who completed this page, who reviewed it, and the dates. | | | | | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 5.1 PLAN HOW YOU'RE GOING TO MEASURE YOUR PROCESS | | | | | | | | | | | |
| 5.1.1 Figure out what needs to be measured | | | | | | | | | | | |
|  | Figure out what kind of process activities need to be measured. | | | | | | | DO | DN | NA |  |
|  |  | Figure out what kind of process characteristics need to be measured. | | | | | | DO | DN | NA |  |
|  | Figure out what kind of inputs and outputs need to be measured. | | | | | | | DO | DN | NA |  |
|  |  | Figure out what kind of output characteristics need to be measured. | | | | | | DO | DN | NA |  |
|  |  | Figure out what kind of input characteristics need to be measured. | | | | | | DO | DN | NA |  |
| 5.1.2 Figure out how measurements will be done | | | | | | | | | | | |
|  | Plan how you're going to measure process elements. | | | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to measure your process outputs. | | | | | | DO | DN | NA |  |
|  |  | | Plan how you're going to measure your outputs against expectations. | | | | | DO | DN | NA |  |
|  |  | | | Plan how you're going to measure how well outputs implement plans. | | | | DO | DN | NA |  |
|  |  | | | Plan how you're going to measure how well outputs achieve objectives. | | | | DO | DN | NA |  |
|  |  | | | Plan how you're going to measure how well outputs meet requirements. | | | | DO | DN | NA |  |
|  |  | | | Plan how you're going to measure how well outputs comply with policies. | | | | DO | DN | NA |  |
|  |  | Plan how you're going to measure your process inputs. | | | | | | DO | DN | NA |  |
|  |  | | Plan how you're going to measure your inputs against expectations. | | | | | DO | DN | NA |  |
|  |  | | | Plan how you're going to measure how well inputs implement plans. | | | | DO | DN | NA |  |
|  |  | | | Plan how you're going to measure how well inputs achieve objectives. | | | | DO | DN | NA |  |
|  |  | | | Plan how you're going to measure how well inputs meet requirements. | | | | DO | DN | NA |  |
|  |  | | | Plan how you're going to measure how well inputs comply with policies. | | | | DO | DN | NA |  |
|  |  | Plan how you're going to measure your process activities. | | | | | | DO | DN | NA |  |
|  |  | | Plan how you're going to measure process management activities. | | | | | DO | DN | NA |  |
|  |  | | | Plan how to measure how well process management activities meet expectations. | | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process management activities apply policies. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process management activities implement plans. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process management activities follow procedures. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process management activities achieve objectives. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process management activities comply with requirements. | | | DO | DN | NA |  |
|  |  | | Plan how you're going to measure process operating activities. | | | | | DO | DN | NA |  |
|  |  | | | Plan how to measure how well process operating activities meet expectations. | | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process operating activities apply policies. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process operating activities implement plans. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process operating activities follow procedures. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process operating activities achieve objectives. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process operating activities comply with requirements. | | | DO | DN | NA |  |
|  |  | | Plan how you're going to measure process maintenance activities. | | | | | DO | DN | NA |  |
|  |  | | | Plan how to measure how well process maintenance activities meet expectations. | | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process maintenance activities apply policies. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process maintenance activities implement plans. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process maintenance activities follow procedures. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process maintenance activities achieve objectives. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process maintenance activities comply with requirements. | | | DO | DN | NA |  |
|  |  | | Plan how you're going to measure process monitoring activities. | | | | | DO | DN | NA |  |
|  |  | | | Plan how to measure how well process monitoring activities meet expectations. | | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process monitoring activities apply policies. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process monitoring activities implement plans. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process monitoring activities follow procedures. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process monitoring activities achieve objectives. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process monitoring activities comply with requirements. | | | DO | DN | NA |  |
|  |  | | Plan how you're going to measure process measurement activities. | | | | | DO | DN | NA |  |
|  |  | | | Plan how to measure how well process measurement activities meet expectations. | | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process measurement activities apply policies. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process measurement activities implement plans. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process measurement activities follow procedures. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process measurement activities achieve objectives. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process measurement activities comply with requirements. | | | DO | DN | NA |  |
|  |  | | Plan how you're going to measure process control activities. | | | | | DO | DN | NA |  |
|  |  | | | Plan how to measure how well process control activities meet expectations. | | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process control activities apply policies. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process control activities implement plans. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process control activities follow procedures. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process control activities achieve objectives. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process control activities comply with requirements. | | | DO | DN | NA |  |
|  |  | | Plan how you're going to measure process evaluation activities. | | | | | DO | DN | NA |  |
|  |  | | | Plan how you're going to measure process audit activities. | | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process audit activities meet expectations. | | | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well process audit activities apply policies. | | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well process audit activities implement plans. | | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well process audit activities follow procedures. | | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well process audit activities achieve objectives. | | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well process audit activities comply with requirements. | | DO | DN | NA |  |
|  |  | | | Plan how you're going to measure process review activities. | | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process review activities meet expectations. | | | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well process review activities apply policies. | | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well process review activities implement plans. | | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well process review activities follow procedures. | | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well process review activities achieve objectives. | | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well process review activities comply with requirements. | | DO | DN | NA |  |
|  |  | | Plan how you're going to measure process modification activities. | | | | | DO | DN | NA |  |
|  |  | | | Plan how you're going to measure process correction activities. | | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process correction activities meet expectations. | | | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well process correction activities apply policies. | | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well process correction activities implement plans. | | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well process correction activities follow procedures. | | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well process correction activities achieve objectives. | | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well process correction activities comply with requirements. | | DO | DN | NA |  |
|  |  | | | Plan how you're going to measure process improvement activities. | | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well process improvement activities meet expectations. | | | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well process improvement activities apply policies. | | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well process improvement activities implement plans. | | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well process improvement activities follow procedures. | | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well process improvement activities achieve objectives. | | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well process improvement activities comply with requirements. | | DO | DN | NA |  |
|  | Plan how you're going to measure customer satisfaction. | | | | | | | DO | DN | NA |  |
|  |  | Learn how your process customers feel about your process outputs. | | | | | | DO | DN | NA |  |
|  |  | | Figure out how to gather information about customer satisfaction. | | | | | DO | DN | NA |  |
|  |  | | | Figure out how to learn about customer satisfaction by doing customer surveys. | | | | DO | DN | NA |  |
|  |  | | | Figure out how to learn about customer satisfaction by using face-to-face meetings. | | | | DO | DN | NA |  |
|  |  | | | Figure out how to learn about customer satisfaction by studying customer feedback. | | | | DO | DN | NA |  |
|  |  | | Figure out how to use information to evaluate customer satisfaction. | | | | | DO | DN | NA |  |
|  |  | | | Figure out how to use output information to evaluate customer satisfaction. | | | | DO | DN | NA |  |
|  |  | | | Figure out how to use delivery information to evaluate customer satisfaction. | | | | DO | DN | NA |  |
|  |  | | | Figure out how to use post-delivery information to evaluate customer satisfaction. | | | | DO | DN | NA |  |
|  |  | | | Figure out how to use corrective action information to evaluate customer satisfaction. | | | | DO | DN | NA |  |
| 5.1.3 Figure out who will perform measurement tasks | | | | | | | | | | | |
|  | Allocate responsibility and authority for measuring customer satisfaction. | | | | | | | DO | DN | NA |  |
|  |  | Allocate responsibility and authority for carrying out customer surveys. | | | | | | DO | DN | NA |  |
|  |  | Allocate responsibility and authority for meeting with process customers. | | | | | | DO | DN | NA |  |
|  |  | Allocate responsibility and authority for studying feedback from customers. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for measuring process elements. | | | | | | | DO | DN | NA |  |
|  |  | Allocate responsibility and authority for measuring process outputs. | | | | | | DO | DN | NA |  |
|  |  | Allocate responsibility and authority for measuring process inputs. | | | | | | DO | DN | NA |  |
|  |  | Allocate responsibility and authority for measuring process activities. | | | | | | DO | DN | NA |  |
|  |  | | Allocate responsibility and authority for measuring process control activities and results. | | | | | DO | DN | NA |  |
|  |  | | Allocate responsibility and authority for measuring process operating activities and results. | | | | | DO | DN | NA |  |
|  |  | | Allocate responsibility and authority for measuring process maintenance activities and results. | | | | | DO | DN | NA |  |
|  |  | | Allocate responsibility and authority for measuring process measurement activities and results. | | | | | DO | DN | NA |  |
|  |  | | Allocate responsibility and authority for measuring process monitoring activities and results. | | | | | DO | DN | NA |  |
|  |  | | Allocate responsibility and authority for measuring process evaluation activities and results. | | | | | DO | DN | NA |  |
|  |  | | | Allocate responsibility and authority for measuring process audit activities and results. | | | | DO | DN | NA |  |
|  |  | | | Allocate responsibility and authority for measuring process review activities and results. | | | | DO | DN | NA |  |
|  |  | | Allocate responsibility and authority for measuring process modification activities and results. | | | | | DO | DN | NA |  |
|  |  | | | Allocate responsibility and authority for measuring process correction activities and results. | | | | DO | DN | NA |  |
|  |  | | | Allocate responsibility and authority for measuring process improvement activities and results. | | | | DO | DN | NA |  |
| 5.2 QUALIFY THE RESOURCES NEEDED TO MEASURE PROCESS | | | | | | | | | | | |
|  | Select measurement resources that are fit for purpose. | | | | | | | DO | DN | NA |  |
|  |  | Select measurement resources that will yield valid and reliable results. | | | | | | DO | DN | NA |  |
|  |  | | Select measurement resources that will ensure that outputs meet requirements. | | | | | DO | DN | NA |  |
|  | Validate measurement resources before you use them. | | | | | | | DO | DN | NA |  |
|  |  | Validate resources that are used to measure process. | | | | | | DO | DN | NA |  |
|  |  | | Validate software before it is used to measure process. | | | | | DO | DN | NA |  |
|  |  | | Validate tools before they are used to measure process. | | | | | DO | DN | NA |  |
|  |  | | Validate equipment before it is used to measure process. | | | | | DO | DN | NA |  |
| 5.3 PROVIDE THE RESOURCES NEEDED TO MEASURE PROCESS | | | | | | | | | | | |
| 5.3.1 Provide the expertise needed to measure your process | | | | | | | | | | | |
|  | Provide the expertise needed to ensure that measuring  methods will yield valid and reliable results. | | | | | | | DO | DN | NA |  |
|  |  | Provide the managers needed to measure your process. | | | | | | DO | DN | NA |  |
|  |  | | Acquire the knowledge that process managers  need to support process measurement activities. | | | | | DO | DN | NA |  |
|  |  | | | Ensure that process managers get the knowledge  they need to support measurement activities. | | | | DO | DN | NA |  |
|  |  | | | | Deliver suitable training and awareness programmes  for managers of process measurement activities. | | | DO | DN | NA |  |
|  |  | Provide the personnel needed to measure your process. | | | | | | DO | DN | NA |  |
|  |  | | Acquire the knowledge that personnel need to measure your process. | | | | | DO | DN | NA |  |
|  |  | | | Consider internal sources of knowledge about process measurement. | | | | DO | DN | NA |  |
|  |  | | | Consider external sources of knowledge about process measurement. | | | | DO | DN | NA |  |
|  |  | | Ensure that personnel get the knowledge they need to measure your process. | | | | | DO | DN | NA |  |
|  |  | | | Deliver suitable training and awareness programmes for process measuring personnel. | | | | DO | DN | NA |  |
| 5.3.2 Provide the technology needed to measure your process | | | | | | | | | | | |
|  | Provide the technology needed to ensure that  measurement methods yield valid and reliable results. | | | | | | | DO | DN | NA |  |
|  |  | Provide the software needed to measure your process. | | | | | | DO | DN | NA |  |
|  |  | | Provide the software needed to support process measurement activities. | | | | | DO | DN | NA |  |
|  |  | Provide the hardware needed to measure your process. | | | | | | DO | DN | NA |  |
|  |  | | Provide the hardware needed to support process measurement activities. | | | | | DO | DN | NA |  |
|  |  | | | Provide the tools and equipment needed to measure your process. | | | | DO | DN | NA |  |
| 5.3.3 Provide the infrastructure needed to measure your process | | | | | | | | | | | |
|  | Provide the infrastructure needed to ensure that  measurement methods yield valid and reliable results. | | | | | | | DO | DN | NA |  |
|  |  | Provide the infrastructure needed to support process  measurement and achieve conformity of outputs. | | | | | | DO | DN | NA |  |
| 5.4 USE AUTHORIZED METHODS TO MEASURE YOUR PROCESS | | | | | | | | | | | |
| 5.4.1 Use authorized methods to measure process elements | | | | | | | | | | | |
|  | Use authorized methods to measure process outputs. | | | | | | | DO | DN | NA |  |
|  |  | Measure your outputs against expectations. | | | | | | DO | DN | NA |  |
|  |  | | Measure how well outputs meet requirements. | | | | | DO | DN | NA |  |
|  |  | | Measure how well outputs achieve objectives. | | | | | DO | DN | NA |  |
|  |  | | Measure how well outputs implement plans. | | | | | DO | DN | NA |  |
|  | Use authorized methods to measure process inputs. | | | | | | | DO | DN | NA |  |
|  |  | Measure your inputs against expectations. | | | | | | DO | DN | NA |  |
|  |  | | Measure how well inputs meet requirements. | | | | | DO | DN | NA |  |
|  |  | | Measure how well inputs achieve objectives. | | | | | DO | DN | NA |  |
|  |  | | Measure how well inputs implement plans. | | | | | DO | DN | NA |  |
|  | Use authorized methods to measure process activities. | | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to measure process operating activities. | | | | | | DO | DN | NA |  |
|  |  | | Measure how well process operating activities meet expectations. | | | | | DO | DN | NA |  |
|  |  | | | Measure how well process operating activities apply policies. | | | | DO | DN | NA |  |
|  |  | | | Measure how well process operating activities implement plans. | | | | DO | DN | NA |  |
|  |  | | | Measure how well process operating activities follow procedures. | | | | DO | DN | NA |  |
|  |  | | | Measure how well process operating activities achieve objectives. | | | | DO | DN | NA |  |
|  |  | | | Measure how well process operating activities comply with requirements. | | | | DO | DN | NA |  |
|  |  | Use authorized methods to measure process maintenance activities. | | | | | | DO | DN | NA |  |
|  |  | | Measure how well process maintenance activities meet expectations. | | | | | DO | DN | NA |  |
|  |  | | | Measure how well process maintenance activities apply policies. | | | | DO | DN | NA |  |
|  |  | | | Measure how well process maintenance activities implement plans. | | | | DO | DN | NA |  |
|  |  | | | Measure how well process maintenance activities follow procedures. | | | | DO | DN | NA |  |
|  |  | | | Measure how well process maintenance activities achieve objectives. | | | | DO | DN | NA |  |
|  |  | | | Measure how well process maintenance activities comply with requirements. | | | | DO | DN | NA |  |
|  |  | Use authorized methods to measure process measurement activities. | | | | | | DO | DN | NA |  |
|  |  | | Measure how well process measurement activities meet expectations. | | | | | DO | DN | NA |  |
|  |  | | | Measure how well process measurement activities apply policies. | | | | DO | DN | NA |  |
|  |  | | | Measure how well process measurement activities implement plans. | | | | DO | DN | NA |  |
|  |  | | | Measure how well process measurement activities follow procedures. | | | | DO | DN | NA |  |
|  |  | | | Measure how well process measurement activities achieve objectives. | | | | DO | DN | NA |  |
|  |  | | | Measure how well process measurement activities comply with requirements. | | | | DO | DN | NA |  |
|  |  | Use authorized methods to measure process monitoring activities. | | | | | | DO | DN | NA |  |
|  |  | | Measure how well process monitoring activities meet expectations. | | | | | DO | DN | NA |  |
|  |  | | | Measure how well process monitoring activities apply policies. | | | | DO | DN | NA |  |
|  |  | | | Measure how well process monitoring activities implement plans. | | | | DO | DN | NA |  |
|  |  | | | Measure how well process monitoring activities follow procedures. | | | | DO | DN | NA |  |
|  |  | | | Measure how well process monitoring activities achieve objectives. | | | | DO | DN | NA |  |
|  |  | | | Measure how well process monitoring activities comply with requirements. | | | | DO | DN | NA |  |
|  |  | Use authorized methods to measure process control activities. | | | | | | DO | DN | NA |  |
|  |  | | Measure how well process control activities meet expectations. | | | | | DO | DN | NA |  |
|  |  | | | Measure how well process control activities apply policies. | | | | DO | DN | NA |  |
|  |  | | | Measure how well process control activities implement plans. | | | | DO | DN | NA |  |
|  |  | | | Measure how well process control activities follow procedures. | | | | DO | DN | NA |  |
|  |  | | | Measure how well process control activities achieve objectives. | | | | DO | DN | NA |  |
|  |  | | | Measure how well process control activities comply with requirements. | | | | DO | DN | NA |  |
|  |  | Use authorized methods to measure process evaluation activities. | | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to measure process audit activities. | | | | | DO | DN | NA |  |
|  |  | | | Measure how well process audit activities meet expectations. | | | | DO | DN | NA |  |
|  |  | | | | Measure how well process audit activities apply policies. | | | DO | DN | NA |  |
|  |  | | | | Measure how well process audit activities implement plans. | | | DO | DN | NA |  |
|  |  | | | | Measure how well process audit activities follow procedures. | | | DO | DN | NA |  |
|  |  | | | | Measure how well process audit activities achieve objectives. | | | DO | DN | NA |  |
|  |  | | | | Measure how well process audit activities comply with requirements. | | | DO | DN | NA |  |
|  |  | | Use authorized methods to measure process review activities. | | | | | DO | DN | NA |  |
|  |  | | | Measure how well process review activities meet expectations. | | | | DO | DN | NA |  |
|  |  | | | | Measure how well process review activities apply policies. | | | DO | DN | NA |  |
|  |  | | | | Measure how well process review activities implement plans. | | | DO | DN | NA |  |
|  |  | | | | Measure how well process review activities follow procedures. | | | DO | DN | NA |  |
|  |  | | | | Measure how well process review activities achieve objectives. | | | DO | DN | NA |  |
|  |  | | | | Measure how well process review activities comply with requirements. | | | DO | DN | NA |  |
|  |  | Use authorized methods to measure process modification activities. | | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to measure process correction activities. | | | | | DO | DN | NA |  |
|  |  | | | Measure how well process correction activities meet expectations. | | | | DO | DN | NA |  |
|  |  | | | | Measure how well process correction activities apply policies. | | | DO | DN | NA |  |
|  |  | | | | Measure how well process correction activities implement plans. | | | DO | DN | NA |  |
|  |  | | | | Measure how well process correction activities follow procedures. | | | DO | DN | NA |  |
|  |  | | | | Measure how well process correction activities achieve objectives. | | | DO | DN | NA |  |
|  |  | | | | Measure how well process correction activities comply with requirements. | | | DO | DN | NA |  |
|  |  | | Use authorized methods to measure process improvement activities. | | | | | DO | DN | NA |  |
|  |  | | | Measure how well process improvement activities meet expectations. | | | | DO | DN | NA |  |
|  |  | | | | Measure how well process improvement activities apply policies. | | | DO | DN | NA |  |
|  |  | | | | Measure how well process improvement activities implement plans. | | | DO | DN | NA |  |
|  |  | | | | Measure how well process improvement activities follow procedures. | | | DO | DN | NA |  |
|  |  | | | | Measure how well process improvement activities achieve objectives. | | | DO | DN | NA |  |
|  |  | | | | Measure how well process improvement activities comply with requirements. | | | DO | DN | NA |  |
| 5.4.2 Use authorized methods to measure process performance | | | | | | | | | | | |
|  | Use authorized methods to measure the performance of process personnel. | | | | | | | DO | DN | NA |  |
|  |  | Measure the competence and effectiveness of your process personnel. | | | | | | DO | DN | NA |  |
|  |  | | Measure the process knowledge and skill that has been acquired. | | | | | DO | DN | NA |  |
|  |  | Measure how well process personnel meet process expectations. | | | | | | DO | DN | NA |  |
|  |  | | Measure how well process personnel apply process policies. | | | | | DO | DN | NA |  |
|  |  | | Measure how well process personnel implement process plans. | | | | | DO | DN | NA |  |
|  |  | | Measure how well process personnel follow process procedures. | | | | | DO | DN | NA |  |
|  |  | | Measure how well process personnel meet process requirements. | | | | | DO | DN | NA |  |
|  |  | | Measure how well process personnel achieve process objectives. | | | | | DO | DN | NA |  |
|  |  | | | Measure how well process personnel achieve safety objectives. | | | | DO | DN | NA |  |
|  |  | | | Measure how well process personnel achieve quality objectives. | | | | DO | DN | NA |  |
|  |  | | | Measure how well process personnel achieve security objectives. | | | | DO | DN | NA |  |
|  |  | | | Measure how well process personnel achieve business objectives. | | | | DO | DN | NA |  |
|  |  | | | Measure how well process personnel achieve technical objectives. | | | | DO | DN | NA |  |
|  |  | | | Measure how well process personnel achieve continuity objectives. | | | | DO | DN | NA |  |
|  |  | | | Measure how well process personnel achieve environmental objectives. | | | | DO | DN | NA |  |
|  | Use authorized methods to measure the performance of process management. | | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to measure process management activities. | | | | | | DO | DN | NA |  |
|  |  | | Measure how well process management activities meet expectations. | | | | | DO | DN | NA |  |
|  |  | | | Measure how well process management activities apply policies. | | | | DO | DN | NA |  |
|  |  | | | Measure how well process management activities implement plans. | | | | DO | DN | NA |  |
|  |  | | | Measure how well process management activities follow procedures. | | | | DO | DN | NA |  |
|  |  | | | Measure how well process management activities meet requirements. | | | | DO | DN | NA |  |
|  |  | | | Measure how well process management activities achieve objectives. | | | | DO | DN | NA |  |
|  |  | | | | Measure how well process managers achieve safety objectives. | | | DO | DN | NA |  |
|  |  | | | | Measure how well process managers achieve quality objectives. | | | DO | DN | NA |  |
|  |  | | | | Measure how well process managers achieve security objectives. | | | DO | DN | NA |  |
|  |  | | | | Measure how well process managers achieve business objectives. | | | DO | DN | NA |  |
|  |  | | | | Measure how well process managers achieve technical objectives. | | | DO | DN | NA |  |
|  |  | | | | Measure how well process managers achieve continuity objectives. | | | DO | DN | NA |  |
|  |  | | | | Measure how well process managers achieve environmental objectives. | | | DO | DN | NA |  |
|  |  | Use authorized methods to measure process management programmes. | | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to measure your risk management programme. | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to measure your safety management programme. | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to measure your quality management programme. | | | | | DO | DN | NA |  |
|  |  | | | Use authorized methods to measure configuration management programme. | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to measure your security management programme. | | | | | DO | DN | NA |  |
|  |  | | | Use authorized methods to measure personnel security management programme. | | | | DO | DN | NA |  |
|  |  | | | Use authorized methods to measure information management programme. | | | | DO | DN | NA |  |
|  |  | | | Use authorized methods to measure component management programme. | | | | DO | DN | NA |  |
|  |  | | | | Use authorized methods to measure counterfeit parts management programme. | | | DO | DN | NA |  |
|  |  | | Use authorized methods to measure your supplier management programme. | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to measure your environmental management programme. | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to measure your business continuity management programme. | | | | | DO | DN | NA |  |
|  | Use authorized methods to measure external providers. | | | | | | | DO | DN | NA |  |
|  |  | Use authorized criteria to measure the performance of external providers. | | | | | | DO | DN | NA |  |
|  |  | | Measure the performance of external process, product, and service providers. | | | | | DO | DN | NA |  |
|  |  | | | Use data and criteria to measure the performance of your external providers. | | | | DO | DN | NA |  |
|  |  | | | | Document performance measuring activities and retain these documents. | | | DO | DN | NA |  |
|  |  | | | | | Control documents that describe your performance measuring activities. | | DO | DN | NA |  |
|  |  | | Measure external process, product, and service verification activities. | | | | | DO | DN | NA |  |
|  |  | | | Measure verifications whenever they are delegated to external providers. | | | | DO | DN | NA |  |
|  | Use authorized methods to measure internal providers. | | | | | | | DO | DN | NA |  |
|  |  | Use authorized criteria to measure the performance of internal providers. | | | | | | DO | DN | NA |  |
| 5.5 CONTROL THE RESOURCES NEEDED TO MEASURE PROCESS | | | | | | | | | | | |
| 5.5.1 Control the documents needed to measure your process | | | | | | | | | | | |
|  | Control the procedures needed to measure your process and its outputs. | | | | | | | DO | DN | NA |  |
|  | Control the instructions needed to measure your process and its outputs. | | | | | | | DO | DN | NA |  |
|  | Control the manuals needed to measure your process and its outputs. | | | | | | | DO | DN | NA |  |
| 5.5.2 Control the technology needed to measure your process | | | | | | | | | | | |
|  | Control the software needed to measure your process and its outputs. | | | | | | | DO | DN | NA |  |
|  | Control the hardware needed to measure your process and its outputs. | | | | | | | DO | DN | NA |  |
|  |  | Control the tools needed to measure your process and its outputs. | | | | | | DO | DN | NA |  |
|  |  | Control the equipment needed to measure your process and its outputs. | | | | | | DO | DN | NA |  |
| 5.5.3 Control the records needed to measure your process | | | | | | | | | | | |
|  | Establish records for process measurement activities and resources. | | | | | | | DO | DN | NA |  |
|  |  | Use records to control your process measuring activities and resources. | | | | | | DO | DN | NA |  |
|  |  | | Establish a register of process measurement activities and resources. | | | | | DO | DN | NA |  |
|  |  | | | Use register to record the identity of measurement resources. | | | | DO | DN | NA |  |
|  |  | | | | Use your register to describe the type or kind of resources being used. | | | DO | DN | NA |  |
|  |  | | | | | Use your register to describe your test hardware and software. | | DO | DN | NA |  |
|  |  | | | | | Use your register to document automated test equipment (ATE). | | DO | DN | NA |  |
|  |  | | | | | Use your register to identify plotters used to produce verification data. | | DO | DN | NA |  |
|  |  | | | | | Use your register to list equipment used to provide evidence of conformity. | | DO | DN | NA |  |
|  |  | | | | | | Use register to list personally owned equipment used to verify conformity. | DO | DN | NA |  |
|  |  | | | | | | Use register to list customer supplied equipment used to verify conformity. | DO | DN | NA |  |
|  |  | | | | Use your register to specify a unique identifier for each piece of equipment. | | | DO | DN | NA |  |
|  |  | | | Use register to specify the location of your measurement tools and equipment. | | | | DO | DN | NA |  |
|  |  | | | Use register to control the calibration of your measurement tools and equipment. | | | | DO | DN | NA |  |
|  |  | | | | Use your register to record calibration or verification methods and results. | | | DO | DN | NA |  |
|  |  | | | | | Use your register to record calibration or verification acceptance criteria. | | DO | DN | NA |  |
|  |  | | | | Use your register to specify equipment calibration or verification frequency. | | | DO | DN | NA |  |
|  |  | | Maintain a register of your process measurement activities and resources. | | | | | DO | DN | NA |  |
|  |  | | | Maintain records that show that measurement resources are still fit for purpose. | | | | DO | DN | NA |  |
|  |  | | | | Control records that show that measurement resources are still fit for purpose. | | | DO | DN | NA |  |
|  |  | Use records to keep track of measurement activities and resources. | | | | | | DO | DN | NA |  |
|  |  | | Establish suitable measurement traceability methods. | | | | | DO | DN | NA |  |
|  |  | | | Maintain suitable measurement traceability resources. | | | | DO | DN | NA |  |
|  |  | | Establish recall methods for your measurement equipment. | | | | | DO | DN | NA |  |
|  |  | | | Implement recall methods for your measurement equipment. | | | | DO | DN | NA |  |
|  |  | | | | Recall measurement equipment that must be verified or calibrated. | | | DO | DN | NA |  |
|  |  | | | Maintain recall records for your process measurement equipment. | | | | DO | DN | NA |  |
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| Consider each task and select a response. If you haven’t done it and it needs to be done, select DO. If you’ve already done it, select DN. If the task is not applicable in your situation and you can justify and explain why it should be ignored or excluded, select NA.  In the spaces below, please enter the name and location of your organization, who completed this page, who reviewed it, and the dates. | | | | | | | | | | | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 6.1 PLAN HOW YOU'RE GOING TO MONITOR YOUR PROCESS | | | | | | | | | | |
| 6.1.1 Figure out what needs to be monitored | | | | | | | | | | |
|  | Figure out what kind of policies and plans need to be monitored. | | | | | | DO | DN | NA |  |
|  | Figure out what kind of practices and procedures need to be monitored. | | | | | | DO | DN | NA |  |
|  | Figure out what kind of issues, factors, and concerns need to be monitored. | | | | | | DO | DN | NA |  |
|  |  | Figure out what kind of internal issues and factors need to be monitored. | | | | | DO | DN | NA |  |
|  |  | Figure out what kind of external issues and factors need to be monitored. | | | | | DO | DN | NA |  |
|  | Figure out what kind of participants and providers need to be monitored. | | | | | | DO | DN | NA |  |
|  |  | Figure out what kind of process participants need to be monitored. | | | | | DO | DN | NA |  |
|  |  | | Figure out what kind of process managers need to be monitored. | | | | DO | DN | NA |  |
|  |  | | Figure out what kind of process personnel need to be monitored. | | | | DO | DN | NA |  |
|  |  | Figure out what kind of process providers need to be monitored. | | | | | DO | DN | NA |  |
|  |  | | Figure out what kind of internal process providers need to be monitored. | | | | DO | DN | NA |  |
|  |  | | Figure out what kind of external process providers need to be monitored. | | | | DO | DN | NA |  |
|  | Figure out what kind of process inputs and outputs need to be monitored. | | | | | | DO | DN | NA |  |
|  |  | Figure out what kind of output characteristics need to be monitored. | | | | | DO | DN | NA |  |
|  |  | Figure out what kind of input characteristics need to be monitored. | | | | | DO | DN | NA |  |
|  | Figure out what kind of internal process resources need to be monitored. | | | | | | DO | DN | NA |  |
|  |  | Figure out what kind of data and information needs to be monitored. | | | | | DO | DN | NA |  |
|  |  | Figure out what kind of documents and records need to be monitored. | | | | | DO | DN | NA |  |
|  |  | Figure out what kind of hardware and software needs to be monitored. | | | | | DO | DN | NA |  |
|  |  | Figure out what kind of parts and components need to be monitored. | | | | | DO | DN | NA |  |
|  |  | Figure out what kind of products and services need to be monitored. | | | | | DO | DN | NA |  |
|  |  | Figure out what kind of property and supplies need to be monitored. | | | | | DO | DN | NA |  |
| 6.1.2 Figure out how monitoring will be done | | | | | | | | | | |
|  | Plan how you're going to monitor customer satisfaction. | | | | | | DO | DN | NA |  |
|  |  | Plan how to monitor customer feelings about process outputs. | | | | | DO | DN | NA |  |
|  |  | | Plan how to monitor information about customer satisfaction. | | | | DO | DN | NA |  |
|  | Plan how you're going to monitor process performance. | | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor process outputs. | | | | | DO | DN | NA |  |
|  |  | | Plan how you're going to monitor output deliveries. | | | | DO | DN | NA |  |
|  |  | | | Plan how to monitor post-delivery performance. | | | DO | DN | NA |  |
|  |  | | Plan how you're going to monitor output characteristics. | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor process activities. | | | | | DO | DN | NA |  |
|  |  | | Plan how you're going to monitor process management activities. | | | | DO | DN | NA |  |
|  |  | | | Plan how to monitor how well process management activities meet expectations. | | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process management activities apply policies. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process management activities implement plans. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process management activities follow procedures. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process management activities achieve objectives. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process management activities comply with requirements. | | DO | DN | NA |  |
|  |  | | Plan how you're going to monitor process operating activities. | | | | DO | DN | NA |  |
|  |  | | | Plan how to monitor how well process operating activities meet expectations. | | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process operating activities apply policies. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process operating activities implement plans. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process operating activities follow procedures. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process operating activities achieve objectives. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process operating activities comply with requirements. | | DO | DN | NA |  |
|  |  | | Plan how you're going to monitor process maintenance activities. | | | | DO | DN | NA |  |
|  |  | | | Plan how to monitor how well process maintenance activities meet expectations. | | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process maintenance activities apply policies. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process maintenance activities implement plans. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process maintenance activities follow procedures. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process maintenance activities achieve objectives. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process maintenance activities comply with requirements. | | DO | DN | NA |  |
|  |  | | Plan how you're going to monitor process monitoring activities. | | | | DO | DN | NA |  |
|  |  | | | Plan how to monitor how well process monitoring activities meet expectations. | | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process monitoring activities apply policies. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process monitoring activities implement plans. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process monitoring activities follow procedures. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process monitoring activities achieve objectives. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process monitoring activities comply with requirements. | | DO | DN | NA |  |
|  |  | | Plan how you're going to monitor process measurement activities. | | | | DO | DN | NA |  |
|  |  | | | Plan how to monitor how well process measurement activities meet expectations. | | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process measurement activities apply policies. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process measurement activities implement plans. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process measurement activities follow procedures. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process measurement activities achieve objectives. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process measurement activities comply with requirements. | | DO | DN | NA |  |
|  |  | | Plan how you're going to monitor process control activities. | | | | DO | DN | NA |  |
|  |  | | | Plan how to monitor how well process control activities meet expectations. | | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process control activities apply policies. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process control activities implement plans. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process control activities follow procedures. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process control activities achieve objectives. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process control activities comply with requirements. | | DO | DN | NA |  |
|  |  | | Plan how you're going to monitor process evaluation activities. | | | | DO | DN | NA |  |
|  |  | | | Plan how you're going to monitor process audit activities. | | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process audit activities meet expectations. | | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well process audit activities apply policies. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well process audit activities implement plans. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well process audit activities follow procedures. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well process audit activities achieve objectives. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well process audit activities comply with requirements. | DO | DN | NA |  |
|  |  | | | Plan how you're going to monitor process review activities. | | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process review activities meet expectations. | | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well process review activities apply policies. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well process review activities implement plans. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well process review activities follow procedures. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well process review activities achieve objectives. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well process review activities comply with requirements. | DO | DN | NA |  |
|  |  | | Plan how you're going to monitor process modification activities. | | | | DO | DN | NA |  |
|  |  | | | Plan how you're going to monitor process correction activities. | | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process correction activities meet expectations. | | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well process correction activities apply policies. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well process correction activities implement plans. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well process correction activities follow procedures. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well process correction activities achieve objectives. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well process correction activities comply with requirements. | DO | DN | NA |  |
|  |  | | | Plan how you're going to monitor process improvement activities. | | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well process improvement activities meet expectations. | | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well process improvement activities apply policies. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well process improvement activities implement plans. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well process improvement activities follow procedures. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well process improvement activities achieve objectives. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well process improvement activities comply with requirements. | DO | DN | NA |  |
|  | Plan how you're going to monitor process resources. | | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor process parts. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor process plans. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor process policies. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor process supplies. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor process hardware. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor process software. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor process services. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor process products. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor process property. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor process providers. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor process documents. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor process components. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor process infrastructure. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor process participants. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor process procedures. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor process practices. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor process records. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor process inputs. | | | | | DO | DN | NA |  |
|  |  | | Plan how you're going to monitor internal process inputs. | | | | DO | DN | NA |  |
|  |  | | Plan how you're going to monitor external process inputs. | | | | DO | DN | NA |  |
|  |  | | | Plan how you're going to monitor reports about counterfeit parts. | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor process technologies. | | | | | DO | DN | NA |  |
|  |  | | Plan how you're going to monitor process tools and equipment. | | | | DO | DN | NA |  |
|  |  | | | Plan how you're going to monitor process monitoring tools and equipment. | | | DO | DN | NA |  |
|  |  | | | | Plan how you're going to recall monitoring tools and  equipment that must be recalibrated or reverified. | | DO | DN | NA |  |
|  |  | | | Plan how you're going to monitor process measurement tools and equipment. | | | DO | DN | NA |  |
|  |  | | | | Plan how you're going to recall measurement tools  and equipment that must be recalibrated or reverified. | | DO | DN | NA |  |
|  | Plan how you're going to monitor process environment. | | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor your process's external context. | | | | | DO | DN | NA |  |
|  |  | | Figure out how you're going to monitor the external  issues and factors that could affect your process. | | | | DO | DN | NA |  |
|  |  | | Figure out how you're going to monitor the external  interested parties that could affect your process. | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor your process's internal context. | | | | | DO | DN | NA |  |
|  |  | | Figure out how you're going to monitor the internal  issues and factors that could affect your process. | | | | DO | DN | NA |  |
|  |  | | Figure out how you're going to monitor the internal  interested parties that could affect your process. | | | | DO | DN | NA |  |
| 6.1.3 Figure out who will perform monitoring tasks | | | | | | | | | | |
|  | Allocate responsibility and authority for monitoring process plans. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring process policies. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring process outputs. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring process supplies. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring process materials. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring process hardware. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring process software. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring process services. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring process products. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring process property. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring process providers. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring process objectives. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring process documents. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring process participants. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring process components. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring process technologies. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring process characteristics. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring process requirements. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring process infrastructure. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring process environment. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring process procedures. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring process practices. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring process records. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring process parties. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring process inputs. | | | | | | DO | DN | NA |  |
| 6.2 QUALIFY THE RESOURCES NEEDED TO MONITOR PROCESS | | | | | | | | | | |
|  | Select monitoring resources that are fit for purpose. | | | | | | DO | DN | NA |  |
|  |  | Select monitoring resources that will yield valid and reliable results. | | | | | DO | DN | NA |  |
|  |  | | Select resources that will help ensure that outputs meet requirements. | | | | DO | DN | NA |  |
|  | Validate monitoring resources before you use them. | | | | | | DO | DN | NA |  |
|  |  | Validate tools before they are used to monitor process. | | | | | DO | DN | NA |  |
|  |  | Validate equipment before it is used to monitor process. | | | | | DO | DN | NA |  |
|  |  | Validate software before it is used to monitor process. | | | | | DO | DN | NA |  |
| 6.3 PROVIDE THE RESOURCES NEEDED TO MONITOR PROCESS | | | | | | | | | | |
| 6.3.1 Provide the expertise needed to monitor your process | | | | | | | | | | |
|  | Provide the expertise needed to ensure that monitoring  methods will consistently yield valid and reliable results. | | | | | | DO | DN | NA |  |
|  |  | Provide the managers needed to monitor your process. | | | | | DO | DN | NA |  |
|  |  | | Acquire the knowledge that managers need to support  process monitoring and achieve conformity of outputs. | | | | DO | DN | NA |  |
|  |  | | Share the knowledge that managers need so that they can  support process monitoring and achieve conformity of outputs. | | | | DO | DN | NA |  |
|  |  | | | Deliver suitable training and awareness programmes  for managers of process monitoring activities. | | | DO | DN | NA |  |
|  |  | Provide the personnel needed to monitor your process. | | | | | DO | DN | NA |  |
|  |  | | Acquire the knowledge that personnel need to monitor  your process and achieve conformity of outputs. | | | | DO | DN | NA |  |
|  |  | | | Consider internal sources of knowledge about process monitoring. | | | DO | DN | NA |  |
|  |  | | | Consider external sources of knowledge about process monitoring. | | | DO | DN | NA |  |
|  |  | | Share the knowledge that personnel need to monitor  your process and achieve conformity of outputs. | | | | DO | DN | NA |  |
|  |  | | | Deliver suitable training and awareness programmes  for your process monitoring personnel. | | | DO | DN | NA |  |
| 6.3.2 Provide the technology needed to monitor your process | | | | | | | | | | |
|  | Provide the technology needed to ensure that your monitoring methods will yield valid and reliable results. | | | | | | DO | DN | NA |  |
|  |  | Provide the software needed to monitor your process. | | | | | DO | DN | NA |  |
|  |  | | Provide the software needed to support process  monitoring and achieve conformity of outputs. | | | | DO | DN | NA |  |
|  |  | Provide the hardware needed to monitor your process. | | | | | DO | DN | NA |  |
|  |  | | Provide the hardware needed to support process  monitoring and achieve conformity of outputs. | | | | DO | DN | NA |  |
| 6.3.3 Provide the infrastructure needed to monitor your process | | | | | | | | | | |
|  | Provide the infrastructure needed to ensure that your monitoring methods will yield valid and reliable results. | | | | | | DO | DN | NA |  |
|  |  | Provide the infrastructure needed to support your process monitoring and achieve conformity of outputs. | | | | | DO | DN | NA |  |
| 6.4 USE AUTHORIZED METHODS TO MONITOR YOUR PROCESS | | | | | | | | | | |
| 6.4.1 Use authorized methods to monitor process activities | | | | | | | | | | |
|  | Use authorized methods to monitor process management activities. | | | | | | DO | DN | NA |  |
|  |  | Monitor how well process management activities meet expectations. | | | | | DO | DN | NA |  |
|  |  | | Monitor how well process management activities apply policies. | | | | DO | DN | NA |  |
|  |  | | Monitor how well process management activities implement plans. | | | | DO | DN | NA |  |
|  |  | | Monitor how well process management activities follow procedures. | | | | DO | DN | NA |  |
|  |  | | Monitor how well process management activities achieve objectives. | | | | DO | DN | NA |  |
|  |  | | Monitor how well process management activities comply with requirements. | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor process operating activities. | | | | | | DO | DN | NA |  |
|  |  | Monitor how well process operating activities meet expectations. | | | | | DO | DN | NA |  |
|  |  | | Monitor how well process operating activities apply policies. | | | | DO | DN | NA |  |
|  |  | | Monitor how well process operating activities implement plans. | | | | DO | DN | NA |  |
|  |  | | Monitor how well process operating activities follow procedures. | | | | DO | DN | NA |  |
|  |  | | Monitor how well process operating activities achieve objectives. | | | | DO | DN | NA |  |
|  |  | | Monitor how well process operating activities comply with requirements. | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor process maintenance activities. | | | | | | DO | DN | NA |  |
|  |  | Monitor how well process maintenance activities meet expectations. | | | | | DO | DN | NA |  |
|  |  | | Monitor how well process maintenance activities apply policies. | | | | DO | DN | NA |  |
|  |  | | Monitor how well process maintenance activities implement plans. | | | | DO | DN | NA |  |
|  |  | | Monitor how well process maintenance activities follow procedures. | | | | DO | DN | NA |  |
|  |  | | Monitor how well process maintenance activities achieve objectives. | | | | DO | DN | NA |  |
|  |  | | Monitor how well process maintenance activities comply with requirements. | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor process measurement activities. | | | | | | DO | DN | NA |  |
|  |  | Monitor how well process measurement activities meet expectations. | | | | | DO | DN | NA |  |
|  |  | | Monitor how well process measurement activities apply policies. | | | | DO | DN | NA |  |
|  |  | | Monitor how well process measurement activities implement plans. | | | | DO | DN | NA |  |
|  |  | | Monitor how well process measurement activities follow procedures. | | | | DO | DN | NA |  |
|  |  | | Monitor how well process measurement activities achieve objectives. | | | | DO | DN | NA |  |
|  |  | | Monitor how well process measurement activities comply with requirements. | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor process monitoring activities. | | | | | | DO | DN | NA |  |
|  |  | Monitor how well process monitoring activities meet expectations. | | | | | DO | DN | NA |  |
|  |  | | Monitor how well process monitoring activities apply policies. | | | | DO | DN | NA |  |
|  |  | | Monitor how well process monitoring activities implement plans. | | | | DO | DN | NA |  |
|  |  | | Monitor how well process monitoring activities follow procedures. | | | | DO | DN | NA |  |
|  |  | | Monitor how well process monitoring activities achieve objectives. | | | | DO | DN | NA |  |
|  |  | | Monitor how well process monitoring activities comply with requirements. | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor process control activities. | | | | | | DO | DN | NA |  |
|  |  | Monitor how well process control activities meet expectations. | | | | | DO | DN | NA |  |
|  |  | | Monitor how well process control activities apply policies. | | | | DO | DN | NA |  |
|  |  | | Monitor how well process control activities implement plans. | | | | DO | DN | NA |  |
|  |  | | Monitor how well process control activities follow procedures. | | | | DO | DN | NA |  |
|  |  | | Monitor how well process control activities achieve objectives. | | | | DO | DN | NA |  |
|  |  | | Monitor how well process control activities comply with requirements. | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor process evaluation activities. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor process audit activities. | | | | | DO | DN | NA |  |
|  |  | | Monitor how well process audit activities meet expectations. | | | | DO | DN | NA |  |
|  |  | | | Monitor how well process audit activities apply policies. | | | DO | DN | NA |  |
|  |  | | | Monitor how well process audit activities implement plans. | | | DO | DN | NA |  |
|  |  | | | Monitor how well process audit activities follow procedures. | | | DO | DN | NA |  |
|  |  | | | Monitor how well process audit activities achieve objectives. | | | DO | DN | NA |  |
|  |  | | | Monitor how well process audit activities comply with requirements. | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor process review activities. | | | | | DO | DN | NA |  |
|  |  | | Monitor how well process review activities meet expectations. | | | | DO | DN | NA |  |
|  |  | | | Monitor how well process review activities apply policies. | | | DO | DN | NA |  |
|  |  | | | Monitor how well process review activities implement plans. | | | DO | DN | NA |  |
|  |  | | | Monitor how well process review activities follow procedures. | | | DO | DN | NA |  |
|  |  | | | Monitor how well process review activities achieve objectives. | | | DO | DN | NA |  |
|  |  | | | Monitor how well process review activities comply with requirements. | | | DO | DN | NA |  |
|  | Use authorized methods to monitor process modification activities. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor process correction activities. | | | | | DO | DN | NA |  |
|  |  | | Monitor how well process correction activities meet expectations. | | | | DO | DN | NA |  |
|  |  | | | Monitor how well process correction activities apply policies. | | | DO | DN | NA |  |
|  |  | | | Monitor how well process correction activities implement plans. | | | DO | DN | NA |  |
|  |  | | | Monitor how well process correction activities follow procedures. | | | DO | DN | NA |  |
|  |  | | | Monitor how well process correction activities achieve objectives. | | | DO | DN | NA |  |
|  |  | | | Monitor how well process correction activities comply with requirements. | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor process improvement activities. | | | | | DO | DN | NA |  |
|  |  | | Monitor how well process improvement activities meet expectations. | | | | DO | DN | NA |  |
|  |  | | | Monitor how well process improvement activities apply policies. | | | DO | DN | NA |  |
|  |  | | | Monitor how well process improvement activities implement plans. | | | DO | DN | NA |  |
|  |  | | | Monitor how well process improvement activities follow procedures. | | | DO | DN | NA |  |
|  |  | | | Monitor how well process improvement activities achieve objectives. | | | DO | DN | NA |  |
|  |  | | | Monitor how well process improvement activities comply with requirements. | | | DO | DN | NA |  |
| 6.4.2 Use authorized methods to monitor process outputs | | | | | | | | | | |
|  | Monitor how well process outputs meet expectations. | | | | | | DO | DN | NA |  |
|  |  | Monitor how well process outputs apply policies. | | | | | DO | DN | NA |  |
|  |  | Monitor how well process outputs implement plans. | | | | | DO | DN | NA |  |
|  |  | Monitor how well process outputs follow procedures. | | | | | DO | DN | NA |  |
|  |  | Monitor how well process outputs achieve objectives. | | | | | DO | DN | NA |  |
|  |  | Monitor how well process outputs comply with requirements. | | | | | DO | DN | NA |  |
|  |  | | Monitor how well process outputs meet customer requirements. | | | | DO | DN | NA |  |
|  |  | | Monitor how well process outputs meet regulatory requirements. | | | | DO | DN | NA |  |
|  |  | | Monitor how well process outputs meet corporate requirements. | | | | DO | DN | NA |  |
| 6.4.3 Use authorized methods to monitor process inputs | | | | | | | | | | |
|  | Monitor supplies that have or could have a major impact on outputs. | | | | | | DO | DN | NA |  |
|  | Monitor services that have or could have a major impact on outputs. | | | | | | DO | DN | NA |  |
|  | Monitor materials that have or could have a major impact on outputs. | | | | | | DO | DN | NA |  |
|  | Monitor products that have or could have a major impact on outputs. | | | | | | DO | DN | NA |  |
|  | Monitor components that have or could have a major impact on outputs. | | | | | | DO | DN | NA |  |
|  |  | Monitor all of your “critical items” and “key characteristics”. | | | | | DO | DN | NA |  |
|  |  | Monitor all relevant counterfeit parts and components. | | | | | DO | DN | NA |  |
|  |  | | Monitor external reports about counterfeit parts. | | | | DO | DN | NA |  |
| 6.4.4 Use authorized methods to monitor process documents | | | | | | | | | | |
|  | Monitor documents that specify how your process should be operated. | | | | | | DO | DN | NA |  |
|  | Monitor documents that specify how your process should be maintained. | | | | | | DO | DN | NA |  |
|  | Monitor documents that specify how your process should be monitored. | | | | | | DO | DN | NA |  |
|  | Monitor documents that specify how your process should be measured. | | | | | | DO | DN | NA |  |
|  | Monitor documents that specify how your process should be controlled. | | | | | | DO | DN | NA |  |
|  | Monitor documents that specify how your process should be audited. | | | | | | DO | DN | NA |  |
|  | Monitor documents that specify how your process should be reviewed. | | | | | | DO | DN | NA |  |
|  | Monitor documents that specify how your process should be corrected. | | | | | | DO | DN | NA |  |
|  | Monitor documents that specify how your process should be improved. | | | | | | DO | DN | NA |  |
| 6.4.5 Use authorized methods to monitor process records | | | | | | | | | | |
|  | Monitor records of personnel performance and competence. | | | | | | DO | DN | NA |  |
|  |  | Retain records of personnel performance and competence. | | | | | DO | DN | NA |  |
|  |  | | Use records to show that personnel know how to perform process tasks. | | | | DO | DN | NA |  |
|  | Monitor records that track the performance of your process. | | | | | | DO | DN | NA |  |
|  |  | Monitor records that keep track of process operations. | | | | | DO | DN | NA |  |
|  |  | | Monitor records that keep track of process outputs. | | | | DO | DN | NA |  |
|  |  | | Monitor records that keep track of process activities. | | | | DO | DN | NA |  |
|  |  | | Monitor records that keep track of process inputs. | | | | DO | DN | NA |  |
|  |  | Monitor records that keep track of process maintenance. | | | | | DO | DN | NA |  |
|  |  | Monitor records that keep track of process measurement. | | | | | DO | DN | NA |  |
|  |  | Monitor records that keep track of process monitoring. | | | | | DO | DN | NA |  |
|  |  | Monitor records that keep track of process control. | | | | | DO | DN | NA |  |
|  |  | Monitor records that keep track of process audits. | | | | | DO | DN | NA |  |
|  |  | Monitor records that keep track of process reviews. | | | | | DO | DN | NA |  |
|  |  | Monitor records that keep track of process corrections. | | | | | DO | DN | NA |  |
|  |  | Monitor records that keep track of process improvements. | | | | | DO | DN | NA |  |
| 6.4.6 Use authorized methods to monitor process property | | | | | | | | | | |
|  | Monitor process property owned by customers and  suppliers that is needed to achieve conformity of outputs. | | | | | | DO | DN | NA |  |
|  |  | Report problematic property to your customers and external providers. | | | | | DO | DN | NA |  |
|  |  | | Report unsuitable property to customers and external providers. | | | | DO | DN | NA |  |
|  |  | | Report lost or damaged property to customers and external providers. | | | | DO | DN | NA |  |
|  | Monitor process property owned by your organization  that is needed to achieve conformity of outputs. | | | | | | DO | DN | NA |  |
| 6.4.7 Use authorized methods to monitor process participants | | | | | | | | | | |
|  | Use authorized methods to monitor process personnel. | | | | | | DO | DN | NA |  |
|  |  | Monitor the process objectives that process personnel must achieve. | | | | | DO | DN | NA |  |
|  |  | | Monitor the safety objectives that process personnel must achieve. | | | | DO | DN | NA |  |
|  |  | | Monitor the quality objectives that process personnel must achieve. | | | | DO | DN | NA |  |
|  |  | | Monitor the security objectives that process personnel must achieve. | | | | DO | DN | NA |  |
|  |  | | Monitor the business objectives that process personnel must achieve. | | | | DO | DN | NA |  |
|  |  | | Monitor the technical objectives that process personnel must achieve. | | | | DO | DN | NA |  |
|  |  | | Monitor the continuity objectives that process personnel must achieve. | | | | DO | DN | NA |  |
|  |  | | Monitor the environmental objectives that process personnel must achieve. | | | | DO | DN | NA |  |
|  |  | Monitor the competence and performance of process personnel. | | | | | DO | DN | NA |  |
|  |  | | Monitor the process knowledge and skill that has been acquired. | | | | DO | DN | NA |  |
|  |  | | | Consider the need to protect and preserve process lessons learned. | | | DO | DN | NA |  |
|  |  | | | Consider the need to protect and preserve your intellectual property. | | | DO | DN | NA |  |
|  |  | | Monitor changes and trends in process knowledge and information. | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor process management. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor process management personnel. | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor process management programmes. | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to monitor risk management programme. | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to monitor safety management programme. | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to monitor quality management programme. | | | | DO | DN | NA |  |
|  |  | | | Use authorized methods to monitor configuration management programme. | | | DO | DN | NA |  |
|  |  | | Use authorized methods to monitor security management programme. | | | | DO | DN | NA |  |
|  |  | | | Use authorized methods to monitor personnel security management programme. | | | DO | DN | NA |  |
|  |  | | | Use authorized methods to monitor information security management programme. | | | DO | DN | NA |  |
|  |  | | | Use authorized methods to monitor component security management programme. | | | DO | DN | NA |  |
|  |  | | | | Use authorized methods to monitor counterfeit parts management programme. | | DO | DN | NA |  |
|  |  | | Use authorized methods to monitor supplier management programme. | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to monitor environmental management programme. | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to monitor business continuity management programme. | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor external providers. | | | | | | DO | DN | NA |  |
|  |  | Use authorized criteria to monitor the performance of external providers. | | | | | DO | DN | NA |  |
|  |  | | Used authorized criteria to monitor verification activities delegated to external providers. | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor interested parties. | | | | | | DO | DN | NA |  |
|  |  | Monitor the external parties that could influence your process. | | | | | DO | DN | NA |  |
|  |  | | Monitor the performance of external process, product, and service providers. | | | | DO | DN | NA |  |
|  |  | | | Expect process managers to use data and criteria to  monitor the performance of their external providers. | | | DO | DN | NA |  |
|  |  | | | | Expect process managers to document performance  monitoring activities and retain these documents. | | DO | DN | NA |  |
|  |  | | | | | Expect process managers to control documents  that describe their performance monitoring activities. | DO | DN | NA |  |
|  |  | | Monitor external process, product, and service verification activities. | | | | DO | DN | NA |  |
|  |  | | | Monitor verifications whenever they are delegated to external providers. | | | DO | DN | NA |  |
|  |  | Monitor the internal parties that could influence your process. | | | | | DO | DN | NA |  |
| 6.4.8 Use authorized methods to monitor process technologies | | | | | | | | | | |
|  | Monitor technology used to perform process operations. | | | | | | DO | DN | NA |  |
|  |  | Monitor software used to perform process operations. | | | | | DO | DN | NA |  |
|  |  | Monitor hardware used to perform process operations. | | | | | DO | DN | NA |  |
|  | Monitor technology used to automate process operations. | | | | | | DO | DN | NA |  |
|  |  | Monitor software used to automate process operations. | | | | | DO | DN | NA |  |
|  |  | Monitor hardware used to automate process operations. | | | | | DO | DN | NA |  |
|  | Monitor technology used to maintain process operations. | | | | | | DO | DN | NA |  |
|  |  | Monitor software used to maintain process operations. | | | | | DO | DN | NA |  |
|  |  | Monitor hardware used to maintain process operations. | | | | | DO | DN | NA |  |
|  | Monitor technology used to monitor process operations. | | | | | | DO | DN | NA |  |
|  |  | Monitor software used to monitor process operations. | | | | | DO | DN | NA |  |
|  |  | Monitor hardware used to monitor process operations. | | | | | DO | DN | NA |  |
|  |  | | Recall monitoring equipment that must be recalibrated or reverified. | | | | DO | DN | NA |  |
|  | Monitor technology used to measure process operations. | | | | | | DO | DN | NA |  |
|  |  | Monitor software used to measure process operations. | | | | | DO | DN | NA |  |
|  |  | Monitor hardware used to measure process operations. | | | | | DO | DN | NA |  |
|  |  | | Recall measuring equipment that must be recalibrated or reverified. | | | | DO | DN | NA |  |
|  | Monitor technology used to control process operations. | | | | | | DO | DN | NA |  |
|  |  | Monitor software used to control process operations. | | | | | DO | DN | NA |  |
|  |  | Monitor hardware used to control process operations. | | | | | DO | DN | NA |  |
| 6.4.9 Use authorized methods to monitor process environment | | | | | | | | | | |
|  | Use authorized methods to monitor your process's external environment. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor external interested parties and their requirements. | | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor your process's internal environment. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor internal interested parties and their requirements. | | | | | DO | DN | NA |  |
| 6.4.10 Use authorized methods to monitor process infrastructure | | | | | | | | | | |
|  | Use authorized methods to monitor process networks and communications. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor internal process networks and communications. | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor external process networks and communications. | | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor process utilities and support services. | | | | | | DO | DN | NA |  |
| 6.5 CONTROL THE RESOURCES NEEDED TO MONITOR PROCESS | | | | | | | | | | |
|  | Control the technology needed to monitor your process. | | | | | | DO | DN | NA |  |
|  |  | Control the tools needed to monitor your process. | | | | | DO | DN | NA |  |
|  |  | Control the software needed to monitor your process. | | | | | DO | DN | NA |  |
|  |  | Control the equipment needed to monitor your process. | | | | | DO | DN | NA |  |
|  | Control the records needed to monitor your process. | | | | | | DO | DN | NA |  |
|  |  | Establish a register of your process monitoring resources. | | | | | DO | DN | NA |  |
|  |  | | Ensure that your monitoring resources continue to be fit for purpose. | | | | DO | DN | NA |  |
|  |  | | | Ensure that register describes the type of monitoring tools and equipment in use. | | | DO | DN | NA |  |
|  |  | | | Ensure that register specifies the location of your monitoring tools and equipment. | | | DO | DN | NA |  |
|  |  | | | Ensure that register tracks the calibration of your monitoring tools and equipment. | | | DO | DN | NA |  |
|  |  | | | | Ensure that your register records equipment calibration or verification methods. | | DO | DN | NA |  |
|  |  | | | | | Ensure that your register records calibration or verification acceptance criteria. | DO | DN | NA |  |
|  |  | | | | Ensure that register specifies equipment calibration or verification frequency. | | DO | DN | NA |  |
|  |  | Maintain a register of your process monitoring resources. | | | | | DO | DN | NA |  |
|  |  | | Maintain records that show that monitoring resources are still fit for purpose. | | | | DO | DN | NA |  |
|  |  | | | Control records that show that monitoring resources are still fit for purpose. | | | DO | DN | NA |  |
|  | | | | | | | | | | |
|  | | | | | | | | | | |
|  | | | | | | | | | | |
| Consider each task and select a response. If you haven’t done it and it needs to be done, select DO. If you’ve already done it, select DN. If the task is not applicable in your situation and you can justify and explain why it should be ignored or excluded, select NA.  In the spaces below, please enter the name and location of your organization, who completed this page, who reviewed it, and the dates. | | | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 7.1 PLAN HOW YOU'RE GOING TO CONTROL PROCESS | | | | | | | | | | | | |
| 7.1.1 Consider how to control your process outputs | | | | | | | | | | | | |
|  | Figure out how you're going to control your process outputs. | | | | | | | | DO | DN | NA |  |
|  |  | Consider process output requirements as you develop output controls. | | | | | | | DO | DN | NA |  |
|  |  | | Consider output safety requirements as you develop output controls. | | | | | | DO | DN | NA |  |
|  |  | | | Consider personnel safety requirements as you develop output controls. | | | | | DO | DN | NA |  |
|  |  | | Consider output quality requirements as you develop output controls. | | | | | | DO | DN | NA |  |
|  |  | | | Consider output reliability requirements as you develop output controls. | | | | | DO | DN | NA |  |
|  |  | | | Consider output purity requirements as you develop output controls. | | | | | DO | DN | NA |  |
|  |  | | | | Consider the need to control undesirable foreign objects. | | | | DO | DN | NA |  |
|  |  | | | | | Consider the need to detect undesirable foreign objects. | | | DO | DN | NA |  |
|  |  | | | | | Consider the need to remove undesirable foreign objects. | | | DO | DN | NA |  |
|  |  | | | | | Consider the need to prevent undesirable foreign objects. | | | DO | DN | NA |  |
|  |  | | | Consider output suitability requirements as you develop output controls. | | | | | DO | DN | NA |  |
|  |  | | | | Consider suitability requirements for parts and materials to be used in outputs. | | | | DO | DN | NA |  |
|  |  | | | | Consider suitability requirements for software to be embedded in outputs. | | | | DO | DN | NA |  |
|  |  | | | | | Consider suitability requirements for software that you plan to purchase. | | | DO | DN | NA |  |
|  |  | | | | | Consider suitability requirements for software that you plan to develop. | | | DO | DN | NA |  |
|  |  | | | Consider output maintenance requirements as you develop output controls. | | | | | DO | DN | NA |  |
|  |  | | | | Consider output maintainability requirements as you develop output controls. | | | | DO | DN | NA |  |
|  |  | | Consider output security requirements as you develop output controls. | | | | | | DO | DN | NA |  |
|  |  | | | Consider output handling requirements as you develop output controls. | | | | | DO | DN | NA |  |
|  |  | | | Consider output packaging requirements as you develop output controls. | | | | | DO | DN | NA |  |
|  |  | | | Consider output availability requirements as you develop output controls. | | | | | DO | DN | NA |  |
|  |  | | | Consider output preservation requirements as you develop output controls. | | | | | DO | DN | NA |  |
|  |  | | | Consider output obsolescence requirements as you develop output controls. | | | | | DO | DN | NA |  |
|  |  | | | | Consider output recycling requirements as you develop output controls. | | | | DO | DN | NA |  |
|  |  | | | | Consider output disposal requirements as you develop output controls. | | | | DO | DN | NA |  |
|  |  | | | | | Consider final disposal requirements as you develop output controls. | | | DO | DN | NA |  |
|  |  | | Consider output production requirements as you develop output controls. | | | | | | DO | DN | NA |  |
|  |  | | | Consider output producibility requirements as you develop output controls. | | | | | DO | DN | NA |  |
|  |  | | Consider output measurement requirements as you develop output controls. | | | | | | DO | DN | NA |  |
|  |  | | Consider output monitoring requirements as you develop output controls. | | | | | | DO | DN | NA |  |
|  |  | | | Consider output inspectability requirements as you develop output controls. | | | | | DO | DN | NA |  |
| 7.1.2 Consider how to control your process inputs | | | | | | | | | | | | |
|  | Figure out how you're going to control your process inputs. | | | | | | | | DO | DN | NA |  |
|  |  | Consider process input requirements as you develop input controls. | | | | | | | DO | DN | NA |  |
|  |  | | Consider input safety requirements as you develop input controls. | | | | | | DO | DN | NA |  |
|  |  | | Consider input security requirements as you develop input controls. | | | | | | DO | DN | NA |  |
|  |  | | Consider input quality requirements as you develop input controls. | | | | | | DO | DN | NA |  |
|  |  | | | Consider input reliability requirements as you develop input controls. | | | | | DO | DN | NA |  |
|  |  | | | Consider input purity requirements as you develop input controls. | | | | | DO | DN | NA |  |
|  |  | | | | Consider the need to control foreign objects that could compromise inputs. | | | | DO | DN | NA |  |
|  |  | | | | | Consider the need to detect foreign objects that could compromise inputs. | | | DO | DN | NA |  |
|  |  | | | | | Consider the need to remove foreign objects that could compromise inputs. | | | DO | DN | NA |  |
|  |  | | | | | Consider the need to prevent foreign objects that could compromise inputs. | | | DO | DN | NA |  |
|  |  | | Consider input availability requirements as you develop input controls. | | | | | | DO | DN | NA |  |
|  |  | | Consider input suitability requirements as you develop input controls. | | | | | | DO | DN | NA |  |
|  |  | | | Consider suitability requirements for parts and materials to be used by process. | | | | | DO | DN | NA |  |
|  |  | | | Consider suitability requirements for software programmes to be used by process. | | | | | DO | DN | NA |  |
|  |  | | Consider input storage requirements as you develop input controls. | | | | | | DO | DN | NA |  |
|  |  | | Consider input handling requirements as you develop input controls. | | | | | | DO | DN | NA |  |
|  |  | | Consider input monitoring requirements as you develop input controls. | | | | | | DO | DN | NA |  |
|  |  | | Consider input maintenance requirements as you develop input controls. | | | | | | DO | DN | NA |  |
|  |  | | Consider input measurement requirements as you develop input controls. | | | | | | DO | DN | NA |  |
|  |  | | Consider input preservation requirements as you develop input controls. | | | | | | DO | DN | NA |  |
| 7.1.3 Consider how to control your process activities | | | | | | | | | | | | |
|  | Figure out how you're going to control your process activities. | | | | | | | | DO | DN | NA |  |
|  |  | Consider process safety requirements as you develop process controls. | | | | | | | DO | DN | NA |  |
|  |  | Consider process quality requirements as you develop process controls. | | | | | | | DO | DN | NA |  |
|  |  | Consider process security requirements as you develop process controls. | | | | | | | DO | DN | NA |  |
|  |  | Consider process reliability requirements as you develop process controls. | | | | | | | DO | DN | NA |  |
|  |  | Consider process monitoring requirements as you develop process controls. | | | | | | | DO | DN | NA |  |
|  |  | Consider process measurement requirements as you develop process controls. | | | | | | | DO | DN | NA |  |
|  |  | Consider process improvement requirements as you develop process controls. | | | | | | | DO | DN | NA |  |
|  |  | Consider process maintenance requirements as you develop process controls. | | | | | | | DO | DN | NA |  |
|  |  | Consider process evaluation requirements as you develop process controls. | | | | | | | DO | DN | NA |  |
|  |  | Consider process correction requirements as you develop process controls. | | | | | | | DO | DN | NA |  |
|  |  | Consider process reporting requirements as you develop process controls. | | | | | | | DO | DN | NA |  |
|  |  | Consider process review requirements as you develop process controls. | | | | | | | DO | DN | NA |  |
|  |  | Consider process audit requirements as you develop process controls. | | | | | | | DO | DN | NA |  |
| 7.1.4 Consider how to control your process providers | | | | | | | | | | | | |
|  | Figure out how you're going to control your external providers. | | | | | | | | DO | DN | NA |  |
|  |  | Consider the requirements that external process providers must meet. | | | | | | | DO | DN | NA |  |
|  |  | Consider the requirements that external product providers must meet. | | | | | | | DO | DN | NA |  |
|  |  | Consider the requirements that external service providers must meet. | | | | | | | DO | DN | NA |  |
|  | Figure out how you're going to control your internal providers. | | | | | | | | DO | DN | NA |  |
|  |  | Consider the requirements that internal process providers must meet. | | | | | | | DO | DN | NA |  |
|  |  | Consider the requirements that internal product providers must meet. | | | | | | | DO | DN | NA |  |
|  |  | Consider the requirements that internal service providers must meet. | | | | | | | DO | DN | NA |  |
| 7.2 DEVELOP WAYS OF CONTROLLING YOUR PROCESS | | | | | | | | | | | | |
| 7.2.1 Develop ways of controlling process elements | | | | | | | | | | | | |
|  | Develop controlled conditions for process outputs. | | | | | | | | DO | DN | NA |  |
|  |  | Develop ways of controlling your process outputs. | | | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling the quality of process outputs. | | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of controlling the reliability of process outputs. | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of controlling the suitability of process outputs. | | | | | DO | DN | NA |  |
|  |  | | | | Develop ways of controlling the suitability of parts and materials to be used in outputs. | | | | DO | DN | NA |  |
|  |  | | | | Develop ways of controlling the suitability of software to be embedded into outputs. | | | | DO | DN | NA |  |
|  |  | | | | | Develop ways of controlling the suitability of software that you plan to purchase. | | | DO | DN | NA |  |
|  |  | | | | | Develop ways of controlling the suitability of software that you plan to develop. | | | DO | DN | NA |  |
|  |  | | | Develop ways of controlling the purity of process outputs. | | | | | DO | DN | NA |  |
|  |  | | | | Develop ways of controlling foreign objects that could affect your outputs. | | | | DO | DN | NA |  |
|  |  | | | | | Develop ways of detecting foreign objects that could compromise quality of outputs. | | | DO | DN | NA |  |
|  |  | | | | | Develop ways of removing foreign objects that could compromise quality of outputs. | | | DO | DN | NA |  |
|  |  | | | | | Develop ways of preventing foreign objects that could compromise quality of outputs. | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling the safety of outputs. | | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of ensuring that outputs can be safely produced. | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of ensuring that outputs can be safely packaged. | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of ensuring that outputs can be safely delivered. | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of ensuring that outputs can be safely handled. | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of ensuring that outputs can be safely stored. | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of ensuring that outputs can be safely used. | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of ensuring that outputs can be safely repaired. | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of ensuring that outputs can be safely maintained. | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of ensuring that outputs can be safely preserved. | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of ensuring that outputs can be safely destroyed. | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of ensuring that outputs can be safely recycled. | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling the security of outputs. | | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of ensuring that outputs can be securely produced. | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of ensuring that outputs can be securely packaged. | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of ensuring that outputs can be securely delivered. | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of ensuring that outputs can be securely handled. | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of ensuring that outputs can be securely stored. | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of ensuring that outputs can be securely used. | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of ensuring that outputs can be securely repaired. | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of ensuring that outputs can be securely maintained. | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of ensuring that outputs can be securely preserved. | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of ensuring that outputs can be securely destroyed. | | | | | DO | DN | NA |  |
|  | Develop controlled conditions for process inputs. | | | | | | | | DO | DN | NA |  |
|  |  | Develop ways of controlling your process inputs. | | | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling the quality of process inputs. | | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of controlling the purity of process inputs. | | | | | DO | DN | NA |  |
|  |  | | | | Develop ways of controlling foreign objects that compromise the quality of inputs. | | | | DO | DN | NA |  |
|  |  | | | | | Develop ways of detecting foreign objects that compromise the quality of inputs. | | | DO | DN | NA |  |
|  |  | | | | | Develop ways of removing foreign objects that compromise the quality of inputs. | | | DO | DN | NA |  |
|  |  | | | | | Develop ways of preventing foreign objects that compromise the quality of inputs. | | | DO | DN | NA |  |
|  |  | | | Develop ways of controlling the suitability of process inputs. | | | | | DO | DN | NA |  |
|  |  | | | | Develop ways of controlling the suitability of parts and materials to be used as inputs. | | | | DO | DN | NA |  |
|  |  | | | | Develop ways of controlling the suitability of software that is embedded in inputs. | | | | DO | DN | NA |  |
|  |  | | | Develop ways of controlling the acceptability of process inputs. | | | | | DO | DN | NA |  |
|  |  | | | | Develop acceptance criteria for your process inputs. | | | | DO | DN | NA |  |
|  |  | | | | | Develop methods and procedures for testing process inputs. | | | DO | DN | NA |  |
|  |  | | | | | Develop methods and procedures for inspecting process inputs. | | | DO | DN | NA |  |
|  |  | | | | | Develop methods and procedures for monitoring process inputs. | | | DO | DN | NA |  |
|  |  | | | | | Develop methods and procedures for measuring process inputs. | | | DO | DN | NA |  |
|  |  | | | | | Develop methods and procedures for evaluating process inputs. | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling the security of process inputs. | | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling the safety of process inputs. | | | | | | DO | DN | NA |  |
|  | Develop controlled conditions for process activities. | | | | | | | | DO | DN | NA |  |
|  |  | Develop ways of controlling your process activities. | | | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling process testing activities. | | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling process control activities. | | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling process inspection activities. | | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling process management activities. | | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling process measurement activities. | | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling process maintenance activities. | | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling process production activities. | | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling process monitoring activities. | | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling process evaluation activities. | | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of controlling process audit activities. | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of controlling process review activities. | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling process modification activities. | | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of controlling process correction activities. | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of controlling process improvement activities. | | | | | DO | DN | NA |  |
|  | Develop controlled conditions for process programmes. | | | | | | | | DO | DN | NA |  |
|  |  | Develop ways of controlling your risk management programme. | | | | | | | DO | DN | NA |  |
|  |  | Develop ways of controlling your safety management programme. | | | | | | | DO | DN | NA |  |
|  |  | Develop ways of controlling your quality management programme. | | | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling your configuration management programme. | | | | | | DO | DN | NA |  |
|  |  | Develop ways of controlling your security management programme. | | | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling your personnel security management programme. | | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling your information security management programme. | | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling your component security management programme. | | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of controlling your counterfeit parts management programme. | | | | | DO | DN | NA |  |
|  |  | Develop ways of controlling your supplier management programme. | | | | | | | DO | DN | NA |  |
|  |  | Develop ways of controlling your environmental management programme. | | | | | | | DO | DN | NA |  |
|  |  | Develop ways of controlling your business continuity management programme. | | | | | | | DO | DN | NA |  |
| 7.2.2 Develop ways of controlling process providers | | | | | | | | | | | | |
|  | Develop ways of controlling external providers. | | | | | | | | DO | DN | NA |  |
|  |  | Plan how to control external processes, products, and services. | | | | | | | DO | DN | NA |  |
|  |  | | Consider the potential impact that externally provided processes, products, and services could have on your ability to consistently meet external requirements. | | | | | | DO | DN | NA |  |
|  |  | | | Consider the potential impact on your ability to meet customer requirements. | | | | | DO | DN | NA |  |
|  |  | | | | Consider the potential impact on statutory and regulatory requirements. | | | | DO | DN | NA |  |
|  |  | | Consider the controls that external process, product, and service providers  have implemented and think about how effective their controls actually are. | | | | | | DO | DN | NA |  |
|  |  | Create controls for external processes, products, and services. | | | | | | | DO | DN | NA |  |
|  |  | | Develop controls for processes that your organization is outsourcing. | | | | | | DO | DN | NA |  |
|  |  | | | Ensure that outsourced processes remain within your organization's control. | | | | | DO | DN | NA |  |
|  |  | | | | Figure out how you're going to control external process providers. | | | | DO | DN | NA |  |
|  |  | | | | | Consider the potential impact that external process providers could have  on your ability to consistently meet customer and legal requirements. | | | DO | DN | NA |  |
|  |  | | | | | Consider the controls that external process providers have implemented  and think about how effective their controls really are in practice. | | | DO | DN | NA |  |
|  |  | | Develop controls for products that your organization is outsourcing. | | | | | | DO | DN | NA |  |
|  |  | | | Ensure that outsourced products remain within your organization's control. | | | | | DO | DN | NA |  |
|  |  | | | | Figure out how you're going to control external product providers. | | | | DO | DN | NA |  |
|  |  | | | | | Consider the potential impact that external product providers could have  on your ability to consistently meet customer and legal requirements. | | | DO | DN | NA |  |
|  |  | | | | | Consider the controls that external product providers have implemented  and think about how effective their controls really are in practice. | | | DO | DN | NA |  |
|  |  | | Develop controls for services that your organization is outsourcing. | | | | | | DO | DN | NA |  |
|  |  | | | Ensure that outsourced services remain within your organization's control. | | | | | DO | DN | NA |  |
|  |  | | | | Figure out how you're going to control external service providers. | | | | DO | DN | NA |  |
|  |  | | | | | Consider the potential impact that external service providers could have  on your ability to consistently meet customer and legal requirements. | | | DO | DN | NA |  |
|  |  | | | | | Consider the controls that external service providers have implemented  and think about how effective their controls really are in practice. | | | DO | DN | NA |  |
|  |  | Design external process, product, and service verification methods. | | | | | | | DO | DN | NA |  |
|  |  | | Plan your external process, product, and service verification activities. | | | | | | DO | DN | NA |  |
|  |  | | | Define the scope and extent of external verification and testing activities. | | | | | DO | DN | NA |  |
|  |  | | | | Define requirements whenever verifications are delegated to external providers. | | | | DO | DN | NA |  |
|  |  | | | | | Maintain a register of verification activities delegated to external providers. | | | DO | DN | NA |  |
|  |  | | | Consider risks when you carry out external verification and testing activities. | | | | | DO | DN | NA |  |
|  |  | | | | Consider the risk of external process, product, and service nonconformities. | | | | DO | DN | NA |  |
|  |  | | | | | Consider the risk that counterfeit parts and components are being used. | | | DO | DN | NA |  |
|  |  | | | | | Consider the risk that raw materials might fail to meet requirements. | | | DO | DN | NA |  |
|  |  | | | Use objective evidence to verify external processes, products, and services. | | | | | DO | DN | NA |  |
|  |  | | | | Use documents and records to verify processes, products, and services. | | | | DO | DN | NA |  |
|  |  | | | | | Examine related test documents and records. | | | DO | DN | NA |  |
|  |  | | | | | Examine related statistical documents and records. | | | DO | DN | NA |  |
|  |  | | | | | Examine related process control documents and records. | | | DO | DN | NA |  |
|  |  | | | | | Examine related conformance documents and records. | | | DO | DN | NA |  |
|  |  | | | | | | Examine the associated certificates of conformity. | | DO | DN | NA |  |
|  |  | | | | | Examine related production documents and records. | | | DO | DN | NA |  |
|  |  | | | | | | Review production verification activities and results. | | DO | DN | NA |  |
|  |  | | | | | | | Assess any changes to production process activities. | DO | DN | NA |  |
|  |  | | | | | | Review data related to production part approval process. | | DO | DN | NA |  |
|  |  | | Develop a process to evaluate the accuracy of test data and test reports. | | | | | | DO | DN | NA |  |
|  |  | | | Validate test data when it is used to verify externally provided products. | | | | | DO | DN | NA |  |
|  |  | | | | Evaluate and validate the accuracy of test data and test reports whenever  they are used to confirm that externally provided products meet requirements. | | | | DO | DN | NA |  |
|  |  | | | | Evaluate and validate the accuracy of test data and test reports whenever a customer or an organization has identified raw material as a “critical item”  or a significant operational risk. | | | | DO | DN | NA |  |
|  | Develop ways of controlling internal providers. | | | | | | | | DO | DN | NA |  |
|  |  | Plan how to control internal processes, products, and services. | | | | | | | DO | DN | NA |  |
|  |  | | Consider the potential impact that internally provided processes, products, and services could have on your ability to consistently meet internal requirements. | | | | | | DO | DN | NA |  |
|  |  | | | Consider the potential impact on your ability to meet customer requirements. | | | | | DO | DN | NA |  |
|  |  | | | | Consider the potential impact on statutory and regulatory requirements. | | | | DO | DN | NA |  |
|  |  | | Consider the controls that internal process, product, and service providers  have implemented and think about how effective their controls actually are. | | | | | | DO | DN | NA |  |
|  |  | Create controls for internal processes, products, and services. | | | | | | | DO | DN | NA |  |
|  |  | Design internal process, product, and service verification methods. | | | | | | | DO | DN | NA |  |
|  |  | | Plan your internal process, product, and service verification activities. | | | | | | DO | DN | NA |  |
|  |  | | | Define the scope and extent of internal verification and testing activities. | | | | | DO | DN | NA |  |
|  |  | | | Consider risks when you carry out internal verification and testing activities. | | | | | DO | DN | NA |  |
|  |  | | | Use objective evidence to verify internal processes, products, and services. | | | | | DO | DN | NA |  |
|  |  | | Develop a process to evaluate the accuracy of test data and test reports. | | | | | | DO | DN | NA |  |
| 7.3 PROVIDE RESOURCES NEEDED TO CONTROL PROCESS | | | | | | | | | | | | |
|  | Provide the people that are needed in order to control your process. | | | | | | | | DO | DN | NA |  |
|  | Provide the training that is needed in order to control your process. | | | | | | | | DO | DN | NA |  |
|  | Provide the policies that are needed in order to control your process. | | | | | | | | DO | DN | NA |  |
|  | Provide the knowledge that is needed in order to control your process. | | | | | | | | DO | DN | NA |  |
|  | Provide the procedures that are needed in order to control your process. | | | | | | | | DO | DN | NA |  |
|  | Provide the technologies that are needed in order to control your process. | | | | | | | | DO | DN | NA |  |
|  | Provide the methodologies that are needed in order to control your process. | | | | | | | | DO | DN | NA |  |
|  | Provide the infrastructure that is needed in order to control your process. | | | | | | | | DO | DN | NA |  |
| 7.4 USE AUTHORIZED METHODS TO CONTROL PROCESS | | | | | | | | | | | | |
| 7.4.1 Use authorized methods to control process inputs | | | | | | | | | | | | |
|  | Control the unique identity of your process inputs. | | | | | | | | DO | DN | NA |  |
|  |  | Establish suitable means for identifying your process inputs. | | | | | | | DO | DN | NA |  |
|  |  | Specify the identity of inputs when conformity must be ensured. | | | | | | | DO | DN | NA |  |
|  |  | | Identify inputs whenever input conformity must be ensured. | | | | | | DO | DN | NA |  |
|  |  | | Identify the monitoring and measurement status of inputs. | | | | | | DO | DN | NA |  |
|  |  | Record the identity of inputs when traceability is a requirement. | | | | | | | DO | DN | NA |  |
|  |  | | Clarify your organization's specific input traceability requirements. | | | | | | DO | DN | NA |  |
|  |  | | Retain the documents and records that are needed to facilitate traceability. | | | | | | DO | DN | NA |  |
|  | Make arrangements to verify inputs at appropriate stages. | | | | | | | | DO | DN | NA |  |
|  |  | Verify that input requirements were met at all appropriate stages. | | | | | | | DO | DN | NA |  |
|  |  | | Retain evidence that shows that input acceptance criteria were met. | | | | | | DO | DN | NA |  |
|  |  | | Retain evidence that shows that your input meets defined requirements. | | | | | | DO | DN | NA |  |
|  |  | Identify the people who may authorize the release of inputs for production. | | | | | | | DO | DN | NA |  |
|  |  | | Retain and control records to facilitate traceability of input releases. | | | | | | DO | DN | NA |  |
|  |  | Release inputs only if verifications are finished or if authorized to do so. | | | | | | | DO | DN | NA |  |
|  | Verify that your input acceptance criteria are being met. | | | | | | | | DO | DN | NA |  |
|  |  | Verify acceptance before inputs are officially released. | | | | | | | DO | DN | NA |  |
|  |  | | Establish a record of your input acceptance activities. | | | | | | DO | DN | NA |  |
|  |  | | | Document your criteria for input acceptance and rejection. | | | | | DO | DN | NA |  |
|  |  | | | Document where in the sequence input verification is performed. | | | | | DO | DN | NA |  |
|  |  | | | Document and retain your input monitoring and measuring results. | | | | | DO | DN | NA |  |
|  |  | | | | Maintain a record of input acceptance and rejection activities. | | | | DO | DN | NA |  |
|  |  | | | Document how input monitoring and measuring must be carried out. | | | | | DO | DN | NA |  |
|  |  | | | | Document all required input monitoring and measuring instructions. | | | | DO | DN | NA |  |
|  |  | | | | Document all required input monitoring and measuring equipment. | | | | DO | DN | NA |  |
|  |  | Verify that critical input items are being controlled. | | | | | | | DO | DN | NA |  |
|  |  | | Control critical input items in accordance with established methods. | | | | | | DO | DN | NA |  |
|  |  | Verify that key input characteristics are being controlled. | | | | | | | DO | DN | NA |  |
|  |  | | Control key input characteristics in accordance with established methods. | | | | | | DO | DN | NA |  |
|  |  | Verify that inputs being used in the process are being controlled. | | | | | | | DO | DN | NA |  |
|  |  | | Identify and record purchased products (inputs) that are released for use in  your process whenever verification activities have not yet been completed. | | | | | | DO | DN | NA |  |
|  |  | | | Use your records to recall and replace purchased products (inputs)  that have been used but do not actually meet requirements. | | | | | DO | DN | NA |  |
|  |  | Verify that all input inspection and verification activities have been completed. | | | | | | | DO | DN | NA |  |
|  |  | | Maintain a record of your input inspection and verification activities and results. | | | | | | DO | DN | NA |  |
|  |  | | | Use records to show that all input inspections and verifications were completed. | | | | | DO | DN | NA |  |
| 7.4.2 Use authorized methods to control process outputs | | | | | | | | | | | | |
|  | Control output design and development activities. | | | | | | | | DO | DN | NA |  |
|  |  | Control how output design and development results are defined. | | | | | | | DO | DN | NA |  |
|  |  | Control how output design and development reviews are carried out. | | | | | | | DO | DN | NA |  |
|  |  | | Ask representatives from all relevant functions to participate in reviews. | | | | | | DO | DN | NA |  |
|  |  | | | Include people concerned with the design and development stage under review. | | | | | DO | DN | NA |  |
|  |  | | | | Evaluate how well design and development results meet requirements. | | | | DO | DN | NA |  |
|  |  | | | | | Control actions taken to address problems identified during reviews. | | | DO | DN | NA |  |
|  |  | Control how output design and development verifications are performed. | | | | | | | DO | DN | NA |  |
|  |  | | Verify that design and development outputs meet input requirements. | | | | | | DO | DN | NA |  |
|  |  | | | Control actions taken to address problems identified during verifications. | | | | | DO | DN | NA |  |
|  |  | Control how output design and development validations are performed. | | | | | | | DO | DN | NA |  |
|  |  | | Confirm that your outputs meet intended use requirements. | | | | | | DO | DN | NA |  |
|  |  | | | Verify that all intended use or application requirements are being met. | | | | | DO | DN | NA |  |
|  |  | | | | Control actions taken to address problems identified during validations. | | | | DO | DN | NA |  |
|  |  | | | Reverify your outputs if changes occur that invalidate previous results. | | | | | DO | DN | NA |  |
|  |  | Control how output design and development progression is authorized. | | | | | | | DO | DN | NA |  |
|  |  | | Control progression to the next stage of output design and development. | | | | | | DO | DN | NA |  |
|  |  | Control how output design and development work is documented. | | | | | | | DO | DN | NA |  |
|  |  | | Control output design and development documents and records. | | | | | | DO | DN | NA |  |
|  | Control outputs while process is being carried out. | | | | | | | | DO | DN | NA |  |
|  |  | Establish suitable means and methods for identifying process outputs. | | | | | | | DO | DN | NA |  |
|  |  | | Control how acceptance authority media are used to identify outputs. | | | | | | DO | DN | NA |  |
|  |  | Specify the identity of outputs whenever conformity must be ensured. | | | | | | | DO | DN | NA |  |
|  |  | | Identify outputs whenever output conformity must be ensured. | | | | | | DO | DN | NA |  |
|  |  | | | Establish the specific identity of your output configurations. | | | | | DO | DN | NA |  |
|  |  | | | | Specify the unique identity of all required output configurations. | | | | DO | DN | NA |  |
|  |  | | | | Specify the unique identity of all actual output configurations. | | | | DO | DN | NA |  |
|  |  | | | Maintain the unique identity of your output configurations. | | | | | DO | DN | NA |  |
|  |  | | | | Determine differences between required and actual configurations. | | | | DO | DN | NA |  |
|  |  | | Identify the monitoring and measurement status of outputs throughout production. | | | | | | DO | DN | NA |  |
|  |  | Record the unique identity of outputs when traceability is a requirement. | | | | | | | DO | DN | NA |  |
|  |  | | Clarify your organization's unique output traceability requirements. | | | | | | DO | DN | NA |  |
|  |  | | | Consider whether identities must be maintained throughout output life cycle. | | | | | DO | DN | NA |  |
|  |  | | | | Consider whether or not you need to be able to trace outputs  generated from the same inputs to the final destination. | | | | DO | DN | NA |  |
|  |  | | | | Consider whether or not you need to maintain a sequential  production record for your outputs so that they can be retrieved. | | | | DO | DN | NA |  |
|  |  | | | | | Consider whether or not you need to maintain a sequential assembly record. | | | DO | DN | NA |  |
|  |  | | | | | Consider whether or not you need to maintain a sequential inspection record. | | | DO | DN | NA |  |
|  |  | | | | | Consider whether or not you need to maintain a sequential verification record. | | | DO | DN | NA |  |
|  |  | | | | | Consider whether or not you need to maintain a sequential manufacturing record. | | | DO | DN | NA |  |
|  |  | | | Consider whether components need to be traceable to final assemblies. | | | | | DO | DN | NA |  |
|  |  | | | | Consider whether or not you need to be able to trace components  to an assembly and from that assembly to the next higher assembly. | | | | DO | DN | NA |  |
|  |  | | Retain the documents and records that are needed to facilitate traceability. | | | | | | DO | DN | NA |  |
|  |  | Verify that input items, characteristics, and activities are being controlled. | | | | | | | DO | DN | NA |  |
|  |  | | Verify that “critical items” and “key characteristics” are being controlled. | | | | | | DO | DN | NA |  |
|  |  | | | Control identified “critical items” in accordance with established methods. | | | | | DO | DN | NA |  |
|  |  | | | | Control “key characteristics” in accordance with established methods. | | | | DO | DN | NA |  |
|  |  | | Verify that inputs being used in the process are being controlled. | | | | | | DO | DN | NA |  |
|  |  | | | Identify and record purchased products (inputs) that are released for use in  your process whenever verification activities have not yet been completed. | | | | | DO | DN | NA |  |
|  |  | | | | Use your records to recall and replace purchased products (inputs)  that have been used but do not actually meet requirements. | | | | DO | DN | NA |  |
|  |  | | Verify that all inspection and verification activities have been completed. | | | | | | DO | DN | NA |  |
|  |  | | | Maintain a record of your inspection and verification activities and results. | | | | | DO | DN | NA |  |
|  |  | | | | Use records to show that all inspections and verifications were completed. | | | | DO | DN | NA |  |
|  | Control how outputs are officially released. | | | | | | | | DO | DN | NA |  |
|  |  | Verify acceptance before outputs are officially released. | | | | | | | DO | DN | NA |  |
|  |  | | Implement arrangements to verify your process outputs. | | | | | | DO | DN | NA |  |
|  |  | | | Verify that output requirements were met at all appropriate stages. | | | | | DO | DN | NA |  |
|  |  | | | | Retain evidence that shows that output acceptance criteria were met. | | | | DO | DN | NA |  |
|  |  | | | | Retain evidence that shows that your output meets defined requirements. | | | | DO | DN | NA |  |
|  |  | | | Identify the people who may authorize the release of outputs to process customers. | | | | | DO | DN | NA |  |
|  |  | | | | Retain and control records to facilitate the traceability of output releases. | | | | DO | DN | NA |  |
|  |  | | | Release outputs only if verifications are finished or if authorized to do so. | | | | | DO | DN | NA |  |
|  |  | | | | Release output to process customers only if planned arrangements were completed or the customer or a relevant authority allows you to do so. | | | | DO | DN | NA |  |
|  |  | | | | Release outputs only if all the documents and records that should  accompany output delivery are, in fact, present at delivery. | | | | DO | DN | NA |  |
|  |  | | Use sampling to see if outputs are acceptable (when applicable). | | | | | | DO | DN | NA |  |
|  |  | | | Use recognized statistical principles to justify your sampling plans. | | | | | DO | DN | NA |  |
|  |  | | | | Make sure that your sampling plans are appropriate for use. | | | | DO | DN | NA |  |
|  |  | | | | | Make sure that sampling plans consider process capability. | | | DO | DN | NA |  |
|  |  | | | | | Make sure that sampling plans consider the criticality of the output. | | | DO | DN | NA |  |
|  |  | | Establish a record of your output acceptance activities. | | | | | | DO | DN | NA |  |
|  |  | | | Document your criteria for output acceptance and rejection. | | | | | DO | DN | NA |  |
|  |  | | | Document where in the sequence output verification is performed. | | | | | DO | DN | NA |  |
|  |  | | | Document and retain your output monitoring and measuring results. | | | | | DO | DN | NA |  |
|  |  | | | | Maintain a record of output acceptance and rejection activities. | | | | DO | DN | NA |  |
|  |  | | | Document how output monitoring and measuring must be carried out. | | | | | DO | DN | NA |  |
|  |  | | | | Document all required output monitoring and measuring instructions. | | | | DO | DN | NA |  |
|  |  | | | | Document all required output monitoring and measuring equipment. | | | | DO | DN | NA |  |
| 7.4.3 Use authorized methods to control process activities | | | | | | | | | | | | |
|  | Use authorized methods to control normal process activities. | | | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to control process control activities. | | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to control process management activities. | | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to control process maintenance activities. | | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to control process measurement activities. | | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to control process monitoring activities. | | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to control process evaluation activities. | | | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to control process audit activities. | | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to control process review activities. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to control process modification activities. | | | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to control process correction activities. | | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to control process improvement activities. | | | | | | DO | DN | NA |  |
|  | Use authorized methods to control “special process” activities. | | | | | | | | DO | DN | NA |  |
|  |  | Establish methods for managing “special process” activities. | | | | | | | DO | DN | NA |  |
|  |  | | Validate “special process” activities and results. | | | | | | DO | DN | NA |  |
|  |  | | | Validate your ability to achieve planned results whenever outputs  cannot be verified by subsequent monitoring or measurement. | | | | | DO | DN | NA |  |
|  |  | | | | Identify in-process inspection and verification points whenever adequate verification of conformity cannot be performed at subsequent stages. | | | | DO | DN | NA |  |
|  |  | | Control “special process” activities and results. | | | | | | DO | DN | NA |  |
|  |  | | | Make arrangements to control special process activities. | | | | | DO | DN | NA |  |
|  |  | | | | Use criteria to control your special process activities. | | | | DO | DN | NA |  |
|  |  | | | | | Use criteria to control how special activities are reviewed. | | | DO | DN | NA |  |
|  |  | | | | | | Use criteria to control how special activities are approved. | | DO | DN | NA |  |
|  |  | | | | | | | Specify the conditions that must be met in order to maintain these approvals. | DO | DN | NA |  |
|  |  | | | | Use approvals to control your special process activities. | | | | DO | DN | NA |  |
|  |  | | | | | Approve equipment before it is used by special process activities. | | | DO | DN | NA |  |
|  |  | | | | | Approve facilities before they are used by special process activities. | | | DO | DN | NA |  |
|  |  | | | | | Approve personnel before they are assigned to special process activities. | | | DO | DN | NA |  |
|  |  | | | | | | Approve their qualifications before assigning them to special process activities. | | DO | DN | NA |  |
|  |  | | | | Use procedures to control your special process activities. | | | | DO | DN | NA |  |
|  |  | | | | | Follow specific procedures when implementing special process activities. | | | DO | DN | NA |  |
|  |  | | | | | Follow specific procedures when maintaining special process activities. | | | DO | DN | NA |  |
|  |  | | | | | Follow specific procedures when monitoring special process activities. | | | DO | DN | NA |  |
|  |  | | | | | Follow specific procedures when measuring special process activities. | | | DO | DN | NA |  |
|  |  | | | | | Follow specific procedures when controlling special process activities. | | | DO | DN | NA |  |
|  |  | | | | Use methods to control your special process activities. | | | | DO | DN | NA |  |
|  |  | | | | | Follow specific methods when implementing special process activities. | | | DO | DN | NA |  |
|  |  | | | | | Follow specific methods when maintaining special process activities. | | | DO | DN | NA |  |
|  |  | | | | | Follow specific methods when monitoring special process activities. | | | DO | DN | NA |  |
|  |  | | | | | Follow specific methods when measuring special process activities. | | | DO | DN | NA |  |
|  |  | | | | | Follow specific methods when controlling special process activities. | | | DO | DN | NA |  |
|  |  | | | | Use documents to control your special process activities. | | | | DO | DN | NA |  |
|  |  | | | | | Specify retention requirements for these documents. | | | DO | DN | NA |  |
|  |  | | | | Use records to control your special process activities. | | | | DO | DN | NA |  |
|  |  | | | | | Specify retention requirements for these records. | | | DO | DN | NA |  |
| 7.4.4 Use authorized methods to control process technology | | | | | | | | | | | | |
|  | Control process equipment, tools, and software programmes. | | | | | | | | DO | DN | NA |  |
|  |  | Validate technology prior to final release for process operations. | | | | | | | DO | DN | NA |  |
|  |  | | Validate technology that is used to perform process operations. | | | | | | DO | DN | NA |  |
|  |  | | | Validate tools before they are used to perform process operations. | | | | | DO | DN | NA |  |
|  |  | | | Validate equipment before it is used to perform process operations. | | | | | DO | DN | NA |  |
|  |  | | | Validate software before it is used to perform process operations. | | | | | DO | DN | NA |  |
|  |  | | Validate technology that is used to automate process operations. | | | | | | DO | DN | NA |  |
|  |  | | | Validate tools before they are used to automate process operations. | | | | | DO | DN | NA |  |
|  |  | | | Validate equipment before it is used to automate process operations. | | | | | DO | DN | NA |  |
|  |  | | | Validate software before it is used to automate process operations. | | | | | DO | DN | NA |  |
|  |  | | Validate technology that is used to maintain process operations. | | | | | | DO | DN | NA |  |
|  |  | | | Validate tools before they are used to maintain process operations. | | | | | DO | DN | NA |  |
|  |  | | | Validate equipment before it is used to maintain process operations. | | | | | DO | DN | NA |  |
|  |  | | | Validate software before it is used to maintain process operations. | | | | | DO | DN | NA |  |
|  |  | | Validate technology that is used to monitor process operations. | | | | | | DO | DN | NA |  |
|  |  | | | Validate tools before they are used to monitor process operations. | | | | | DO | DN | NA |  |
|  |  | | | Validate equipment before it is used to monitor process operations. | | | | | DO | DN | NA |  |
|  |  | | | Validate software before it is used to monitor process operations. | | | | | DO | DN | NA |  |
|  |  | | Validate technology that is used to measure process operations. | | | | | | DO | DN | NA |  |
|  |  | | | Validate tools before they are used to measure process operations. | | | | | DO | DN | NA |  |
|  |  | | | Validate equipment before it is used to measure process operations. | | | | | DO | DN | NA |  |
|  |  | | | Validate software before it is used to measure process operations. | | | | | DO | DN | NA |  |
|  |  | | Validate technology that is used to control process operations. | | | | | | DO | DN | NA |  |
|  |  | | | Validate tools before they are used to control process operations. | | | | | DO | DN | NA |  |
|  |  | | | Validate equipment before it is used to control process operations. | | | | | DO | DN | NA |  |
|  |  | | | Validate software before it is used to control process operations. | | | | | DO | DN | NA |  |
| 7.4.5 Use authorized methods to control process programmes | | | | | | | | | | | | |
|  | Use authorized methods to control risk management programme. | | | | | | | | DO | DN | NA |  |
|  | Use authorized methods to control safety management programme. | | | | | | | | DO | DN | NA |  |
|  | Use authorized methods to control quality management programme. | | | | | | | | DO | DN | NA |  |
|  | Use authorized methods to control security management programme. | | | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to control personnel security management programme. | | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to control information security management programme. | | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to control component security management programme. | | | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to control your counterfeit parts programme. | | | | | | DO | DN | NA |  |
|  | Use authorized methods to control supplier management programme. | | | | | | | | DO | DN | NA |  |
|  | Use authorized methods to control environmental management programme. | | | | | | | | DO | DN | NA |  |
|  | Use authorized methods to control business continuity management programme. | | | | | | | | DO | DN | NA |  |
| 7.4.6 Use authorized methods to control process performance | | | | | | | | | | | | |
|  | Use authorized methods to control internal personnel. | | | | | | | | DO | DN | NA |  |
|  |  | Identify the people who can affect process performance. | | | | | | | DO | DN | NA |  |
|  |  | Qualify the people who can affect process performance. | | | | | | | DO | DN | NA |  |
|  |  | | Make sure that they have the competence they need. | | | | | | DO | DN | NA |  |
|  |  | | | Make sure that they have the appropriate training. | | | | | DO | DN | NA |  |
|  |  | | | Make sure that they have the appropriate education. | | | | | DO | DN | NA |  |
|  |  | | | Make sure that they have the appropriate experience. | | | | | DO | DN | NA |  |
|  |  | Supervise the people who can affect process performance. | | | | | | | DO | DN | NA |  |
|  | Use authorized methods to control external providers. | | | | | | | | DO | DN | NA |  |
|  |  | Establish control of all externally provided processes, products, and services. | | | | | | | DO | DN | NA |  |
|  |  | | Ensure that external processes, products, and services meet requirements. | | | | | | DO | DN | NA |  |
|  |  | | | Ensure that externally provided products and services meet  requirements if they are incorporated into your process outputs. | | | | | DO | DN | NA |  |
|  |  | | | | Ensure that externally provided products and services meet requirements  if external providers deliver them directly to your process customers. | | | | DO | DN | NA |  |
|  |  | | | Ensure that externally provided processes and functions meet requirements. | | | | | DO | DN | NA |  |
|  |  | | | | Ensure that outsourced parts of processes and functions meet requirements. | | | | DO | DN | NA |  |
|  |  | Control the use of externally provided processes, products, and services. | | | | | | | DO | DN | NA |  |
|  |  | | Use customer-designated or customer-approved external providers if required. | | | | | | DO | DN | NA |  |
|  |  | | | Use customer-designated or customer-approved external process sources. | | | | | DO | DN | NA |  |
|  |  | | | | Use customer-designated or customer-approved “special processes”. | | | | DO | DN | NA |  |
|  |  | | Manage risks associated with the selection and use of external providers. | | | | | | DO | DN | NA |  |
|  |  | | | Manage risks related to externally provided processes, products, and services. | | | | | DO | DN | NA |  |
|  |  | | Tell external providers to control their direct and sub-tier external providers. | | | | | | DO | DN | NA |  |
|  |  | | | Tell your providers to ensure that their own providers meet requirements. | | | | | DO | DN | NA |  |
|  |  | Perform external process, product, and service verification activities. | | | | | | | DO | DN | NA |  |
|  |  | | Carry out product inspections and service verifications upon receipt. | | | | | | DO | DN | NA |  |
|  |  | | | Carry out periodic inspections and audits at external provider's premises. | | | | | DO | DN | NA |  |
|  |  | Accept external processes, products, and services only if they meet requirements. | | | | | | | DO | DN | NA |  |
|  |  | | Complete verifications before processes, products, and services are accepted. | | | | | | DO | DN | NA |  |
|  |  | | | Complete all verifications before accepting products for use in production. | | | | | DO | DN | NA |  |
|  |  | | | | Identify externally provided products that were released for use in production. | | | | DO | DN | NA |  |
|  |  | | | | | Record externally provided products that have been released for use  in production pending completion of required verification activities. | | | DO | DN | NA |  |
|  |  | | | | Recall and replace product if it subsequently fails to meet requirements. | | | | DO | DN | NA |  |
| 7.4.7 Use authorized methods to control process documentation | | | | | | | | | | | | |
|  | Control how process documents and records are controlled. | | | | | | | | DO | DN | NA |  |
|  |  | Control how process documents and records are created. | | | | | | | DO | DN | NA |  |
|  |  | | Make sure that process documents and records are suitable for use. | | | | | | DO | DN | NA |  |
|  |  | | | Make sure that documents and records are properly identified and described. | | | | | DO | DN | NA |  |
|  |  | | | | Make sure that they have the right names and descriptive titles. | | | | DO | DN | NA |  |
|  |  | | | | Make sure that they have the right dates and reference numbers. | | | | DO | DN | NA |  |
|  |  | | | Make sure that documents and records are properly formatted and presented. | | | | | DO | DN | NA |  |
|  |  | | | | Make sure that process documents and records use the appropriate media. | | | | DO | DN | NA |  |
|  |  | | | | Make sure that process documents and records use the appropriate graphics. | | | | DO | DN | NA |  |
|  |  | | | | Make sure that process documents and records use the appropriate language. | | | | DO | DN | NA |  |
|  |  | | | | Make sure that process documents and records use the appropriate software. | | | | DO | DN | NA |  |
|  |  | Control how process documents and records are identified. | | | | | | | DO | DN | NA |  |
|  |  | | Control how internal documents and records are identified and described. | | | | | | DO | DN | NA |  |
|  |  | | Control how external documents and records are identified and described. | | | | | | DO | DN | NA |  |
|  |  | Control how process documents and records are distributed. | | | | | | | DO | DN | NA |  |
|  |  | Control how process documents and records are stored. | | | | | | | DO | DN | NA |  |
|  |  | Control how process documents and records are retrieved. | | | | | | | DO | DN | NA |  |
|  |  | Control how process documents and records are accessed. | | | | | | | DO | DN | NA |  |
|  |  | | Prevent unauthorized access to documents and records. | | | | | | DO | DN | NA |  |
|  |  | | | Make sure that documents and records are available for use where needed. | | | | | DO | DN | NA |  |
|  |  | | | Make sure that documents and records are available for use when needed. | | | | | DO | DN | NA |  |
|  |  | Control how process documents and records are used. | | | | | | | DO | DN | NA |  |
|  |  | | Control how active process documents and records are used. | | | | | | DO | DN | NA |  |
|  |  | | | Control how documents and records are used to plan your process. | | | | | DO | DN | NA |  |
|  |  | | | | Control how internal documents and records are used to plan your process. | | | | DO | DN | NA |  |
|  |  | | | | Control how external documents and records are used to plan your process. | | | | DO | DN | NA |  |
|  |  | | | Control how documents and records are used to operate your process. | | | | | DO | DN | NA |  |
|  |  | | | | Control how internal documents and records are used to operate process. | | | | DO | DN | NA |  |
|  |  | | | | Control how external documents and records are used to operate process. | | | | DO | DN | NA |  |
|  |  | | | Control how documents and records are used to implement your process. | | | | | DO | DN | NA |  |
|  |  | | | | Control how internal documents and records are used to implement process. | | | | DO | DN | NA |  |
|  |  | | | | Control how external documents and records are used to implement process. | | | | DO | DN | NA |  |
|  |  | | | Control how documents and records are used to maintain your process. | | | | | DO | DN | NA |  |
|  |  | | | | Control how internal documents and records are used to maintain process. | | | | DO | DN | NA |  |
|  |  | | | | Control how external documents and records are used to maintain process. | | | | DO | DN | NA |  |
|  |  | | | Control how documents and records are used to monitor your process. | | | | | DO | DN | NA |  |
|  |  | | | | Control how internal documents and records are used to monitor process. | | | | DO | DN | NA |  |
|  |  | | | | Control how external documents and records are used to monitor process. | | | | DO | DN | NA |  |
|  |  | | | Control how documents and records are used to measure your process. | | | | | DO | DN | NA |  |
|  |  | | | | Control how internal documents and records are used to measure process. | | | | DO | DN | NA |  |
|  |  | | | | Control how external documents and records are used to measure process. | | | | DO | DN | NA |  |
|  |  | | | Control how documents and records are used to control your process. | | | | | DO | DN | NA |  |
|  |  | | | | Control how internal documents and records are used to control process. | | | | DO | DN | NA |  |
|  |  | | | | Control how external documents and records are used to control process. | | | | DO | DN | NA |  |
|  |  | | | Control how documents and records are used to evaluate your process. | | | | | DO | DN | NA |  |
|  |  | | | | Control how documents and records are used to audit your process. | | | | DO | DN | NA |  |
|  |  | | | | | Control how internal documents and records are used to audit process. | | | DO | DN | NA |  |
|  |  | | | | | Control how external documents and records are used to audit process. | | | DO | DN | NA |  |
|  |  | | | | Control how documents and records are used to review your process. | | | | DO | DN | NA |  |
|  |  | | | | | Control how internal documents and records are used to review process. | | | DO | DN | NA |  |
|  |  | | | | | Control how external documents and records are used to review process. | | | DO | DN | NA |  |
|  |  | | | Control how documents and records are used to modify your process. | | | | | DO | DN | NA |  |
|  |  | | | | Control how documents and records are used to correct your process. | | | | DO | DN | NA |  |
|  |  | | | | | Control how internal documents and records are used to correct process. | | | DO | DN | NA |  |
|  |  | | | | | Control how external documents and records are used to correct process. | | | DO | DN | NA |  |
|  |  | | | | Control how documents and records are used to improve your process. | | | | DO | DN | NA |  |
|  |  | | | | | Control how internal documents and records are used to improve process. | | | DO | DN | NA |  |
|  |  | | | | | Control how external documents and records are used to improve process. | | | DO | DN | NA |  |
|  |  | | Control how inactive process documents and records are used. | | | | | | DO | DN | NA |  |
|  |  | | | Control how obsolete process documents and records are used. | | | | | DO | DN | NA |  |
|  |  | | | | Prevent the unintended use of obsolete documented information. | | | | DO | DN | NA |  |
|  |  | | | | | Identify your obsolete process documents and records. | | | DO | DN | NA |  |
|  |  | | | | | Control your obsolete process documents and records. | | | DO | DN | NA |  |
|  |  | | | | | Remove your obsolete process documents and records. | | | DO | DN | NA |  |
|  |  | Control how process documents and records are protected. | | | | | | | DO | DN | NA |  |
|  |  | | Control how paper documents and records are protected. | | | | | | DO | DN | NA |  |
|  |  | | | Ensure that paper documents and records are protected. | | | | | DO | DN | NA |  |
|  |  | | | | Protect the integrity of your paper documents and records. | | | | DO | DN | NA |  |
|  |  | | | | | Prevent unauthorized or improper use of paper documents and records. | | | DO | DN | NA |  |
|  |  | | | | Protect the confidentiality of paper documents and records. | | | | DO | DN | NA |  |
|  |  | | | | Protect the legibility of paper documents and records. | | | | DO | DN | NA |  |
|  |  | | Control how electronic documents and records are protected. | | | | | | DO | DN | NA |  |
|  |  | | | Ensure that electronic documents and records are protected. | | | | | DO | DN | NA |  |
|  |  | | | | Define and develop suitable data protection methods. | | | | DO | DN | NA |  |
|  |  | | | | | Protect process documents and records from loss. | | | DO | DN | NA |  |
|  |  | | | | | Protect process documents and records from corruption. | | | DO | DN | NA |  |
|  |  | | | | | Protect process documents and records from physical damage. | | | DO | DN | NA |  |
|  |  | | | | | Protect process documents and records from unauthorized access. | | | DO | DN | NA |  |
|  |  | | | | | Protect process documents and records from unintended alteration. | | | DO | DN | NA |  |
|  |  | | | | | Protect process documents and records from inappropriate changes. | | | DO | DN | NA |  |
|  |  | Control how process documents and records are changed. | | | | | | | DO | DN | NA |  |
|  |  | | Control how paper documents and records are changed. | | | | | | DO | DN | NA |  |
|  |  | | | Use version control to manage changes to paper documents and records. | | | | | DO | DN | NA |  |
|  |  | | | | Prevent unintended alterations or modifications of paper documents  and records that are maintained as evidence of conformity. | | | | DO | DN | NA |  |
|  |  | | Control how electronic documents and records are changed. | | | | | | DO | DN | NA |  |
|  |  | Control how process documents and records are preserved. | | | | | | | DO | DN | NA |  |
|  |  | | Control the retention of documents and records. | | | | | | DO | DN | NA |  |
|  |  | | Control the disposal of documents and records. | | | | | | DO | DN | NA |  |
|  | Control all the process documents and records that you need. | | | | | | | | DO | DN | NA |  |
|  |  | Control all the internal documents and records that your process needs. | | | | | | | DO | DN | NA |  |
|  |  | | Control information that your process needs in order to be effective. | | | | | | DO | DN | NA |  |
|  |  | | | Control all the documents and records needed to operate your process. | | | | | DO | DN | NA |  |
|  |  | | | | Control all the documents and records used to facilitate process operations. | | | | DO | DN | NA |  |
|  |  | | | | Control all the documents and records used to facilitate output compliance. | | | | DO | DN | NA |  |
|  |  | | | Control all the documents and records needed to maintain your process. | | | | | DO | DN | NA |  |
|  |  | | | | Control all the documents and records used to maintain process operations. | | | | DO | DN | NA |  |
|  |  | | | | Control all the documents and records used to maintain output compliance. | | | | DO | DN | NA |  |
|  |  | | | Control all the documents and records needed to monitor your process. | | | | | DO | DN | NA |  |
|  |  | | | | Control all the documents and records used to monitor process operations. | | | | DO | DN | NA |  |
|  |  | | | | Control all the documents and records used monitor output compliance. | | | | DO | DN | NA |  |
|  |  | | | Control all the documents and records needed to measure your process. | | | | | DO | DN | NA |  |
|  |  | | | | Control all the documents and records used to measure process operations. | | | | DO | DN | NA |  |
|  |  | | | | Control all the documents and records used to measure output compliance. | | | | DO | DN | NA |  |
|  |  | | | Control all the documents and records needed to control your process. | | | | | DO | DN | NA |  |
|  |  | | | | Control all the documents and records used to control process operations. | | | | DO | DN | NA |  |
|  |  | | | | Control all the documents and records used to control output compliance. | | | | DO | DN | NA |  |
|  |  | | | Control all the documents and records needed to evaluate your process. | | | | | DO | DN | NA |  |
|  |  | | | | Control all the documents and records needed to audit your process. | | | | DO | DN | NA |  |
|  |  | | | | | Control all the documents and records used to audit process operations. | | | DO | DN | NA |  |
|  |  | | | | | Control all the documents and records used to audit output compliance. | | | DO | DN | NA |  |
|  |  | | | | Control all the documents and records needed to review your process. | | | | DO | DN | NA |  |
|  |  | | | | | Control all the documents and records used to review process operations. | | | DO | DN | NA |  |
|  |  | | | | | Control all the documents and records used to review output compliance. | | | DO | DN | NA |  |
|  |  | | | Control all the documents and records needed to modify your process. | | | | | DO | DN | NA |  |
|  |  | | | | Control all the documents and records needed to correct your process. | | | | DO | DN | NA |  |
|  |  | | | | | Control all the documents and records used to correct process operations. | | | DO | DN | NA |  |
|  |  | | | | | Control all the documents and records used to correct output compliance. | | | DO | DN | NA |  |
|  |  | | | | Control all the documents and records needed to improve your process. | | | | DO | DN | NA |  |
|  |  | | | | | Control all the documents and records used to improve process operations. | | | DO | DN | NA |  |
|  |  | | | | | Control all the documents and records used to improve output compliance. | | | DO | DN | NA |  |
|  |  | Control all the external documents and records that your process needs. | | | | | | | DO | DN | NA |  |
|  |  | | Control all external documented information needed in order to plan process. | | | | | | DO | DN | NA |  |
|  |  | | Control all external documented information needed in order to operate process. | | | | | | DO | DN | NA |  |
|  | | | | | | | | | | | | |
| Consider each task and select a response. If you haven’t done it and it needs to be done, select DO. If you’ve already done it, select DN. If the task is not applicable in your situation and you can justify and explain why it should be ignored or excluded, select NA.  In the spaces below, please enter the name and location of your organization, who completed this page, who reviewed it, and the dates. | | | | | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 8.1 PLAN HOW YOU'RE GOING TO EVALAUTE PROCESS | | | | | | | | | | | |
| 8.1.1 Plan how you're going to audit your process | | | | | | | | | | | |
|  | Develop an internal audit programme. | | | | | | | DO | DN | NA |  |
|  |  | Develop a programme that can find out if your process meets requirements. | | | | | | DO | DN | NA |  |
|  |  | | Make sure it can determine how well your process meets corporate expectations. | | | | | DO | DN | NA |  |
|  |  | | Make sure it can determine how well your process meets international standards. | | | | | DO | DN | NA |  |
|  |  | Develop a programme that can determine if your process is actually effective. | | | | | | DO | DN | NA |  |
|  |  | | Make sure that your programme is capable of producing valid results. | | | | | DO | DN | NA |  |
|  | Establish your internal audit programme. | | | | | | | DO | DN | NA |  |
|  |  | Assign internal audit responsibilities. | | | | | | DO | DN | NA |  |
|  |  | Develop your internal audit methods. | | | | | | DO | DN | NA |  |
|  |  | Clarify your internal audit standards. | | | | | | DO | DN | NA |  |
|  |  | | Expect auditors to be objective. | | | | | DO | DN | NA |  |
|  |  | | Expect auditors to be impartial. | | | | | DO | DN | NA |  |
|  |  | Specify internal audit planning requirements. | | | | | | DO | DN | NA |  |
|  |  | | Expect auditors to consider the results of previous audits. | | | | | DO | DN | NA |  |
|  |  | | Expect auditors to consider the impact proposed changes could have. | | | | | DO | DN | NA |  |
|  |  | | Expect auditors to consider the importance of the processes being audited. | | | | | DO | DN | NA |  |
|  |  | Define internal audit reporting requirements. | | | | | | DO | DN | NA |  |
|  |  | | Expect auditors to report results to management. | | | | | DO | DN | NA |  |
|  |  | Formulate internal audit schedules. | | | | | | DO | DN | NA |  |
|  |  | | Expect audits to be done at planned intervals. | | | | | DO | DN | NA |  |
| 8.1.2 Plan how you're going to analyze your process | | | | | | | | | | | |
|  | Plan how you're going to analyze the opinions and satisfaction of process customers. | | | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to use your analytical results to evaluate satisfaction. | | | | | | DO | DN | NA |  |
|  |  | | Plan how you're going to analyze the degree of customer satisfaction. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to use your analytical results to evaluate effectiveness. | | | | | | DO | DN | NA |  |
|  |  | | Plan how you're going to analyze the effectiveness of process operations. | | | | | DO | DN | NA |  |
|  |  | | | Plan how you're going to determine if you need to improve effectiveness. | | | | DO | DN | NA |  |
|  |  | | Plan how you're going to analyze the effectiveness of your process planning. | | | | | DO | DN | NA |  |
|  |  | | | Plan how you're going to determine if plans were effectively implemented. | | | | DO | DN | NA |  |
|  |  | | Plan how you're going to analyze the effectiveness of actions taken by managers. | | | | | DO | DN | NA |  |
|  |  | | | Plan how you're going to analyze the effectiveness of actions taken to address risks. | | | | DO | DN | NA |  |
|  |  | | | Plan how you're going to analyze the effectiveness of actions taken to exploit opportunities. | | | | DO | DN | NA |  |
|  | Plan how you're going to analyze the conformance and effectiveness of your process. | | | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to use your analytical results to evaluate conformance. | | | | | | DO | DN | NA |  |
|  |  | | Plan how you're going to analyze the conformity of process outputs. | | | | | DO | DN | NA |  |
|  |  | | | Plan how you're going to analyze your process output problems. | | | | DO | DN | NA |  |
|  |  | | | | Plan how you're going to analyze output problems reported by external sources. | | | DO | DN | NA |  |
|  |  | | | | | Plan how you're going to analyze output problems reported using advisories. | | DO | DN | NA |  |
|  |  | | | | | Plan how you're going to analyze output problems reported by means of alerts. | | DO | DN | NA |  |
|  |  | | | | | | Plan how you're going to analyze problems reported by means of industry alerts. | DO | DN | NA |  |
|  |  | | | | | | Plan how you're going to analyze problems reported by means of government alerts. | DO | DN | NA |  |
|  |  | | | | Plan how you're going to analyze output problems revealed by internal sources. | | | DO | DN | NA |  |
|  |  | Plan how you're going to use your analytical results to evaluate effectiveness. | | | | | | DO | DN | NA |  |
|  |  | | Plan how you're going to analyze the effectiveness of your process operations. | | | | | DO | DN | NA |  |
|  |  | | | Plan how you're going to determine if you need to improve its effectiveness. | | | | DO | DN | NA |  |
|  | Plan how you're going to analyze the competence and performance of process personnel. | | | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to analyze the effectiveness of actions taken to acquire competence. | | | | | | DO | DN | NA |  |
|  | Plan how you're going to analyze the conformance and performance of external providers. | | | | | | | DO | DN | NA |  |
|  |  | Plan how to analyze process, product, and service conformity of each external provider. | | | | | | DO | DN | NA |  |
|  |  | | Plan how to analyze the on-time delivery performance of each external provider. | | | | | DO | DN | NA |  |
|  |  | | | Plan how you're going to analyze the approval status of each external provider. | | | | DO | DN | NA |  |
|  |  | Plan how to define actions to take when external providers fail to meet requirements. | | | | | | DO | DN | NA |  |
| 8.1.3 Plan how you're going to review your process | | | | | | | | | | | |
|  | Consider how you're going to review your process. | | | | | | | DO | DN | NA |  |
|  |  | Consider how you're going to review the suitability of your process. | | | | | | DO | DN | NA |  |
|  |  | Consider how you're going to review the adequacy of your process. | | | | | | DO | DN | NA |  |
|  |  | Consider how you're going to review the effectiveness of your process. | | | | | | DO | DN | NA |  |
|  | Consider the issues that are relevant to your process. | | | | | | | DO | DN | NA |  |
|  |  | Consider changes in the external issues that influence your process. | | | | | | DO | DN | NA |  |
|  |  | Consider changes in the internal issues that influence your process. | | | | | | DO | DN | NA |  |
|  | Consider the status of your previous management reviews. | | | | | | | DO | DN | NA |  |
|  |  | Consider the status of the actions that were previously taken. | | | | | | DO | DN | NA |  |
| 8.2 PROVIDE RESOURCES NEEDED TO EVALUATE PROCESS | | | | | | | | | | | |
| 8.2.1 Provide the people that you need to evalaute your process | | | | | | | | | | | |
|  | Provide the people that you need in order to audit your process. | | | | | | | DO | DN | NA |  |
|  | Provide the people that you need in order to analyze your process. | | | | | | | DO | DN | NA |  |
|  | Provide the people that you need in order to review your process. | | | | | | | DO | DN | NA |  |
| 8.2.2 Provide the knowledge that YOU need to evaluate your process | | | | | | | | | | | |
|  | Provide the knowledge that you need in order to audit your process. | | | | | | | DO | DN | NA |  |
|  | Provide the knowledge that you need in order to analyze your process. | | | | | | | DO | DN | NA |  |
|  | Provide the knowledge that you need in order to review your process. | | | | | | | DO | DN | NA |  |
| 8.2.3 Provide the technology that YOU need to evaluate your process | | | | | | | | | | | |
|  | Provide the technology that you need in order to audit your process. | | | | | | | DO | DN | NA |  |
|  | Provide the technology that you need in order to analyze your process. | | | | | | | DO | DN | NA |  |
|  | Provide the technology that you need in order to review your process. | | | | | | | DO | DN | NA |  |
| 8.2.4 Provide the infrastructure that you need to evaluate your process | | | | | | | | | | | |
|  | Provide the infrastructure that you need in order to audit your process. | | | | | | | DO | DN | NA |  |
|  | Provide the infrastructure that you need in order to analyze your process. | | | | | | | DO | DN | NA |  |
|  | Provide the infrastructure that you need in order to review your process. | | | | | | | DO | DN | NA |  |
| 8.3 USE AUTHORIZED METHODS TO EVALUATE PROCESS | | | | | | | | | | | |
| 8.3.1 Use authorized methods to audit your process | | | | | | | | | | | |
|  | Plan your internal process audit activities. | | | | | | | DO | DN | NA |  |
|  |  | Define the scope for each internal process audit. | | | | | | DO | DN | NA |  |
|  |  | Specify audit criteria for each internal process audit. | | | | | | DO | DN | NA |  |
|  |  | Clarify internal process audit methods and techniques. | | | | | | DO | DN | NA |  |
|  |  | Select impartial and objective internal process auditors. | | | | | | DO | DN | NA |  |
|  |  | Schedule internal process audits at planned intervals. | | | | | | DO | DN | NA |  |
|  | Carry out internal process audits at planned intervals. | | | | | | | DO | DN | NA |  |
|  |  | Conduct internal conformance audits of your process. | | | | | | DO | DN | NA |  |
|  |  | | Determine if your process meets relevant requirements. | | | | | DO | DN | NA |  |
|  |  | | | Determine if your process meets internal requirements. | | | | DO | DN | NA |  |
|  |  | | | Determine if your process meets external requirements. | | | | DO | DN | NA |  |
|  |  | | | | Determine if your process meets external customer requirements. | | | DO | DN | NA |  |
|  |  | | | | Determine if your process meets external statutory requirements. | | | DO | DN | NA |  |
|  |  | | | | Determine if your process meets external regulatory requirements. | | | DO | DN | NA |  |
|  |  | | | | | Determine if your process complies with government regulations. | | DO | DN | NA |  |
|  |  | | | | | Determine if your process complies with international standards. | | DO | DN | NA |  |
|  |  | | | | | | Determine how well process meets safety management requirements. | DO | DN | NA |  |
|  |  | | | | | | Determine how well process meets security management requirements. | DO | DN | NA |  |
|  |  | | | | | | Determine how well process meets quality management requirements. | DO | DN | NA |  |
|  |  | | | | | | Determine how well process meets environmental management requirements. | DO | DN | NA |  |
|  |  | | | | | | Determine how well process meets business continuity management requirements. | DO | DN | NA |  |
|  |  | Conduct internal effectiveness audits of your process. | | | | | | DO | DN | NA |  |
|  |  | | Determine how effective process implementation was. | | | | | DO | DN | NA |  |
|  |  | | | Use performance indicators to see if process was effectively implemented. | | | | DO | DN | NA |  |
|  |  | | Determine how effective process operations are. | | | | | DO | DN | NA |  |
|  |  | | | Use performance indicators to see if process is being effectively operated. | | | | DO | DN | NA |  |
|  |  | | Determine how effective process control is. | | | | | DO | DN | NA |  |
|  |  | | | Use performance indicators to see if process is being effectively controlled. | | | | DO | DN | NA |  |
|  |  | | Determine how effective process maintenance is. | | | | | DO | DN | NA |  |
|  |  | | | Use performance indicators to see if process is being effectively maintained. | | | | DO | DN | NA |  |
|  |  | | Determine how effective process monitoring is. | | | | | DO | DN | NA |  |
|  |  | | | Use performance indicators to see if process is being effectively monitored. | | | | DO | DN | NA |  |
|  |  | | Determine how effective process measurement is. | | | | | DO | DN | NA |  |
|  |  | | | Use performance indicators to see if process is being effectively measured. | | | | DO | DN | NA |  |
|  |  | | Determine how effective process evaluations are. | | | | | DO | DN | NA |  |
|  |  | | | Use performance indicators to see if process is being effectively evaluated. | | | | DO | DN | NA |  |
|  |  | | | | Use performance indicators to see if process is being effectively audited. | | | DO | DN | NA |  |
|  |  | | | | Use performance indicators to see if process is being effectively reviewed. | | | DO | DN | NA |  |
|  |  | | Determine how effective process modifications are. | | | | | DO | DN | NA |  |
|  |  | | | Use performance indicators to see if process is being effectively modified. | | | | DO | DN | NA |  |
|  |  | | | | Use performance indicators to see if process corrections are effective. | | | DO | DN | NA |  |
|  |  | | | | Use performance indicators to see if process improvements are effective. | | | DO | DN | NA |  |
|  | Report process audit results to management. | | | | | | | DO | DN | NA |  |
|  | Maintain your internal process audit programme. | | | | | | | DO | DN | NA |  |
|  |  | Retain documented information about your process audit programme. | | | | | | DO | DN | NA |  |
|  |  | | Retain your internal process audit results and control these results. | | | | | DO | DN | NA |  |
| 8.3.2 Use authorized methods to analyze your process | | | | | | | | | | | |
|  | Analyze the opinions of process customers. | | | | | | | DO | DN | NA |  |
|  |  | Use your analytical results to evaluate satisfaction. | | | | | | DO | DN | NA |  |
|  |  | | Evaluate the degree of customer satisfaction. | | | | | DO | DN | NA |  |
|  | Analyze the performance of your process. | | | | | | | DO | DN | NA |  |
|  |  | Use your results to analyze conformance. | | | | | | DO | DN | NA |  |
|  |  | | Analyze the conformity of process outputs. | | | | | DO | DN | NA |  |
|  |  | | | Analyze your process output problems. | | | | DO | DN | NA |  |
|  |  | | | | Analyze output problems reported by external sources. | | | DO | DN | NA |  |
|  |  | | | | | Analyze output problems reported using advisories. | | DO | DN | NA |  |
|  |  | | | | | Analyze output problems reported by means of alerts. | | DO | DN | NA |  |
|  |  | | | | | | Analyze problems reported by means of industry alerts. | DO | DN | NA |  |
|  |  | | | | | | Analyze problems reported by means of government alerts. | DO | DN | NA |  |
|  |  | | | | Analyze output problems revealed by internal sources. | | | DO | DN | NA |  |
|  |  | Use your results to analyze effectiveness. | | | | | | DO | DN | NA |  |
|  |  | | Analyze the effectiveness of your process operations. | | | | | DO | DN | NA |  |
|  |  | | | Determine if you need to improve its effectiveness. | | | | DO | DN | NA |  |
|  | Analyze the effectiveness of your process. | | | | | | | DO | DN | NA |  |
|  |  | Use your results to analyze process effectiveness. | | | | | | DO | DN | NA |  |
|  |  | | Analyze the effectiveness of process operations. | | | | | DO | DN | NA |  |
|  |  | | | Determine if you need to improve process operations. | | | | DO | DN | NA |  |
|  |  | | Analyze the effectiveness of process maintenance. | | | | | DO | DN | NA |  |
|  |  | | | Determine if you need to improve process maintenance. | | | | DO | DN | NA |  |
|  |  | | Analyze the effectiveness of process monitoring. | | | | | DO | DN | NA |  |
|  |  | | | Determine if you need to improve process monitoring. | | | | DO | DN | NA |  |
|  |  | | Analyze the effectiveness of process measurement. | | | | | DO | DN | NA |  |
|  |  | | | Determine if you need to improve process measurement. | | | | DO | DN | NA |  |
|  |  | | Analyze the effectiveness of process evaluations. | | | | | DO | DN | NA |  |
|  |  | | | Analyze the effectiveness of process audits. | | | | DO | DN | NA |  |
|  |  | | | | Determine if you need to improve process audits. | | | DO | DN | NA |  |
|  |  | | | Analyze the effectiveness of process reviews. | | | | DO | DN | NA |  |
|  |  | | | | Determine if you need to improve process reviews. | | | DO | DN | NA |  |
|  |  | | Analyze the effectiveness of process modifications. | | | | | DO | DN | NA |  |
|  |  | | | Analyze the effectiveness of process corrections. | | | | DO | DN | NA |  |
|  |  | | | | Determine if you need to improve process correction activities. | | | DO | DN | NA |  |
|  |  | | | Analyze the effectiveness of process improvements. | | | | DO | DN | NA |  |
|  |  | | | | Determine if you need to improve process improvement activities. | | | DO | DN | NA |  |
|  |  | Use your results to analyze process management. | | | | | | DO | DN | NA |  |
|  |  | | Analyze the effectiveness of actions taken by managers. | | | | | DO | DN | NA |  |
|  |  | | | Analyze the effectiveness of actions taken to address process risks. | | | | DO | DN | NA |  |
|  |  | | | Analyze the effectiveness of actions taken to address process opportunities. | | | | DO | DN | NA |  |
|  |  | | | Analyze the effectiveness of actions taken to address process nonconformities. | | | | DO | DN | NA |  |
|  |  | | | Analyze the effectiveness of actions taken to address process performance problems. | | | | DO | DN | NA |  |
|  | Analyze the competence of process participants. | | | | | | | DO | DN | NA |  |
|  |  | Analyze the competence and performance of process personnel. | | | | | | DO | DN | NA |  |
|  |  | | Analyze the effectiveness of actions taken to acquire competence. | | | | | DO | DN | NA |  |
|  |  | Analyze the competence and performance of external providers. | | | | | | DO | DN | NA |  |
|  |  | | Analyze the process, product, and service conformity of each external provider. | | | | | DO | DN | NA |  |
|  |  | | | Analyze the on-time delivery performance of each external provider. | | | | DO | DN | NA |  |
|  |  | | | | Analyze the approval status of each external provider. | | | DO | DN | NA |  |
|  |  | | Define the actions to take when external providers fail to meet requirements. | | | | | DO | DN | NA |  |
| 8.3.3 Use authorized methods to review your process | | | | | | | | | | | |
|  | Review the performance of your process. | | | | | | | DO | DN | NA |  |
|  |  | Review your process nonconformities. | | | | | | DO | DN | NA |  |
|  |  | Review process output nonconformities. | | | | | | DO | DN | NA |  |
|  |  | | Review customer perceptions and satisfaction. | | | | | DO | DN | NA |  |
|  |  | | | Use output conformity information to review customer satisfaction. | | | | DO | DN | NA |  |
|  |  | | | Use on-time delivery performance to review customer satisfaction. | | | | DO | DN | NA |  |
|  |  | | | Use corrective action requests to review customer satisfaction. | | | | DO | DN | NA |  |
|  |  | | | Use customer complaints to review customer satisfaction. | | | | DO | DN | NA |  |
|  |  | Review the performance of process personnel. | | | | | | DO | DN | NA |  |
|  |  | | Review how well objectives are being met. | | | | | DO | DN | NA |  |
|  |  | | Review the competence of process personnel. | | | | | DO | DN | NA |  |
|  |  | Review process management activities and results. | | | | | | DO | DN | NA |  |
|  |  | | Review process control methods and results. | | | | | DO | DN | NA |  |
|  |  | | Review process operations methods and results. | | | | | DO | DN | NA |  |
|  |  | | Review process monitoring methods and results. | | | | | DO | DN | NA |  |
|  |  | | Review process measurement methods and results. | | | | | DO | DN | NA |  |
|  |  | | Review process maintenance methods and results. | | | | | DO | DN | NA |  |
|  |  | | Review process evaluation methods and results. | | | | | DO | DN | NA |  |
|  |  | | | Review process audit activities and results. | | | | DO | DN | NA |  |
|  |  | | | Review process analysis activities and results. | | | | DO | DN | NA |  |
|  |  | | Review process modification methods and results. | | | | | DO | DN | NA |  |
|  |  | | | Review actual process modifications. | | | | DO | DN | NA |  |
|  |  | | | | Review actions taken to modify your process. | | | DO | DN | NA |  |
|  |  | | | | | Review the effectiveness of actions taken to improve process. | | DO | DN | NA |  |
|  |  | | | | | Review the effectiveness of corrective and preventive actions. | | DO | DN | NA |  |
|  |  | | | | | | Review corrective actions taken to address process nonconformities. | DO | DN | NA |  |
|  |  | | | | | | Review preventive actions taken to address process nonconformities. | DO | DN | NA |  |
|  |  | | | Review potential process modifications. | | | | DO | DN | NA |  |
|  |  | | | | Review potential improvement opportunities. | | | DO | DN | NA |  |
|  |  | | | | Review potential corrective and preventive actions. | | | DO | DN | NA |  |
|  |  | Review process risks and opportunities. | | | | | | DO | DN | NA |  |
|  |  | | Review actions taken to address risks and opportunities. | | | | | DO | DN | NA |  |
|  |  | | | Review the effectiveness of the actions that were taken. | | | | DO | DN | NA |  |
|  |  | Review suitability of process environment. | | | | | | DO | DN | NA |  |
|  |  | | Review external process, product, and service providers. | | | | | DO | DN | NA |  |
|  |  | | | Review your external process, product, and service verification activities. | | | | DO | DN | NA |  |
|  |  | | | | Review verifications whenever they are delegated to external providers. | | | DO | DN | NA |  |
|  |  | | Review the issues that could influence process performance. | | | | | DO | DN | NA |  |
|  |  | | | Review and evaluate the issues and concerns of interested parties. | | | | DO | DN | NA |  |
|  |  | | | | Review and evaluate their changing needs and expectations. | | | DO | DN | NA |  |
|  |  | Review the adequacy of process resources. | | | | | | DO | DN | NA |  |
|  | Generate suitable management review outputs. | | | | | | | DO | DN | NA |  |
| 8.4 RECORD THE RESULTS OF PROCESS EVALUATIONS | | | | | | | | | | | |
|  | Record your process audit activities and results. | | | | | | | DO | DN | NA |  |
|  |  | Maintain and control your process audit records. | | | | | | DO | DN | NA |  |
|  | Record your process analysis activities and results. | | | | | | | DO | DN | NA |  |
|  |  | Maintain and control your process analysis records. | | | | | | DO | DN | NA |  |
|  | Record your process review activities and results. | | | | | | | DO | DN | NA |  |
|  |  | Maintain and control your process review records. | | | | | | DO | DN | NA |  |
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| Consider each task and select a response. If you haven’t done it and it needs to be done, select DO. If you’ve already done it, select DN. If the task is not applicable in your situation and you can justify and explain why it should be ignored or excluded, select NA.  In the spaces below, please enter the name and location of your organization, who completed this page, who reviewed it, and the dates. | | | | | | | | | | | |

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| 9.1 ESTABLISH YOUR PROCESS MODIFICATION METHODS | | | | | | | | | | |
| 9.1.1 Establish methods for correcting process and outputs | | | | | | | | | | |
|  | Establish appropriate corrective action methods and procedures. | | | | | | DO | DN | NA |  |
|  |  | Document your corrective action methods and procedures. | | | | | DO | DN | NA |  |
|  |  | | Maintain documents that describe your corrective action methods and procedures. | | | | DO | DN | NA |  |
|  | Establish appropriate corrective action record keeping methods. | | | | | | DO | DN | NA |  |
|  |  | Figure out how you're going to record the actions taken to correct process and outputs. | | | | | DO | DN | NA |  |
|  |  | Figure out how you're going to record the process and output corrections that are made. | | | | | DO | DN | NA |  |
| 9.1.2 Establish methods for improving process and outputs | | | | | | | | | | |
|  | Establish appropriate process and output improvement methods and procedures. | | | | | | DO | DN | NA |  |
|  |  | Document your process and output improvement methods and procedures. | | | | | DO | DN | NA |  |
|  |  | | Maintain documents describing process and output improvement methods and procedures. | | | | DO | DN | NA |  |
|  | Establish appropriate process and output improvement record keeping methods. | | | | | | DO | DN | NA |  |
|  |  | Figure out how you're going to record the actions taken to improve process and outputs. | | | | | DO | DN | NA |  |
|  |  | Figure out how you're going to record the process and output improvements that are made. | | | | | DO | DN | NA |  |
| 9.2 IDENTIFY OPPORTUNITIES TO MODIFY YOUR PROCESS | | | | | | | | | | |
| 9.2.1 Discover opportunities to modify process and outputs | | | | | | | | | | |
|  | Discover opportunities to correct your process and its outputs. | | | | | | DO | DN | NA |  |
|  |  | Discover opportunities to make corrections by examining audit reports. | | | | | DO | DN | NA |  |
|  |  | Discover opportunities to make corrections by examining review results. | | | | | DO | DN | NA |  |
|  |  | Discover opportunities to make corrections by examining best practices. | | | | | DO | DN | NA |  |
|  |  | Discover opportunities to make corrections by examining lessons learned. | | | | | DO | DN | NA |  |
|  |  | Discover opportunities to make corrections by examining nonconformities. | | | | | DO | DN | NA |  |
|  |  | Discover opportunities to make corrections by examining customer feedback. | | | | | DO | DN | NA |  |
|  | Discover opportunities to improve your process and its outputs. | | | | | | DO | DN | NA |  |
|  |  | Discover improvement opportunities by examining audit reports. | | | | | DO | DN | NA |  |
|  |  | Discover improvement opportunities by examining review results. | | | | | DO | DN | NA |  |
|  |  | Discover improvement opportunities by examining best practices. | | | | | DO | DN | NA |  |
|  |  | Discover improvement opportunities by examining lessons learned. | | | | | DO | DN | NA |  |
|  |  | Discover improvement opportunities by examining nonconformities. | | | | | DO | DN | NA |  |
|  |  | Discover improvement opportunities by examining customer feedback. | | | | | DO | DN | NA |  |
| 9.2.2 Define opportunities to modify your process and outputs | | | | | | | | | | |
|  | Define opportunities to correct and improve process outputs. | | | | | | DO | DN | NA |  |
|  |  | Define opportunities to correct and improve the quality of your outputs. | | | | | DO | DN | NA |  |
|  |  | Define opportunities to correct and improve the safety of your outputs. | | | | | DO | DN | NA |  |
|  |  | Define opportunities to correct and improve the security of your outputs. | | | | | DO | DN | NA |  |
|  | Define opportunities to correct and improve process performance. | | | | | | DO | DN | NA |  |
|  |  | Define opportunities to correct and improve process operations. | | | | | DO | DN | NA |  |
|  |  | Define opportunities to correct and improve process maintenance. | | | | | DO | DN | NA |  |
|  |  | Define opportunities to correct and improve process monitoring. | | | | | DO | DN | NA |  |
|  |  | Define opportunities to correct and improve process measurement. | | | | | DO | DN | NA |  |
|  |  | Define opportunities to correct and improve process controls. | | | | | DO | DN | NA |  |
|  |  | Define opportunities to correct and improve process evaluations. | | | | | DO | DN | NA |  |
|  |  | | Define opportunities to correct and improve process audits. | | | | DO | DN | NA |  |
|  |  | | Define opportunities to correct and improve process reviews. | | | | DO | DN | NA |  |
| 9.2.3 Confirm that process and output modifications are needed | | | | | | | | | | |
|  | Confirm that proposed process modifications are necessary. | | | | | | DO | DN | NA |  |
|  |  | Confirm that proposed process modifications would be feasible. | | | | | DO | DN | NA |  |
|  |  | Confirm that proposed process modifications would be appropriate. | | | | | DO | DN | NA |  |
|  |  | Confirm that proposed process modifications would be effective. | | | | | DO | DN | NA |  |
|  |  | | Confirm that proposed process modifications would be cost-effective. | | | | DO | DN | NA |  |
|  | Confirm that proposed output modifications would be necessary. | | | | | | DO | DN | NA |  |
|  |  | Confirm that proposed output modifications would be feasible. | | | | | DO | DN | NA |  |
|  |  | Confirm that proposed output modifications would be appropriate. | | | | | DO | DN | NA |  |
|  |  | Confirm that proposed output modifications would be effective. | | | | | DO | DN | NA |  |
|  |  | | Confirm that proposed output modifications would be cost-effective. | | | | DO | DN | NA |  |
| 9.2.4 Approve opportunities to modify your process and outputs | | | | | | | | | | |
|  | Authorize proposed process corrections and improvements. | | | | | | DO | DN | NA |  |
|  | Authorize proposed output corrections and improvements. | | | | | | DO | DN | NA |  |
| 9.3 PLAN HOW YOU'RE GOING TO MODIFY YOUR PROCESS | | | | | | | | | | |
| 9.3.1 Plan how you're going to correct process and its outputs | | | | | | | | | | |
|  | Plan how you're going to apply your corrective action methods and procedures. | | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to react to your process and output nonconformities. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to control and correct process and output nonconformities. | | | | | DO | DN | NA |  |
|  |  | | Plan how you're going to deal with all relevant effects and consequences. | | | | DO | DN | NA |  |
|  | Plan how you're going to document your corrective action activities and results. | | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to document the actions taken and the results achieved. | | | | | DO | DN | NA |  |
|  |  | | Plan how you're going to retain and control your record of actions and results. | | | | DO | DN | NA |  |
|  | Plan how you're going to evaluate the need to eliminate causes. | | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to review and analyze the nonconformity. | | | | | DO | DN | NA |  |
|  |  | | Plan how you're going to determine the causes of the nonconformity. | | | | DO | DN | NA |  |
|  |  | | | Plan how to determine if human factors are responsible for the nonconformity. | | | DO | DN | NA |  |
|  |  | | | Plan how to determine if external providers are responsible for the nonconformity. | | | DO | DN | NA |  |
|  |  | | | | Plan how to flow down corrective action requirements to your external providers. | | DO | DN | NA |  |
|  |  | Plan how you're going to decide if corrective action should be taken. | | | | | DO | DN | NA |  |
|  | Plan how you're going to develop corrective actions to address causes. | | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to make sure that your actions are feasible. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to make sure that your actions are appropriate. | | | | | DO | DN | NA |  |
|  |  | | Plan how you're going to make sure that actions also consider consequences. | | | | DO | DN | NA |  |
|  |  | Plan how you're going to make sure that your actions are effective. | | | | | DO | DN | NA |  |
|  |  | | Plan how you're going to make sure that your actions are cost-effective. | | | | DO | DN | NA |  |
|  | Plan how you're going to get managers to authorize corrective action. | | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to submit corrective action requests. | | | | | DO | DN | NA |  |
|  | Plan how you're going to take corrective actions to deal with causes. | | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to correct your process and its outputs. | | | | | DO | DN | NA |  |
|  | Plan how you're going to review the effectiveness of corrective actions. | | | | | | DO | DN | NA |  |
|  | Plan how you're going to respond when correction actions aren't taken. | | | | | | DO | DN | NA |  |
|  | Plan how you're going to update your list of process and output risks. | | | | | | DO | DN | NA |  |
| 9.3.2 Plan how you're going to improve process and its outputs | | | | | | | | | | |
|  | Plan improvements and other changes to your process. | | | | | | DO | DN | NA |  |
|  |  | Identify people authorized to approve changes in your process. | | | | | DO | DN | NA |  |
|  |  | Use your process purpose and scope to guide process improvements. | | | | | DO | DN | NA |  |
|  |  | | Use process policy statements to guide process improvements. | | | | DO | DN | NA |  |
|  |  | | | Use your quality policy to guide your process improvements. | | | DO | DN | NA |  |
|  |  | | | | Use your quality objectives to guide process improvements. | | DO | DN | NA |  |
|  |  | | | Use your safety policy to guide your process improvements. | | | DO | DN | NA |  |
|  |  | | | | Use your safety objectives to guide process improvements. | | DO | DN | NA |  |
|  |  | | | Use your security policy to guide your process improvements. | | | DO | DN | NA |  |
|  |  | | | | Use your security objectives to guide process improvements. | | DO | DN | NA |  |
|  |  | | | Use your environmental policy to guide your process improvements. | | | DO | DN | NA |  |
|  |  | | | | Use your environmental objectives to guide process improvements. | | DO | DN | NA |  |
|  |  | | | Use your business continuity policy to guide your process improvements. | | | DO | DN | NA |  |
|  |  | | | | Use your business continuity objectives to guide process improvements. | | DO | DN | NA |  |
|  |  | Consider improvements and other changes to your process. | | | | | DO | DN | NA |  |
|  |  | | Consider the purpose and effects of the changes you intend to make. | | | | DO | DN | NA |  |
|  |  | | Consider responsibilities and authorities whenever you make changes. | | | | DO | DN | NA |  |
|  |  | | | Consider allocating or reallocating responsibilities and authorities. | | | DO | DN | NA |  |
|  |  | | Consider the consequences that changes could potentially produce. | | | | DO | DN | NA |  |
|  |  | | Consider the availability of resources whenever you make changes | | | | DO | DN | NA |  |
|  |  | | Consider the integrity of your process whenever you make changes. | | | | DO | DN | NA |  |
|  |  | Figure out how you're going to control changes in your process. | | | | | DO | DN | NA |  |
|  |  | | Ensure that process continues to meet requirements even though changes are being made. | | | | DO | DN | NA |  |
|  | Plan improvements and other changes to process outputs. | | | | | | DO | DN | NA |  |
|  |  | Identify people authorized to approve changes in process outputs. | | | | | DO | DN | NA |  |
|  |  | Use your process purpose and scope to guide output improvements. | | | | | DO | DN | NA |  |
|  |  | | Use process policy statements to guide process improvements. | | | | DO | DN | NA |  |
|  |  | | | Use your quality policy to guide your output improvements. | | | DO | DN | NA |  |
|  |  | | | | Use your quality objectives to guide output improvements. | | DO | DN | NA |  |
|  |  | | | Use your safety policy to guide your output improvements. | | | DO | DN | NA |  |
|  |  | | | | Use your safety objectives to guide output improvements. | | DO | DN | NA |  |
|  |  | | | Use your security policy to guide your output improvements. | | | DO | DN | NA |  |
|  |  | | | | Use your security objectives to guide output improvements. | | DO | DN | NA |  |
|  |  | | | Use your environmental policy to guide your output improvements. | | | DO | DN | NA |  |
|  |  | | | | Use your environmental objectives to guide output improvements. | | DO | DN | NA |  |
|  |  | Consider improvements and other changes to your outputs. | | | | | DO | DN | NA |  |
|  |  | | Consider the purpose and effects of the output changes you intend to make. | | | | DO | DN | NA |  |
|  |  | | Consider responsibilities and authorities whenever you make output changes. | | | | DO | DN | NA |  |
|  |  | | Consider the consequences that output changes could potentially produce. | | | | DO | DN | NA |  |
|  |  | | Consider the availability of resources whenever you make output changes. | | | | DO | DN | NA |  |
|  |  | | Consider the integrity of your outputs whenever you make changes. | | | | DO | DN | NA |  |
|  |  | Figure out how you're going to control changes in your process outputs. | | | | | DO | DN | NA |  |
|  |  | | Ensure that outputs continue to meet requirements even though changes are being made. | | | | DO | DN | NA |  |
| 9.4 USE AUTHORIZED METHODS TO MODIFY YOUR PROCESS | | | | | | | | | | |
| 9.4.1 Use authorized methods to correct process and outputs | | | | | | | | | | |
|  | Apply your corrective action methods and procedures. | | | | | | DO | DN | NA |  |
|  |  | Evaluate the need to eliminate causes of nonconformity. | | | | | DO | DN | NA |  |
|  |  | | Review and analyze your process and output nonconformities. | | | | DO | DN | NA |  |
|  |  | | | Determine the causes of process and output nonconformities. | | | DO | DN | NA |  |
|  |  | | | | Determine if human factors are responsible for the nonconformity. | | DO | DN | NA |  |
|  |  | | | | Determine if external providers are responsible for the nonconformity. | | DO | DN | NA |  |
|  |  | | | | | Flow down corrective action requirements to your external providers. | DO | DN | NA |  |
|  |  | | Decide if the causes of process or output nonconformity must be addressed. | | | | DO | DN | NA |  |
|  |  | Develop corrective actions to address causes of nonconformity. | | | | | DO | DN | NA |  |
|  |  | | Make sure that your corrective actions are feasible. | | | | DO | DN | NA |  |
|  |  | | Make sure that your corrective actions are appropriate. | | | | DO | DN | NA |  |
|  |  | | | Make sure that actions also consider effects. | | | DO | DN | NA |  |
|  |  | | Make sure that your corrective actions are effective. | | | | DO | DN | NA |  |
|  |  | | | Make sure that your corrective actions are cost-effective. | | | DO | DN | NA |  |
|  |  | Take corrective action to address the causes of nonconformity. | | | | | DO | DN | NA |  |
|  | Provide the resources needed to correct process and outputs. | | | | | | DO | DN | NA |  |
|  |  | Provide suitable resources needed to correct process outputs. | | | | | DO | DN | NA |  |
|  |  | Provide suitable resources needed to correct process activities. | | | | | DO | DN | NA |  |
|  | Control your corrective action activities and results. | | | | | | DO | DN | NA |  |
|  | Monitor your corrective action activities and results. | | | | | | DO | DN | NA |  |
|  | Record your corrective action activities and results. | | | | | | DO | DN | NA |  |
|  |  | Document the actions taken and the results achieved. | | | | | DO | DN | NA |  |
|  |  | | Retain and control your record of corrective actions taken. | | | | DO | DN | NA |  |
| 9.4.2 Use authorized methods to improve process and outputs | | | | | | | | | | |
|  | Apply process and output improvement methods and procedures. | | | | | | DO | DN | NA |  |
|  |  | Evaluate the need to make process and output improvements. | | | | | DO | DN | NA |  |
|  | Provide the resources needed to make process and output improvements. | | | | | | DO | DN | NA |  |
|  |  | Provide suitable resources needed to improve your process outputs. | | | | | DO | DN | NA |  |
|  |  | Provide suitable resources needed to improve your process activities. | | | | | DO | DN | NA |  |
|  | Develop improvements to your process and process outputs. | | | | | | DO | DN | NA |  |
|  |  | Make sure that your process and output improvements are feasible. | | | | | DO | DN | NA |  |
|  |  | Make sure that your process and output improvements are appropriate. | | | | | DO | DN | NA |  |
|  |  | | Make sure that process and output improvements also consider effects. | | | | DO | DN | NA |  |
|  |  | Make sure that your process and output improvements are effective. | | | | | DO | DN | NA |  |
|  |  | | Make sure that your process and output improvements are cost-effective. | | | | DO | DN | NA |  |
|  | Implement improvements to your process and process outputs. | | | | | | DO | DN | NA |  |
|  |  | Improve the suitability, adequacy, and effectiveness of process. | | | | | DO | DN | NA |  |
|  |  | Improve the quality, safety, and security of your process outputs. | | | | | DO | DN | NA |  |
|  | Control improvements to your process and process outputs. | | | | | | DO | DN | NA |  |
|  |  | Control improvements and other changes affecting process software. | | | | | DO | DN | NA |  |
|  |  | Control improvements and other changes affecting process operations. | | | | | DO | DN | NA |  |
|  |  | Control improvements and other changes affecting process equipment. | | | | | DO | DN | NA |  |
|  |  | Control improvements and other changes affecting process tools. | | | | | DO | DN | NA |  |
|  | Monitor improvements to your process and process outputs. | | | | | | DO | DN | NA |  |
|  |  | Monitor the implementation of process and output improvement activities. | | | | | DO | DN | NA |  |
|  | Record improvements to your process and process outputs. | | | | | | DO | DN | NA |  |
| 9.5 REVIEW AND EVALUATE PROCESS MODIFICATIONS | | | | | | | | | | |
| 9.5.1 Review and evaluate process and output corrections | | | | | | | | | | |
|  | Review and evaluate actions taken to correct your process. | | | | | | DO | DN | NA |  |
|  |  | Document your process correction reviews and the actions that are taken. | | | | | DO | DN | NA |  |
|  |  | Establish a record of process correction reviews and actions taken. | | | | | DO | DN | NA |  |
|  | Review and evaluate actions taken to correct outputs. | | | | | | DO | DN | NA |  |
|  |  | Document your output correction reviews and the actions that are taken. | | | | | DO | DN | NA |  |
|  |  | Establish a record of output correction reviews and actions taken. | | | | | DO | DN | NA |  |
| 9.5.2 Review and evaluate process and output improvements | | | | | | | | | | |
|  | Review and evaluate improvements and changes to your process. | | | | | | DO | DN | NA |  |
|  |  | Document your process improvement reviews and the actions that are taken. | | | | | DO | DN | NA |  |
|  |  | Establish a record of process improvement reviews and the actions taken. | | | | | DO | DN | NA |  |
|  | Review and evaluate improvements and changes to process outputs. | | | | | | DO | DN | NA |  |
|  |  | Document your output improvement reviews and the actions that are taken. | | | | | DO | DN | NA |  |
|  |  | Establish a record of output improvement reviews and the actions taken. | | | | | DO | DN | NA |  |
|  | | | | | | | | | | |
| Consider each task and select a response. If you haven’t done it and it needs to be done, select DO. If you’ve already done it, select DN. If the task is not applicable in your situation and you can justify and explain why it should be ignored or excluded, select NA.  In the spaces below, please enter the name and location of your organization, who completed this page, who reviewed it, and the dates. | | | | | | | | | | |

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| --- | --- |
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