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|  | **INTRODUCTION TO QUALITY MANAGEMENT SYSTEMS** | |
|  | Almost all quality management standards expect organizations to establish  quality management systems. These include at least the following:  ▪ ISO 9001 Quality Management Standard  ▪ ISO 13485 Quality Management Standard for Medical Devices  ▪ IATF 16949 Quality Management Standard for Automotive Sector  ▪ AS9100 Quality Management Standard for Aerospace and Defense  A *Quality* *Management System (QMS)* is a network of interrelated and interacting  elements that organizations use to carry out activities and continuously improve. Management systems facilitate improvement because they are iterative: they repeat themselves. Improvement is possible because all aspects of the system are continuously measured, monitored, audited, analyzed, and reviewed. That's how organizations improve and that's why management systems are both popular and powerful.  QMS *elements* include policies, procedures, programs, processes, practices, projects, plans, objectives, rules, roles, responsibilities, relationships, contracts, agreements, documents, records, methods, techniques, technologies, tools, equipment, as well as all the resources that support these elements. | This means that even if your *Management System* is imperfect and incomplete, it will inevitably improve over time.  When you look at all the  *elements* that make up a *Quality* *Management System*, you'll notice many familiar items. That's because most organization's already have most of these elements. This should make it easier to organize your activities into a single system*.* |
|  | Diagram  Description automatically generated | The "callout" images around  the edge of the System represent the seven processes that make up any Quality Management System. They are carried out more-or-less simultaneously and continuously.  We identified the processes and elements that make up  a Quality *Management System (QMS)* by looking for all of the activities and outcomes that  are common to all quality management system standards. |

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|  | **OUTLINE OF PLAIN ENGLISH FRAMEWORK** | |
| **1. OPERATIONS MANAGEMENT PROCESS** | 1.1 Provide resources to facilitate system operations  1.2 Ask system owners to manage system operations  1.3 Expect personnel to carry out system operations |
| **2. MAINTENANCE MANAGEMENT PROCESS** | 2.1 Provide the resources needed to maintain system  2.2 Use authorized methods to maintain your system |
| **3. MEASUREMENT MANAGEMENT PROCESS** | 3.1 Plan how you're going to measure your system  3.2 Qualify the resources needed to measure system  3.3 Provide the resources needed to measure system  3.4 Use authorized methods to measure your system  3.5 Control the resources needed to measure system |
| **4. MONITORING MANAGEMENT PROCESS** | 4.1 Plan how you're going to monitor your system  4.2 Qualify the resources needed to monitor system  4.3 Provide the resources needed to monitor system  4.4 Use authorized methods to monitor your system  4.5 Control the resources needed to monitor system |
| **5. CONTROL MANAGEMENT PROCESS** | 5.1 Plan how you're going to control system  5.2 Develop ways of controlling your system  5.3 Provide resources needed to control system  5.4 Use authorized methods to control system |
| **6. EVALUATION MANAGEMENT PROCESS** | 6.1 Plan how you're going to evaluate system  6.2 Provide resources needed to evaluate system  6.3 Use authorized methods to evaluate system  6.4 Record the results of system evaluations |
| **7. CHANGE MANAGEMENT PROCESS** | 7.1 Establish change management methods  7.2 Generate opportunities to change system  7.3 Plan changes to your management system  7.4 Use approved methods to change system  7.5 Review and evaluate changes to system |
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|  | **FRAMEWORK FOR QUALITY MANAGEMENT SYSTEMS** | |
|  | **1. OPERATIONS MANAGEMENT PROCESS** | 1.1 Provide resources to facilitate system operations  1.1.1 Provide the expertise needed to operate your system  1.1.2 Provide the technology needed to operate your system  1.1.3 Provide the infrastructure needed to operate your system  1.2 Ask system owners to manage system operations  1.2.1 Expect system managers to address risks and opportunities  1.2.2 Expect system managers to implement policies and procedures  1.2.3 Expect system managers to specify output requirements and capabilities  1.2.4 Expect system managers to communicate with their system customers  1.2.5 Expect system managers to evaluate and select their external providers  1.2.6 Expect system managers to supervise and control all system activities  1.2.7 Expect system managers to measure conformance and performance  1.2.8 Expect system managers to meet expectations and requirements  1.2.9 Expect system managers to be accountable for their system  1.3 Expect personnel to carry out system operations  1.3.1 Expect personnel to focus on system customers  1.3.2 Expect personnel to handle risks and opportunities  1.3.3 Expect personnel to implement policies and procedures  1.3.4 Expect personnel to comply with all relevant requirements  1.3.5 Expect personnel to take appropriate action when necessary  1.3.6 Expect personnel to control system documents and records |
|  | **2. MAINTENANCE MANAGEMENT PROCESS** | 2.1 Provide the resources needed to maintain system  2.1.1 Provide the expertise needed to maintain your system  2.1.2 Provide the technology needed to maintain your system  2.2 Use authorized methods to maintain your system  2.2.1 Use authorized methods to maintain your documents  2.2.2 Use authorized methods to maintain your records  2.2.3 Use authorized methods to maintain your property  2.2.4 Use authorized methods to maintain your procedures  2.2.5 Use authorized methods to maintain your competence  2.2.6 Use authorized methods to maintain your technologies  2.2.7 Use authorized methods to maintain your infrastructure  2.2.8 Use authorized methods to maintain your communications |
|  | **3. MEASUREMENT MANAGEMENT PROCESS** | 3.1 Plan how you're going to measure your system  3.1.1 Figure out what needs to be measured  3.1.2 Figure out how measurements will be done  3.1.3 Figure out who will perform measurement tasks  3.2 Qualify the resources needed to measure system  3.2.1 Make sure that resources can measure your system  3.2.2 Make sure that resources are validated before use  3.3 Provide the resources needed to measure system  3.3.1 Provide the expertise needed to measure your system  3.3.2 Provide the technology needed to measure your system  3.3.3 Provide the infrastructure needed to measure your system  3.4 Use authorized methods to measure your system  3.4.1 Use authorized methods to measure system elements  3.4.2 Use authorized methods to measure system participants  3.5 Control the resources needed to measure system  3.5.1 Control the documents needed to measure your system  3.5.2 Control the technology needed to measure your system  3.5.3 Control the records needed to measure your system |
|  | **4. MONITORING MANAGEMENT PROCESS** | 4.1 Plan how you're going to monitor your system  4.1.1 Figure out what needs to be monitored  4.1.2 Figure out how monitoring will be done  4.1.3 Figure out who will perform monitoring tasks  4.2 Qualify the resources needed to monitor system  4.2.1 Make sure that resources can monitor your system  4.2.2 Make sure that resources are validated before use  4.3 Provide the resources needed to monitor system  4.3.1 Provide the expertise needed to monitor your system  4.3.2 Provide the technology needed to monitor your system  4.3.3 Provide the infrastructure needed to monitor your system  4.4 Use authorized methods to monitor your system  4.4.1 Use authorized methods to monitor system activities  4.4.2 Use authorized methods to monitor system outputs  4.4.3 Use authorized methods to monitor system inputs  4.4.4 Use authorized methods to monitor system documents  4.4.5 Use authorized methods to monitor system records  4.4.6 Use authorized methods to monitor system property  4.4.7 Use authorized methods to monitor system participants  4.4.8 Use authorized methods to monitor system technologies  4.4.9 Use authorized methods to monitor system environment  4.4.10 Use authorized methods to monitor system infrastructure  4.5 Control the resources needed to monitor system  4.5.1 Control the technologies needed to monitor system  4.5.2 Control the records needed to monitor system |
|  | **5. CONTROL MANAGEMENT PROCESS** | 5.1 Plan how you're going to control system  5.1.1 Consider how to control your system outputs  5.1.2 Consider how to control your system inputs  5.1.3 Consider how to control your system activities  5.1.4 Consider how to control your system providers  5.2 Develop ways of controlling your system  5.2.1 Develop ways of controlling system elements  5.2.2 Develop ways of controlling system providers  5.3 Provide resources needed to control system  5.3.1 Provide human resources needed to control system  5.3.2 Provide technical resources needed to control system  5.4 Use authorized methods to control system  5.4.1 Use authorized methods to control system inputs  5.4.2 Use authorized methods to control system outputs  5.4.3 Use authorized methods to control system activities  5.4.4 Use authorized methods to control system technology  5.4.5 Use authorized methods to control system performance  5.4.6 Use authorized methods to control system documentation |
|  | **6. EVALUATION MANAGEMENT PROCESS** | 6.1 Plan how you're going to evaluate system  6.1.1 Plan how you're going to audit your system  6.1.2 Plan how you're going to analyze your system  6.1.3 Plan how you're going to review your system  6.2 Provide resources needed to evaluate system  6.2.1 Provide the people that you need to evaluate your system  6.2.2 Provide the knowledge that you need to evaluate your system  6.2.3 Provide the technology that you need to evaluate your system  6.2.4 Provide the infrastructure that you need to evaluate your system  6.3 Use authorized methods to evaluate system  6.3.1 Use authorized methods to audit your system  6.3.2 Use authorized methods to analyze your system  6.3.3 Use authorized methods to review your system  6.4 Record the results of system evaluations  6.4.1 Record the results of management system audits  6.4.2 Record the results of management system analyses  6.4.3 Record the results of management system reviews |
|  | **7. CHANGE MANAGEMENT PROCESS** | 7.1 Establish change management methods  7.1.1 Establish methods for correcting system and outputs  7.1.2 Establish methods for improving system and outputs  7.2 Generate opportunities to change system  7.2.1 Discover opportunities to change system and outputs  7.2.2 Confirm that system and output changes are needed  7.2.3 Approve opportunities to change system and outputs  7.3 Plan changes to your management system  7.3.1 Plan how you're going to correct system and outputs  7.3.2 Plan how you're going to improve system and outputs  7.4 Use approved methods to change system  7.4.1 Use approved methods to correct system and outputs  7.4.2 Use approved methods to improve system and outputs  7.5 Review and evaluate changes to system  7.5.1 Review and evaluate system and output corrections  7.5.2 Review and evaluate system and output improvements |
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| 1.1 PROVIDE RESOURCES TO FACILITATE SYSTEM OPERATIONS | | | | | | | | | | |
| 1.1.1 Provide the expertise needed to operate your system | | | | | | | | | | |
|  | Provide the personnel needed to manage system operations. | | | | | | DO | DN | NA |  |
|  |  | Acquire the knowledge that managers need to manage  system operations and achieve conformity of outputs. | | | | | DO | DN | NA |  |
|  |  | | Consider internal sources of knowledge about managing systems. | | | | DO | DN | NA |  |
|  |  | | Consider external sources of knowledge about managing systems. | | | | DO | DN | NA |  |
|  |  | Share the knowledge that managers need to manage  system operations and achieve conformity of outputs. | | | | | DO | DN | NA |  |
|  |  | | Deliver suitable system management training and  awareness programmes to system managers. | | | | DO | DN | NA |  |
|  | Provide the personnel needed to operate your system. | | | | | | DO | DN | NA |  |
|  |  | Acquire the knowledge that personnel need to operate  your system and achieve conformity of outputs. | | | | | DO | DN | NA |  |
|  |  | | Consider internal sources of knowledge about system operations. | | | | DO | DN | NA |  |
|  |  | | Consider external sources of knowledge about system operations. | | | | DO | DN | NA |  |
|  |  | Share the knowledge that personnel need to operate  your system and achieve conformity of outputs. | | | | | DO | DN | NA |  |
|  |  | | Deliver suitable system training and awareness  programmes to support system operations. | | | | DO | DN | NA |  |
| 1.1.2 Provide the technology needed to operate your system | | | | | | | | | | |
|  | Provide the software needed to operate your quality management system. | | | | | | DO | DN | NA |  |
|  |  | Provide software needed to support operations and achieve conformity of outputs. | | | | | DO | DN | NA |  |
|  | Provide the hardware needed to operate your quality management system. | | | | | | DO | DN | NA |  |
|  |  | Provide hardware needed to support operations and achieve conformity of outputs. | | | | | DO | DN | NA |  |
| 1.1.3 Provide the infrastructure needed to operate your system | | | | | | | | | | |
|  | Provide the infrastructure needed to support system  operations and achieve conformity of outputs. | | | | | | DO | DN | NA |  |
|  |  | Provide the physical infrastructure needed to support  system operations and achieve conformity of outputs. | | | | | DO | DN | NA |  |
|  |  | Provide the electrical infrastructure needed to support  system operations and achieve conformity of outputs. | | | | | DO | DN | NA |  |
|  |  | Provide the transportation infrastructure needed to support  system operations and achieve conformity of outputs. | | | | | DO | DN | NA |  |
|  |  | Provide the communications infrastructure needed to support  system operations and achieve conformity of outputs. | | | | | DO | DN | NA |  |
| 1.2 ASK SYSTEM OWNERS TO MANAGE SYSTEM OPERATIONS | | | | | | | | | | |
| 1.2.1 Expect system managers to address risks and opportunities | | | | | | | | | | |
|  | Expect system managers to identify risks and opportunities. | | | | | | DO | DN | NA |  |
|  |  | Expect managers to identify the operational risks  that could affect their ability to meet requirements. | | | | | DO | DN | NA |  |
|  |  | Expect managers to identify the operational opportunities  that could improve their ability to meet requirements. | | | | | DO | DN | NA |  |
|  | Expect system managers to address risks and opportunities. | | | | | | DO | DN | NA |  |
|  |  | Expect system managers to manage and control 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 system 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 system 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 system 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 system. | DO | DN | NA |  |
|  |  | | | | | Expect them to figure out how they're going to evaluate the  effectiveness of the actions they take to address system risks. | DO | DN | NA |  |
|  |  | Expect system managers to exploit system improvement opportunities. | | | | | DO | DN | NA |  |
|  |  | | Expect managers to define actions to exploit system improvement opportunities. | | | | DO | DN | NA |  |
| 1.2.2 Expect system managers to implement policies and procedures | | | | | | | | | | |
|  | Expect system managers to implement system 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 privacy policies. | | | | | DO | DN | NA |  |
|  |  | Expect managers to implement security policies. | | | | | DO | DN | NA |  |
|  |  | Expect managers to implement continuity policies. | | | | | DO | DN | NA |  |
|  | Expect system managers to implement system 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 privacy procedures. | | | | | DO | DN | NA |  |
|  |  | Expect managers to implement security procedures. | | | | | DO | DN | NA |  |
|  |  | Expect managers to implement continuity procedures. | | | | | DO | DN | NA |  |
|  | Expect system managers to implement system plans. | | | | | | DO | DN | NA |  |
|  |  | Expect managers to implement business plans. | | | | | DO | DN | NA |  |
|  |  | Expect managers to implement quality plans. | | | | | DO | DN | NA |  |
|  |  | Expect managers to implement safety plans. | | | | | DO | DN | NA |  |
|  |  | Expect managers to implement privacy plans. | | | | | DO | DN | NA |  |
|  |  | Expect managers to implement security plans. | | | | | DO | DN | NA |  |
|  |  | Expect managers to implement continuity plans. | | | | | DO | DN | NA |  |
| 1.2.3 Expect system managers to specify output requirements and caPABilities | | | | | | | | | | |
|  | Expect system 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 system managers to review output requirements before accepting orders. | | | | | | DO | DN | NA |  |
|  |  | Expect them to review requirements before agreeing to supply outputs to customers. | | | | | DO | DN | NA |  |
|  |  | | Expect managers to coordinate reviews with other 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 your system’s 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 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 system managers to clarify differences between original proposals and final orders. | | | | | | DO | DN | NA |  |
|  |  | Expect managers to review orders and contractual requirements that were modified. | | | | | DO | DN | NA |  |
|  |  | | Expect them to resolve all differences between original proposals and final orders. | | | | DO | DN | NA |  |
|  | Expect system managers to confirm that they can meet output requirements. | | | | | | DO | DN | NA |  |
|  |  | Expect system managers to confirm that they can meet undocumented  customer requirements before making a commitment to supply outputs. | | | | | DO | DN | NA |  |
|  | Expect system managers to document the review of output requirements. | | | | | | DO | DN | NA |  |
|  |  | Expect system managers to document the results of output requirement reviews. | | | | | DO | DN | NA |  |
|  |  | | Expect system managers to retain documents that record results of their reviews. | | | | DO | DN | NA |  |
|  |  | | Expect system managers to control documents that record results of their reviews. | | | | DO | DN | NA |  |
|  |  | Expect system managers to document any new or changed output requirements. | | | | | DO | DN | NA |  |
|  |  | | Expect system managers to retain documents that record new or changed requirements. | | | | DO | DN | NA |  |
|  |  | | Expect system managers to control documents that record new or changed requirements. | | | | DO | DN | NA |  |
|  | Expect system 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 |  |
| 1.2.4 Expect system managers to communicate with their system customers | | | | | | | | | | |
|  | Expect quality management system managers to provide information to customers. | | | | | | DO | DN | NA |  |
|  |  | Expect quality management system managers to share information about outputs. | | | | | DO | DN | NA |  |
|  | Expect quality management system managers to obtain information from customers. | | | | | | DO | DN | NA |  |
|  |  | Expect system managers to obtain information about customer orders and contracts. | | | | | DO | DN | NA |  |
|  |  | | Expect system managers to receive information about changes to orders and contracts. | | | | DO | DN | NA |  |
|  |  | Expect quality system managers to obtain information about system outputs. | | | | | DO | DN | NA |  |
|  |  | | Expect system managers to gather customer feedback about system outputs. | | | | DO | DN | NA |  |
|  |  | | Expect quality system managers to gather complaints about system outputs. | | | | DO | DN | NA |  |
|  |  | Expect system managers to obtain information about property supplied by customers. | | | | | DO | DN | NA |  |
|  |  | | Expect system managers to manage and control property supplied by customers. | | | | DO | DN | NA |  |
| 1.2.5 Expect system managers to evaluate and select their external providers | | | | | | | | | | |
|  | Expect system 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 system 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 system 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 and criteria to select  external process, product, and service providers. | | | | | DO | DN | NA |  |
|  | Expect system managers to specify what they expect  from external process, product, and service providers. | | | | | | DO | DN | NA |  |
|  |  | Expect system managers to identify external process requirements. | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify external process approval requirements. | | | | DO | DN | NA |  |
|  |  | Expect system managers to identify product requirements. | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify external product acceptance requirements. | | | | 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 system 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 system managers to identify equipment requirements. | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify external equipment approval requirements. | | | | DO | DN | NA |  |
|  |  | Expect system managers to identify “special requirements”. | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify “critical items” and “key characteristics”. | | | | DO | DN | NA |  |
|  |  | Expect system managers to identify information requirements. | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify technical data and information requirements. | | | | DO | DN | NA |  |
|  |  | Expect system 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 system managers to identify methodological requirements. | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify how external methods are approved. | | | | DO | DN | NA |  |
|  |  | Expect system managers to identify interaction requirements. | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify how external providers interact with your system. | | | | DO | DN | NA |  |
|  |  | Expect system 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 |  |
|  |  | | Expect them to specify nonconformance notification requirements. | | | | DO | DN | NA |  |
|  |  | | | Expect them to specify nonconformance approval and disposition requirements. | | | DO | DN | NA |  |
|  |  | Expect system managers to identify design and development requirements. | | | | | DO | DN | NA |  |
|  |  | | Expect them to specify design and development control requirements. | | | | DO | DN | NA |  |
|  |  | Expect system managers to identify verification and validation requirements. | | | | | DO | DN | NA |  |
|  |  | | Expect them to identify verification and validation activities to be done externally. | | | | DO | DN | NA |  |
|  |  | Expect system managers to identify production requirements. | | | | | DO | DN | NA |  |
|  |  | | Expect them to specify production system verification requirements. | | | | DO | DN | NA |  |
|  |  | Expect system managers to identify test and inspection requirements. | | | | | DO | DN | NA |  |
|  |  | Expect system managers to identify part and component requirements. | | | | | DO | DN | NA |  |
|  |  | Expect system managers to identify outsourcing requirements. | | | | | DO | DN | NA |  |
|  |  | Expect system managers to identify supply chain requirements. | | | | | DO | DN | NA |  |
|  |  | Expect system managers to identify external staff awareness requirements. | | | | | DO | DN | NA |  |
|  |  | Expect system managers to identify external competence requirements. | | | | | DO | DN | NA |  |
|  |  | Expect system managers to identify monitoring and control requirements. | | | | | DO | DN | NA |  |
|  |  | Expect system managers to identify quality management requirements. | | | | | DO | DN | NA |  |
|  |  | Expect system managers to identify documentation requirements. | | | | | DO | DN | NA |  |
| 1.2.6 Expect system managers to supervise and control all system activities | | | | | | | | | | |
|  | Expect system managers to verify that resources can produce required results. | | | | | | DO | DN | NA |  |
|  |  | Expect system managers to validate resources that will be used to operate system. | | | | | DO | DN | NA |  |
|  |  | | Expect system managers to validate tools before they are used to operate system. | | | | DO | DN | NA |  |
|  |  | | Expect system managers to validate equipment before it is used to operate system. | | | | DO | DN | NA |  |
|  |  | | Expect system managers to validate software before it is used to operate system. | | | | DO | DN | NA |  |
|  |  | Expect system managers to validate resources that will be used to automate system. | | | | | DO | DN | NA |  |
|  |  | | Expect system managers to validate tools before they are used to automate system. | | | | DO | DN | NA |  |
|  |  | | Expect system managers to validate equipment before it is used to automate system. | | | | DO | DN | NA |  |
|  |  | | Expect system managers to validate software before it is used to automate system. | | | | DO | DN | NA |  |
|  |  | Expect system managers to validate resources that will be used to control system. | | | | | DO | DN | NA |  |
|  |  | | Expect system managers to validate tools before they are used to control system. | | | | DO | DN | NA |  |
|  |  | | Expect system managers to validate equipment before it is used to control system. | | | | DO | DN | NA |  |
|  |  | | Expect system managers to validate software before it is used to control system. | | | | DO | DN | NA |  |
|  |  | Expect system managers to validate resources that will be used to monitor system. | | | | | DO | DN | NA |  |
|  |  | | Expect system managers to validate tools before they are used to monitor system. | | | | DO | DN | NA |  |
|  |  | | Expect system managers to validate equipment before it is used to monitor system. | | | | DO | DN | NA |  |
|  |  | | Expect system managers to validate software before it is used to monitor system. | | | | DO | DN | NA |  |
|  |  | Expect system managers to validate resources that will be used to measure system. | | | | | DO | DN | NA |  |
|  |  | | Expect system managers to validate tools before they are used to measure system. | | | | DO | DN | NA |  |
|  |  | | Expect system managers to validate equipment before it is used to measure system. | | | | DO | DN | NA |  |
|  |  | | Expect system managers to validate software before it is used to measure system. | | | | DO | DN | NA |  |
|  | Expect system managers to supervise and control all quality system personnel. | | | | | | DO | DN | NA |  |
|  |  | Expect system managers to plan and control all relevant 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 system managers to control system documents and record keeping. | | | | | | DO | DN | NA |  |
|  |  | Expect them to ensure that documents and records are properly reviewed and approved. | | | | | DO | DN | NA |  |
| 1.2.7 Expect system managers to measure conformance and performance | | | | | | | | | | |
|  | Expect system managers to measure system performance and conformance. | | | | | | DO | DN | NA |  |
|  | Expect system managers to measure output performance and conformance. | | | | | | DO | DN | NA |  |
|  |  | Expect system managers to measure output delivery performance and conformance. | | | | | DO | DN | NA |  |
|  |  | | Expect system managers to measure post-delivery performance and conformance. | | | | DO | DN | NA |  |
| 1.2.8 Expect system managers to meet expectations and requirements | | | | | | | | | | |
|  | Expect system managers to ensure that legal expectations and requirements are being met. | | | | | | DO | DN | NA |  |
|  | Expect system managers to ensure that safety expectations and requirements are being met. | | | | | | DO | DN | NA |  |
|  | Expect system managers to ensure that privacy expectations and requirements are being met. | | | | | | DO | DN | NA |  |
|  | Expect system managers to ensure that quality expectations and requirements are being met. | | | | | | DO | DN | NA |  |
|  | Expect system managers to ensure that security expectations and requirements are being met. | | | | | | DO | DN | NA |  |
|  | Expect system managers to ensure that business expectations and requirements are being met. | | | | | | DO | DN | NA |  |
|  | Expect system managers to ensure that customer expectations and requirements are being met. | | | | | | DO | DN | NA |  |
| 1.2.9 Expect system managers to be accountable for their system | | | | | | | | | | |
|  | Expect managers to ensure that system produces intended outputs. | | | | | | DO | DN | NA |  |
|  |  | Expect managers to preserve outputs during system operations. | | | | | DO | DN | NA |  |
|  |  | | Expect them to figure out how to preserve outputs during system 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 preserve outputs by establishing handling methods and storage facilities. | | | DO | DN | NA |  |
|  |  | | | Expect them to preserve outputs by establishing marking methods and labeling practices. | | | 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 use suitable monitoring and measurement resources to control delivery. | | | | | DO | DN | NA |  |
|  |  | Expect them to use a suitable system environment to control output delivery system. | | | | | DO | DN | NA |  |
|  |  | Expect them to use competent qualified personnel to control 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 consider the need to provide, update, and control output documents. | | | | DO | DN | NA |  |
|  |  | | Expect them to consider the external work that must be done to support outputs. | | | | DO | DN | NA |  |
|  |  | | Expect them to consider the actions that must be taken after outputs are delivered. | | | | 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 system outputs. | | | | DO | DN | NA |  |
|  |  | | Expect them to use suitable monitoring and measurement resources to control post-delivery. | | | | DO | DN | NA |  |
|  |  | | Expect them to use a suitable system environment to control post-delivery activities. | | | | DO | DN | NA |  |
|  |  | | Expect them to use competent qualified personnel to control post-delivery activities. | | | | DO | DN | NA |  |
|  | Expect managers to identify and control all nonconforming outputs. | | | | | | DO | DN | NA |  |
|  |  | Expect quality management system managers to evaluate nonconforming outputs. | | | | | DO | DN | NA |  |
|  |  | | Expect them to consider the nature of nonconforming outputs and to evaluate their effects. | | | | DO | DN | NA |  |
|  |  | Expect quality system 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 quality system managers to document nonconforming system outputs. | | | | | DO | DN | NA |  |
|  |  | | Expect system managers to document the actions and decisions taken to  prevent the unintended use or delivery of nonconforming outputs. | | | | DO | DN | NA |  |
|  | Expect managers to submit system performance reports. | | | | | | DO | DN | NA |  |
| 1.3 EXPECT PERSONNEL TO CARRY OUT SYSTEM OPERATIONS | | | | | | | | | | |
| 1.3.1 Expect personnel to focus on system customers | | | | | | | | | | |
|  | Expect system personnel to identify customer needs and expectations. | | | | | | DO | DN | NA |  |
|  |  | Expect system personnel to identify customer assumptions and perceptions. | | | | | DO | DN | NA |  |
|  | Expect system personnel to understand customer needs and expectations. | | | | | | DO | DN | NA |  |
|  |  | Expect system personnel to understand customer assumptions and perceptions. | | | | | DO | DN | NA |  |
|  | Expect system personnel to meet relevant customer needs and expectations. | | | | | | DO | DN | NA |  |
|  |  | Expect system personnel to focus on enhancing customer satisfaction. | | | | | DO | DN | NA |  |
| 1.3.2 Expect personnel to handle risks and opportunities | | | | | | | | | | |
|  | Expect quality system 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 system customers. | | | | DO | DN | NA |  |
|  |  | | Expect them to identify the opportunities that could possibly enhance  their ability to provide compliant outputs to system 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 quality system 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 system customers. | | | | DO | DN | NA |  |
|  |  | | Expect them to address the opportunities that could enhance  their ability to provide compliant outputs to system 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 |  |
| 1.3.3 Expect personnel to implement policies and procedures | | | | | | | | | | |
|  | Expect quality system personnel to follow system policies. | | | | | | DO | DN | NA |  |
|  |  | Expect them to implement and follow safety policies. | | | | | DO | DN | NA |  |
|  |  | Expect them to implement and follow quality policies. | | | | | DO | DN | NA |  |
|  |  | Expect them to implement and follow security policies. | | | | | DO | DN | NA |  |
|  |  | Expect them to implement and follow privacy policies. | | | | | DO | DN | NA |  |
|  |  | Expect them to implement and follow business policies. | | | | | DO | DN | NA |  |
|  |  | Expect them to implement and follow continuity policies. | | | | | DO | DN | NA |  |
|  | Expect quality system personnel to follow system procedures. | | | | | | DO | DN | NA |  |
|  |  | Expect them to implement and follow safety procedures. | | | | | DO | DN | NA |  |
|  |  | Expect them to implement and follow quality procedures. | | | | | DO | DN | NA |  |
|  |  | Expect them to implement and follow privacy procedures. | | | | | DO | DN | NA |  |
|  |  | Expect them to implement and follow security procedures. | | | | | DO | DN | NA |  |
|  |  | Expect them to implement and follow business procedures. | | | | | DO | DN | NA |  |
|  |  | Expect them to implement and follow continuity procedures. | | | | | DO | DN | NA |  |
| 1.3.4 Expect personnel to comply with all relevant requirements | | | | | | | | | | |
|  | Expect system 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 system personnel to meet all relevant requirements. | | | | | | DO | DN | NA |  |
|  |  | Expect them to meet all relevant 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 all relevant 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 |  |
| 1.3.5 Expect personnel to take appropriate action when necessary | | | | | | | | | | |
|  | Expect system personnel to take action when planned results aren't being achieved. | | | | | | DO | DN | NA |  |
|  | Expect system personnel to take action when planned results won't be achieved. | | | | | | DO | DN | NA |  |
|  | Expect system personnel to take action when planned results can’t be achieved. | | | | | | DO | DN | NA |  |
| 1.3.6 Expect personnel to control system documents and records | | | | | | | | | | |
|  | Expect system personnel to retain and control system documents. | | | | | | DO | DN | NA |  |
|  | Expect system personnel to maintain and control system records. | | | | | | 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 THE RESOURCES NEEDED TO MAINTAIN SYSTEM | | | | | | | | |
| 2.1.1 Provide the expertise needed to maintain your system | | | | | | | | |
|  | Provide the managers needed to maintain your quality system. | | | | DO | DN | NA |  |
|  |  | Acquire the knowledge that managers need in order to  support system maintenance and achieve conformity of outputs. | | | DO | DN | NA |  |
|  |  | Share the knowledge that managers need so that they can  support system maintenance and achieve conformity of outputs. | | | DO | DN | NA |  |
|  |  | | Deliver suitable awareness programmes to the  people who manage system maintenance activities. | | DO | DN | NA |  |
|  |  | | Deliver suitable training programmes to the  people who manage system maintenance activities. | | DO | DN | NA |  |
|  | Provide people needed to maintain your quality system. | | | | DO | DN | NA |  |
|  |  | Acquire the knowledge that your personnel need in order  to maintain system and achieve conformity of outputs. | | | DO | DN | NA |  |
|  |  | Share the knowledge that personnel need in order to  maintain system and achieve conformity of outputs. | | | DO | DN | NA |  |
|  |  | | Deliver suitable awareness programmes  for your system maintenance personnel. | | DO | DN | NA |  |
|  |  | | Deliver suitable training programmes  for your system maintenance personnel. | | DO | DN | NA |  |
| 2.1.2 Provide the technology needed to maintain your system | | | | | | | | |
|  | Provide the software needed to maintain quality system. | | | | DO | DN | NA |  |
|  |  | Provide the software needed to support system  maintenance and achieve conformity of outputs. | | | DO | DN | NA |  |
|  | Provide the hardware needed to maintain quality system. | | | | DO | DN | NA |  |
|  |  | Provide the hardware needed to support system  maintenance and achieve conformity of outputs. | | | DO | DN | NA |  |
| 2.2 USE AUTHORIZED METHODS TO MAINTAIN YOUR SYSTEM | | | | | | | | |
| 2.2.1 Use authorized methods to maintain YOUR documents | | | | | | | | |
|  | Maintain documents that describe how work should be carried out. | | | | DO | DN | NA |  |
|  |  | Maintain documents that describe how system operations should be carried out. | | | DO | DN | NA |  |
|  |  | Maintain documents that describe how system maintenance should be carried out. | | | DO | DN | NA |  |
|  |  | Maintain documents that describe how system monitoring should be carried out. | | | DO | DN | NA |  |
|  |  | Maintain documents that describe how system measurement should be carried out. | | | DO | DN | NA |  |
|  |  | Maintain documents that describe how system control should be carried out. | | | DO | DN | NA |  |
|  |  | Maintain documents that describe how system evaluation should be carried out. | | | DO | DN | NA |  |
|  |  | | Maintain documents that describe how system audits should be carried out. | | DO | DN | NA |  |
|  |  | | Maintain documents that describe how system reviews should be carried out. | | DO | DN | NA |  |
|  |  | Maintain documents that describe how systemic change should be carried out. | | | DO | DN | NA |  |
|  |  | | Maintain documents that describe how system correction should be carried out. | | DO | DN | NA |  |
|  |  | | Maintain documents that describe how system improvements should be carried out. | | DO | DN | NA |  |
| 2.2.2 Use authorized methods to maintain YOUR records | | | | | | | | |
|  | Maintain records that describe the scope of your quality management system. | | | | DO | DN | NA |  |
|  | Maintain records of quality management system responsibilities and authorities. | | | | DO | DN | NA |  |
|  | Maintain records of quality management system performance and competence. | | | | DO | DN | NA |  |
|  |  | Retain your documentation and use it as evidence to show that your  quality management system personnel are in fact competent. | | | DO | DN | NA |  |
|  | Maintain records showing that quality management system is performing as planned. | | | | DO | DN | NA |  |
|  |  | Maintain records that show that system operations are being carried out as planned. | | | DO | DN | NA |  |
|  |  | Maintain records that show that system maintenance is being carried out as planned. | | | DO | DN | NA |  |
|  |  | Maintain records that show that system monitoring is being carried out as planned. | | | DO | DN | NA |  |
|  |  | Maintain records that show that system measurement is being carried out as planned. | | | DO | DN | NA |  |
|  |  | Maintain records that show that system control is being carried out as planned. | | | DO | DN | NA |  |
|  |  | Maintain records that show that system evaluation is being carried out as planned. | | | DO | DN | NA |  |
|  |  | | Maintain records that show that system audits are being carried out as planned. | | DO | DN | NA |  |
|  |  | | Maintain records that show that system reviews are being carried out as planned. | | DO | DN | NA |  |
|  |  | Maintain records that show that system changes are being carried out as planned. | | | DO | DN | NA |  |
|  |  | | Maintain records that show that system corrections are being carried out as planned. | | DO | DN | NA |  |
|  |  | | Maintain records that show that system improvements are being carried out as planned. | | DO | DN | NA |  |
| 2.2.3 Use authorized methods to maintain YOUR property | | | | | | | | |
|  | Maintain system 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 |  |
|  |  | 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 |  |
|  | Maintain property owned by your quality management system  that is needed to achieve conformity of system outputs. | | | | DO | DN | NA |  |
|  |  | Maintain equipment that your system needs in order to achieve conformity of outputs. | | | DO | DN | NA |  |
|  |  | Maintain software that your system needs in order to achieve conformity of outputs. | | | DO | DN | NA |  |
|  |  | Maintain tools that your system needs in order to achieve conformity of outputs. | | | DO | DN | NA |  |
| 2.2.4 Use authorized methods to maintain YOUR procedures | | | | | | | | |
|  | Use authorized methods to maintain system management procedures. | | | | DO | DN | NA |  |
|  |  | Use authorized methods to maintain system control procedures. | | | DO | DN | NA |  |
|  |  | Use authorized methods to maintain system operational procedures. | | | DO | DN | NA |  |
|  |  | Use authorized methods to maintain system maintenance procedures. | | | DO | DN | NA |  |
|  |  | Use authorized methods to maintain system monitoring procedures. | | | DO | DN | NA |  |
|  |  | | Use authorized methods to maintain system feedback procedures. | | DO | DN | NA |  |
|  |  | Use authorized methods to maintain system measurement procedures. | | | DO | DN | NA |  |
|  |  | | Use authorized methods to maintain equipment calibration procedures. | | DO | DN | NA |  |
|  |  | Use authorized methods to maintain system evaluation procedures. | | | DO | DN | NA |  |
|  |  | | Use authorized methods to maintain system audit procedures. | | DO | DN | NA |  |
|  |  | | Use authorized methods to maintain system review procedures. | | DO | DN | NA |  |
|  |  | Use authorized methods to maintain system change procedures. | | | DO | DN | NA |  |
|  |  | | Use authorized methods to maintain system correction procedures. | | DO | DN | NA |  |
|  |  | | Use authorized methods to maintain system improvement procedures. | | DO | DN | NA |  |
| 2.2.5 Use authorized methods to maintain YOUR competence | | | | | | | | |
|  | Share information and knowledge with management system personnel. | | | | DO | DN | NA |  |
|  |  | Make sure that they are aware of management system plans. | | | DO | DN | NA |  |
|  |  | Make sure that they are aware of management system policies. | | | DO | DN | NA |  |
|  |  | Make sure that they are aware of management system objectives. | | | DO | DN | NA |  |
|  |  | Make sure that they are aware of management system procedures. | | | DO | DN | NA |  |
|  |  | Make sure that they are aware of management system documents and records. | | | DO | DN | NA |  |
|  |  | | Make sure that personnel stay abreast of changes in knowledge and information. | | DO | DN | NA |  |
|  |  | Make sure that they are aware of the important contribution they make. | | | DO | DN | NA |  |
|  |  | | Make sure that they understand how they affect system performance. | | DO | DN | NA |  |
|  |  | | Make sure that they understand how they influence system outputs. | | DO | DN | NA |  |
|  |  | Make sure that they are aware of all relevant requirements. | | | DO | DN | NA |  |
|  |  | | Explain why compliance is important to your system. | | DO | DN | NA |  |
|  |  | Make sure that they are aware of how they can help. | | | DO | DN | NA |  |
|  |  | | Explain how they can help enhance system effectiveness. | | DO | DN | NA |  |
|  | Acquire competence whenever shortcomings are discovered. | | | | DO | DN | NA |  |
|  |  | Acquire the necessary competence whenever system  personnel fail to meet system 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 system 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 |  |
| 2.2.6 Use authorized methods to maintain YOUR technologies | | | | | | | | |
|  | Maintain technology used to perform management system operations. | | | | DO | DN | NA |  |
|  |  | Maintain tools used to perform management system operations. | | | DO | DN | NA |  |
|  |  | | Define storage requirements for tools used for system operations. | | DO | DN | NA |  |
|  |  | | | Define how and when to check the status of tools used for system operations. | DO | DN | NA |  |
|  |  | Maintain equipment used to perform management system operations. | | | DO | DN | NA |  |
|  |  | | Define storage requirements for equipment used for system operations. | | DO | DN | NA |  |
|  |  | | | Define how and when to check the status of equipment used for system operations. | DO | DN | NA |  |
|  |  | Maintain software used to perform management system operations. | | | DO | DN | NA |  |
|  |  | | Define how and when to check the status of software used for system operations. | | DO | DN | NA |  |
|  | Maintain technology used to automate management system operations. | | | | DO | DN | NA |  |
|  |  | Maintain tools used to automate management system operations. | | | DO | DN | NA |  |
|  |  | | Define storage requirements for tools used to automate system operations. | | DO | DN | NA |  |
|  |  | Maintain equipment used to automate management system operations. | | | DO | DN | NA |  |
|  |  | | Define storage requirements for equipment used to automate system operations. | | DO | DN | NA |  |
|  |  | Maintain software used to automate management system 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 management system operations. | | | | DO | DN | NA |  |
|  |  | Maintain tools used to control management system operations. | | | DO | DN | NA |  |
|  |  | Maintain equipment used to control management system operations. | | | DO | DN | NA |  |
|  |  | Maintain software used to control management system operations. | | | DO | DN | NA |  |
|  | Maintain technology used to monitor management system operations. | | | | DO | DN | NA |  |
|  |  | Maintain tools used to monitor management system operations. | | | DO | DN | NA |  |
|  |  | Maintain equipment used to monitor management system operations. | | | DO | DN | NA |  |
|  |  | Maintain software used to monitor management system operations. | | | DO | DN | NA |  |
|  | Maintain technology used to measure management system operations. | | | | DO | DN | NA |  |
|  |  | Maintain software used to measure management system operations. | | | DO | DN | NA |  |
|  |  | Maintain tools used to measure management system operations. | | | DO | DN | NA |  |
|  |  | Maintain equipment used to measure management system operations. | | | DO | DN | NA |  |
|  |  | | Define storage requirements for equipment used to measure operations. | | DO | DN | NA |  |
|  |  | | Establish an identification system for measurement equipment. | | DO | DN | NA |  |
|  |  | | Verify or calibrate your system measurement equipment. | | DO | DN | NA |  |
|  |  | | Safeguard your system measurement equipment. | | DO | DN | NA |  |
| 2.2.7 Use authorized methods to maintain YOUR infrastructure | | | | | | | | |
|  | Maintain the infrastructure that your system needs in order to achieve conformity of outputs. | | | | DO | DN | NA |  |
|  |  | Maintain the facilities that your system needs in order to achieve conformity of outputs. | | | DO | DN | NA |  |
|  |  | Maintain the utilities that your system needs in order to achieve conformity of outputs. | | | DO | DN | NA |  |
|  |  | Maintain the services that your system needs in order to achieve conformity of outputs. | | | DO | DN | NA |  |
|  |  | Maintain the technologies that your system needs in order to achieve conformity of outputs. | | | DO | DN | NA |  |
|  |  | | Maintain the hardware that your system needs in order to achieve conformity of outputs. | | DO | DN | NA |  |
|  |  | | Maintain the software that your system needs in order to achieve conformity of outputs. | | DO | DN | NA |  |
| 2.2.8 Use authorized methods to maintain YOUR communications | | | | | | | | |
|  | Maintain the internal communications that system needs to achieve conformity of outputs. | | | | DO | DN | NA |  |
|  | Maintain the external communications that system needs to achieve conformity of outputs. | | | | 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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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 3.1 PLAN HOW YOU'RE GOING TO MEASURE YOUR SYSTEM | | | | | | | | | | |
| 3.1.1 Figure out what needs to be measured | | | | | | | | | | |
|  | Figure out what kind of system activities need to be measured. | | | | | | DO | DN | NA |  |
|  |  | Figure out what kind of system 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 |  |
| 3.1.2 Figure out how measurements will be done | | | | | | | | | | |
|  | Plan how you're going to measure system elements. | | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to measure your system 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 system 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 system activities. | | | | | DO | DN | NA |  |
|  |  | | Plan how you're going to measure system management activities. | | | | DO | DN | NA |  |
|  |  | | | Plan how to measure how well system management activities meet expectations. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system management activities apply policies. | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system management activities implement plans. | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system management activities follow procedures. | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system management activities achieve objectives. | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system management activities comply with requirements. | | DO | DN | NA |  |
|  |  | | Plan how you're going to measure system operating activities. | | | | DO | DN | NA |  |
|  |  | | | Plan how to measure how well system operating activities meet expectations. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system operating activities apply policies. | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system operating activities implement plans. | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system operating activities follow procedures. | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system operating activities achieve objectives. | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system operating activities comply with requirements. | | DO | DN | NA |  |
|  |  | | Plan how you're going to measure system maintenance activities. | | | | DO | DN | NA |  |
|  |  | | | Plan how to measure how well system maintenance activities meet expectations. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system maintenance activities apply policies. | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system maintenance activities implement plans. | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system maintenance activities follow procedures. | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system maintenance activities achieve objectives. | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system maintenance activities comply with requirements. | | DO | DN | NA |  |
|  |  | | Plan how you're going to measure system monitoring activities. | | | | DO | DN | NA |  |
|  |  | | | Plan how to measure how well system monitoring activities meet expectations. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system monitoring activities apply policies. | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system monitoring activities implement plans. | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system monitoring activities follow procedures. | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system monitoring activities achieve objectives. | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system monitoring activities comply with requirements. | | DO | DN | NA |  |
|  |  | | Plan how you're going to measure system measurement activities. | | | | DO | DN | NA |  |
|  |  | | | Plan how to measure how well system measurement activities meet expectations. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system measurement activities apply policies. | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system measurement activities implement plans. | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system measurement activities follow procedures. | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system measurement activities achieve objectives. | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system measurement activities comply with requirements. | | DO | DN | NA |  |
|  |  | | Plan how you're going to measure system control activities. | | | | DO | DN | NA |  |
|  |  | | | Plan how to measure how well system control activities meet expectations. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system control activities apply policies. | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system control activities implement plans. | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system control activities follow procedures. | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system control activities achieve objectives. | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system control activities comply with requirements. | | DO | DN | NA |  |
|  |  | | Plan how you're going to measure system evaluation activities. | | | | DO | DN | NA |  |
|  |  | | | Plan how you're going to measure system audit activities. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system audit activities meet expectations. | | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well system audit activities apply policies. | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well system audit activities implement plans. | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well system audit activities follow procedures. | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well system audit activities achieve objectives. | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well system audit activities comply with requirements. | DO | DN | NA |  |
|  |  | | | Plan how you're going to measure system review activities. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system review activities meet expectations. | | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well system review activities apply policies. | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well system review activities implement plans. | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well system review activities follow procedures. | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well system review activities achieve objectives. | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well system review activities comply with requirements. | DO | DN | NA |  |
|  |  | | Plan how you're going to measure system change activities. | | | | DO | DN | NA |  |
|  |  | | | Plan how you're going to measure system correction activities. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system correction activities meet expectations. | | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well system correction activities apply policies. | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well system correction activities implement plans. | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well system correction activities follow procedures. | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well system correction activities achieve objectives. | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well system correction activities comply with requirements. | DO | DN | NA |  |
|  |  | | | Plan how you're going to measure system improvement activities. | | | DO | DN | NA |  |
|  |  | | | | Plan how to measure how well system improvement activities meet expectations. | | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well system improvement activities apply policies. | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well system improvement activities implement plans. | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well system improvement activities follow procedures. | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well system improvement activities achieve objectives. | DO | DN | NA |  |
|  |  | | | | | Plan how to measure how well system improvement activities comply with requirements. | DO | DN | NA |  |
|  | Plan how you're going to measure customer satisfaction. | | | | | | DO | DN | NA |  |
|  |  | Learn how management system customers feel about your 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 |  |
| 3.1.3 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 system customers. | | | | | DO | DN | NA |  |
|  |  | Allocate responsibility and authority for studying feedback from customers. | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for measuring system elements. | | | | | | DO | DN | NA |  |
|  |  | Allocate responsibility and authority for measuring system outputs. | | | | | DO | DN | NA |  |
|  |  | Allocate responsibility and authority for measuring system inputs. | | | | | DO | DN | NA |  |
|  |  | Allocate responsibility and authority for measuring system activities. | | | | | DO | DN | NA |  |
|  |  | | Allocate responsibility and authority for measuring system control activities and results. | | | | DO | DN | NA |  |
|  |  | | Allocate responsibility and authority for measuring system operating activities and results. | | | | DO | DN | NA |  |
|  |  | | Allocate responsibility and authority for measuring system maintenance activities and results. | | | | DO | DN | NA |  |
|  |  | | Allocate responsibility and authority for measuring system measurement activities and results. | | | | DO | DN | NA |  |
|  |  | | Allocate responsibility and authority for measuring system monitoring activities and results. | | | | DO | DN | NA |  |
|  |  | | Allocate responsibility and authority for measuring system evaluation activities and results. | | | | DO | DN | NA |  |
|  |  | | | Allocate responsibility and authority for measuring system audit activities and results. | | | DO | DN | NA |  |
|  |  | | | Allocate responsibility and authority for measuring system review activities and results. | | | DO | DN | NA |  |
|  |  | | Allocate responsibility and authority for measuring system change activities and results. | | | | DO | DN | NA |  |
|  |  | | | Allocate responsibility and authority for measuring system correction activities and results. | | | DO | DN | NA |  |
|  |  | | | Allocate responsibility and authority for measuring system improvement activities and results. | | | DO | DN | NA |  |
| 3.2 QUALIFY THE RESOURCES NEEDED TO MEASURE SYSTEM | | | | | | | | | | |
| 3.2.1 MAKE SURE THAT RESOURCES CAN MEASURE YOUR SYSTEM | | | | | | | | | | |
|  | 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 can handle your unique circumstances. | | | | | DO | DN | NA |  |
|  |  | Select measurement resources that will ensure that outputs meet requirements. | | | | | DO | DN | NA |  |
|  |  | Select measurement resources that are capable of providing the information you need. | | | | | DO | DN | NA |  |
| 3.2.2 MAKE SURE THAT RESOURCES ARE VALIDATED BEFORE USE | | | | | | | | | | |
|  | Validate measurement resources before you use them. | | | | | | DO | DN | NA |  |
|  |  | Validate resources that are used to measure management system. | | | | | DO | DN | NA |  |
|  |  | | Validate software before it is used to measure management system. | | | | DO | DN | NA |  |
|  |  | | Validate tools before they are used to measure management system. | | | | DO | DN | NA |  |
|  |  | | Validate equipment before it is used to measure management system. | | | | DO | DN | NA |  |
| 3.3 PROVIDE THE RESOURCES NEEDED TO MEASURE SYSTEM | | | | | | | | | | |
| 3.3.1 Provide the expertise needed to measure your system | | | | | | | | | | |
|  | 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 system. | | | | | DO | DN | NA |  |
|  |  | | Acquire the knowledge that system managers  need to support system measurement activities. | | | | DO | DN | NA |  |
|  |  | | | Ensure that system managers get the knowledge  they need to support measurement activities. | | | DO | DN | NA |  |
|  |  | | | | Deliver suitable training and awareness programmes  for managers of system measurement activities. | | DO | DN | NA |  |
|  |  | Provide the personnel needed to measure your system. | | | | | DO | DN | NA |  |
|  |  | | Acquire the knowledge that personnel need to measure your system. | | | | DO | DN | NA |  |
|  |  | | | Consider internal sources of knowledge about system measurement. | | | DO | DN | NA |  |
|  |  | | | Consider external sources of knowledge about system measurement. | | | DO | DN | NA |  |
|  |  | | Ensure that personnel get the knowledge they need to measure your system. | | | | DO | DN | NA |  |
|  |  | | | Deliver suitable training and awareness programmes for system measuring personnel. | | | DO | DN | NA |  |
| 3.3.2 Provide the technology needed to measure your system | | | | | | | | | | |
|  | Provide the technology needed to ensure that  measurement methods yield valid and reliable results. | | | | | | DO | DN | NA |  |
|  |  | Provide the software needed to measure your system. | | | | | DO | DN | NA |  |
|  |  | | Provide the software needed to support system measurement activities. | | | | DO | DN | NA |  |
|  |  | Provide the hardware needed to measure your system. | | | | | DO | DN | NA |  |
|  |  | | Provide the hardware needed to support system measurement activities. | | | | DO | DN | NA |  |
|  |  | | | Provide the tools and equipment needed to measure your system. | | | DO | DN | NA |  |
| 3.3.3 Provide the infrastructure needed to measure your system | | | | | | | | | | |
|  | Provide the infrastructure needed to ensure that  measurement methods yield valid and reliable results. | | | | | | DO | DN | NA |  |
|  |  | Provide the infrastructure needed to support system  measurement and achieve conformity of outputs. | | | | | DO | DN | NA |  |
| 3.4 USE AUTHORIZED METHODS TO MEASURE YOUR SYSTEM | | | | | | | | | | |
| 3.4.1 Use authorized methods to measure system elements | | | | | | | | | | |
|  | Use authorized methods to measure system 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 system 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 system activities. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to measure system operating activities. | | | | | DO | DN | NA |  |
|  |  | | Measure how well system operating activities meet expectations. | | | | DO | DN | NA |  |
|  |  | | | Measure how well system operating activities apply policies. | | | DO | DN | NA |  |
|  |  | | | Measure how well system operating activities implement plans. | | | DO | DN | NA |  |
|  |  | | | Measure how well system operating activities follow procedures. | | | DO | DN | NA |  |
|  |  | | | Measure how well system operating activities achieve objectives. | | | DO | DN | NA |  |
|  |  | | | Measure how well system operating activities comply with requirements. | | | DO | DN | NA |  |
|  |  | Use authorized methods to measure system maintenance activities. | | | | | DO | DN | NA |  |
|  |  | | Measure how well system maintenance activities meet expectations. | | | | DO | DN | NA |  |
|  |  | | | Measure how well system maintenance activities apply policies. | | | DO | DN | NA |  |
|  |  | | | Measure how well system maintenance activities implement plans. | | | DO | DN | NA |  |
|  |  | | | Measure how well system maintenance activities follow procedures. | | | DO | DN | NA |  |
|  |  | | | Measure how well system maintenance activities achieve objectives. | | | DO | DN | NA |  |
|  |  | | | Measure how well system maintenance activities comply with requirements. | | | DO | DN | NA |  |
|  |  | Use authorized methods to measure system measurement activities. | | | | | DO | DN | NA |  |
|  |  | | Measure how well system measurement activities meet expectations. | | | | DO | DN | NA |  |
|  |  | | | Measure how well system measurement activities apply policies. | | | DO | DN | NA |  |
|  |  | | | Measure how well system measurement activities implement plans. | | | DO | DN | NA |  |
|  |  | | | Measure how well system measurement activities follow procedures. | | | DO | DN | NA |  |
|  |  | | | Measure how well system measurement activities achieve objectives. | | | DO | DN | NA |  |
|  |  | | | Measure how well system measurement activities comply with requirements. | | | DO | DN | NA |  |
|  |  | Use authorized methods to measure system monitoring activities. | | | | | DO | DN | NA |  |
|  |  | | Measure how well system monitoring activities meet expectations. | | | | DO | DN | NA |  |
|  |  | | | Measure how well system monitoring activities apply policies. | | | DO | DN | NA |  |
|  |  | | | Measure how well system monitoring activities implement plans. | | | DO | DN | NA |  |
|  |  | | | Measure how well system monitoring activities follow procedures. | | | DO | DN | NA |  |
|  |  | | | Measure how well system monitoring activities achieve objectives. | | | DO | DN | NA |  |
|  |  | | | Measure how well system monitoring activities comply with requirements. | | | DO | DN | NA |  |
|  |  | Use authorized methods to measure system control activities. | | | | | DO | DN | NA |  |
|  |  | | Measure how well system control activities meet expectations. | | | | DO | DN | NA |  |
|  |  | | | Measure how well system control activities apply policies. | | | DO | DN | NA |  |
|  |  | | | Measure how well system control activities implement plans. | | | DO | DN | NA |  |
|  |  | | | Measure how well system control activities follow procedures. | | | DO | DN | NA |  |
|  |  | | | Measure how well system control activities achieve objectives. | | | DO | DN | NA |  |
|  |  | | | Measure how well system control activities comply with requirements. | | | DO | DN | NA |  |
|  |  | Use authorized methods to measure system evaluation activities. | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to measure system audit activities. | | | | DO | DN | NA |  |
|  |  | | | Measure how well system audit activities meet expectations. | | | DO | DN | NA |  |
|  |  | | | | Measure how well system audit activities apply policies. | | DO | DN | NA |  |
|  |  | | | | Measure how well system audit activities implement plans. | | DO | DN | NA |  |
|  |  | | | | Measure how well system audit activities follow procedures. | | DO | DN | NA |  |
|  |  | | | | Measure how well system audit activities achieve objectives. | | DO | DN | NA |  |
|  |  | | | | Measure how well system audit activities comply with requirements. | | DO | DN | NA |  |
|  |  | | Use authorized methods to measure system review activities. | | | | DO | DN | NA |  |
|  |  | | | Measure how well system review activities meet expectations. | | | DO | DN | NA |  |
|  |  | | | | Measure how well system review activities apply policies. | | DO | DN | NA |  |
|  |  | | | | Measure how well system review activities implement plans. | | DO | DN | NA |  |
|  |  | | | | Measure how well system review activities follow procedures. | | DO | DN | NA |  |
|  |  | | | | Measure how well system review activities achieve objectives. | | DO | DN | NA |  |
|  |  | | | | Measure how well system review activities comply with requirements. | | DO | DN | NA |  |
|  |  | Use authorized methods to measure system change activities. | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to measure system correction activities. | | | | DO | DN | NA |  |
|  |  | | | Measure how well system correction activities meet expectations. | | | DO | DN | NA |  |
|  |  | | | | Measure how well system correction activities apply policies. | | DO | DN | NA |  |
|  |  | | | | Measure how well system correction activities implement plans. | | DO | DN | NA |  |
|  |  | | | | Measure how well system correction activities follow procedures. | | DO | DN | NA |  |
|  |  | | | | Measure how well system correction activities achieve objectives. | | DO | DN | NA |  |
|  |  | | | | Measure how well system correction activities comply with requirements. | | DO | DN | NA |  |
|  |  | | Use authorized methods to measure system improvement activities. | | | | DO | DN | NA |  |
|  |  | | | Measure how well system improvement activities meet expectations. | | | DO | DN | NA |  |
|  |  | | | | Measure how well system improvement activities apply policies. | | DO | DN | NA |  |
|  |  | | | | Measure how well system improvement activities implement plans. | | DO | DN | NA |  |
|  |  | | | | Measure how well system improvement activities follow procedures. | | DO | DN | NA |  |
|  |  | | | | Measure how well system improvement activities achieve objectives. | | DO | DN | NA |  |
|  |  | | | | Measure how well system improvement activities comply with requirements. | | DO | DN | NA |  |
| 3.4.2 Use authorized methods to measure system participants | | | | | | | | | | |
|  | Use authorized methods to measure the performance of system personnel. | | | | | | DO | DN | NA |  |
|  |  | Measure the competence and effectiveness of your system personnel. | | | | | DO | DN | NA |  |
|  |  | | Measure the system knowledge and skill that has been acquired. | | | | DO | DN | NA |  |
|  |  | Measure how well system personnel meet system expectations. | | | | | DO | DN | NA |  |
|  |  | | Measure how well system personnel apply system policies. | | | | DO | DN | NA |  |
|  |  | | Measure how well system personnel implement system plans. | | | | DO | DN | NA |  |
|  |  | | Measure how well system personnel follow system procedures. | | | | DO | DN | NA |  |
|  |  | | Measure how well system personnel meet system requirements. | | | | DO | DN | NA |  |
|  |  | | Measure how well system personnel achieve system objectives. | | | | DO | DN | NA |  |
|  |  | | | Measure how well system personnel achieve safety objectives. | | | DO | DN | NA |  |
|  |  | | | Measure how well system personnel achieve quality objectives. | | | DO | DN | NA |  |
|  |  | | | Measure how well system personnel achieve privacy objectives. | | | DO | DN | NA |  |
|  |  | | | Measure how well system personnel achieve security objectives. | | | DO | DN | NA |  |
|  |  | | | Measure how well system personnel achieve business objectives. | | | DO | DN | NA |  |
|  |  | | | Measure how well system personnel achieve technical objectives. | | | DO | DN | NA |  |
|  |  | | | Measure how well system personnel achieve continuity objectives. | | | DO | DN | NA |  |
|  | Use authorized methods to measure the performance of system management. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to measure system management activities. | | | | | DO | DN | NA |  |
|  |  | | Measure how well system management activities meet expectations. | | | | DO | DN | NA |  |
|  |  | | | Measure how well system management activities apply policies. | | | DO | DN | NA |  |
|  |  | | | Measure how well system management activities implement plans. | | | DO | DN | NA |  |
|  |  | | | Measure how well system management activities follow procedures. | | | DO | DN | NA |  |
|  |  | | | Measure how well system management activities meet requirements. | | | DO | DN | NA |  |
|  |  | | | Measure how well system management activities achieve objectives. | | | DO | DN | NA |  |
|  |  | | | | Measure how well system managers achieve safety objectives. | | DO | DN | NA |  |
|  |  | | | | Measure how well system managers achieve quality objectives. | | DO | DN | NA |  |
|  |  | | | | Measure how well system managers achieve privacy objectives. | | DO | DN | NA |  |
|  |  | | | | Measure how well system managers achieve security objectives. | | DO | DN | NA |  |
|  |  | | | | Measure how well system managers achieve business objectives. | | DO | DN | NA |  |
|  |  | | | | Measure how well system managers achieve technical objectives. | | DO | DN | NA |  |
|  |  | | | | Measure how well system managers achieve continuity objectives. | | DO | DN | NA |  |
|  | Use authorized methods to measure external product and service providers. | | | | | | DO | DN | NA |  |
|  |  | Use authorized criteria to measure the performance of external providers. | | | | | DO | DN | NA |  |
|  |  | | Measure the performance of external system, 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 system, 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 product and service providers. | | | | | | DO | DN | NA |  |
|  |  | Use authorized criteria to measure the performance of internal providers. | | | | | DO | DN | NA |  |
| 3.5 CONTROL THE RESOURCES NEEDED TO MEASURE SYSTEM | | | | | | | | | | |
| 3.5.1 Control the documents needed to measure your system | | | | | | | | | | |
|  | Control the procedures needed to measure your system and its outputs. | | | | | | DO | DN | NA |  |
|  | Control the instructions needed to measure your system and its outputs. | | | | | | DO | DN | NA |  |
|  | Control the manuals needed to measure your system and its outputs. | | | | | | DO | DN | NA |  |
| 3.5.2 Control the technology needed to measure your system | | | | | | | | | | |
|  | Control the software needed to measure your system and its outputs. | | | | | | DO | DN | NA |  |
|  | Control the hardware needed to measure your system and its outputs. | | | | | | DO | DN | NA |  |
|  |  | Control the tools needed to measure your system and its outputs. | | | | | DO | DN | NA |  |
|  |  | Control the equipment needed to measure your system and its outputs. | | | | | DO | DN | NA |  |
| 3.5.3 Control the records needed to measure your system | | | | | | | | | | |
|  | Control the records needed to measure system activities and resources. | | | | | | DO | DN | NA |  |
|  |  | Use records to control your system measuring activities and resources. | | | | | DO | DN | NA |  |
|  |  | | Establish a register of system measurement activities and resources. | | | | DO | DN | NA |  |
|  |  | | | Use this 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 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 |  |
|  |  | | Maintain a register of your system measurement activities and resources. | | | | 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 system measurement equipment. | | | DO | DN | NA |  |
|  | | | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 4.1 PLAN HOW YOU'RE GOING TO MONITOR YOUR SYSTEM | | | | | | | | | | |
| 4.1.1 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 system participants need to be monitored. | | | | | DO | DN | NA |  |
|  |  | | Figure out what kind of system managers need to be monitored. | | | | DO | DN | NA |  |
|  |  | | Figure out what kind of system personnel need to be monitored. | | | | DO | DN | NA |  |
|  |  | Figure out what kind of system providers need to be monitored. | | | | | DO | DN | NA |  |
|  |  | | Figure out what kind of internal system providers need to be monitored. | | | | DO | DN | NA |  |
|  |  | | Figure out what kind of external system providers need to be monitored. | | | | DO | DN | NA |  |
|  | Figure out what kind of system 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 system 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 |  |
| 4.1.2 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 system outputs. | | | | | DO | DN | NA |  |
|  |  | | Plan how to monitor information about customer satisfaction. | | | | DO | DN | NA |  |
|  | Plan how you're going to monitor system performance. | | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor system 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 system activities. | | | | | DO | DN | NA |  |
|  |  | | Plan how you're going to monitor system management activities. | | | | DO | DN | NA |  |
|  |  | | | Plan how to monitor how well system management activities meet expectations. | | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system management activities apply policies. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system management activities implement plans. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system management activities follow procedures. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system management activities achieve objectives. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system management activities comply with requirements. | | DO | DN | NA |  |
|  |  | | Plan how you're going to monitor system operating activities. | | | | DO | DN | NA |  |
|  |  | | | Plan how to monitor how well system operating activities meet expectations. | | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system operating activities apply policies. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system operating activities implement plans. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system operating activities follow procedures. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system operating activities achieve objectives. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system operating activities comply with requirements. | | DO | DN | NA |  |
|  |  | | Plan how you're going to monitor system maintenance activities. | | | | DO | DN | NA |  |
|  |  | | | Plan how to monitor how well system maintenance activities meet expectations. | | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system maintenance activities apply policies. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system maintenance activities implement plans. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system maintenance activities follow procedures. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system maintenance activities achieve objectives. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system maintenance activities comply with requirements. | | DO | DN | NA |  |
|  |  | | Plan how you're going to monitor system monitoring activities. | | | | DO | DN | NA |  |
|  |  | | | Plan how to monitor how well system monitoring activities meet expectations. | | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system monitoring activities apply policies. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system monitoring activities implement plans. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system monitoring activities follow procedures. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system monitoring activities achieve objectives. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system monitoring activities comply with requirements. | | DO | DN | NA |  |
|  |  | | Plan how you're going to monitor system measurement activities. | | | | DO | DN | NA |  |
|  |  | | | Plan how to monitor how well system measurement activities meet expectations. | | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system measurement activities apply policies. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system measurement activities implement plans. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system measurement activities follow procedures. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system measurement activities achieve objectives. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system measurement activities comply with requirements. | | DO | DN | NA |  |
|  |  | | Plan how you're going to monitor system control activities. | | | | DO | DN | NA |  |
|  |  | | | Plan how to monitor how well system control activities meet expectations. | | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system control activities apply policies. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system control activities implement plans. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system control activities follow procedures. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system control activities achieve objectives. | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system control activities comply with requirements. | | DO | DN | NA |  |
|  |  | | Plan how you're going to monitor system evaluation activities. | | | | DO | DN | NA |  |
|  |  | | | Plan how you're going to monitor system audit activities. | | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system audit activities meet expectations. | | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well system audit activities apply policies. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well system audit activities implement plans. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well system audit activities follow procedures. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well system audit activities achieve objectives. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well system audit activities comply with requirements. | DO | DN | NA |  |
|  |  | | | Plan how you're going to monitor system review activities. | | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system review activities meet expectations. | | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well system review activities apply policies. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well system review activities implement plans. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well system review activities follow procedures. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well system review activities achieve objectives. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well system review activities comply with requirements. | DO | DN | NA |  |
|  |  | | Plan how you're going to monitor system change activities. | | | | DO | DN | NA |  |
|  |  | | | Plan how you're going to monitor system correction activities. | | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system correction activities meet expectations. | | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well system correction activities apply policies. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well system correction activities implement plans. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well system correction activities follow procedures. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well system correction activities achieve objectives. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well system correction activities comply with requirements. | DO | DN | NA |  |
|  |  | | | Plan how you're going to monitor system improvement activities. | | | DO | DN | NA |  |
|  |  | | | | Plan how to monitor how well system improvement activities meet expectations. | | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well system improvement activities apply policies. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well system improvement activities implement plans. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well system improvement activities follow procedures. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well system improvement activities achieve objectives. | DO | DN | NA |  |
|  |  | | | | | Plan how to monitor how well system improvement activities comply with requirements. | DO | DN | NA |  |
|  | Plan how you're going to monitor system resources. | | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor system parts. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor system plans. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor system policies. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor system supplies. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor system hardware. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor system software. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor system services. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor system products. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor system property. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor system providers. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor system documents. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor system components. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor system infrastructure. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor system participants. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor system procedures. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor system practices. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor system records. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor system inputs. | | | | | DO | DN | NA |  |
|  |  | | Plan how you're going to monitor internal system inputs. | | | | DO | DN | NA |  |
|  |  | | Plan how you're going to monitor external system inputs. | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor system technologies. | | | | | DO | DN | NA |  |
|  |  | | Plan how you're going to monitor system tools and equipment. | | | | DO | DN | NA |  |
|  |  | | | Plan how you're going to monitor system monitoring devices. | | | 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 system measurement devices. | | | 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 system environment. | | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor your system's external context. | | | | | DO | DN | NA |  |
|  |  | | Figure out how you're going to monitor the external  issues and factors that could affect your system. | | | | DO | DN | NA |  |
|  |  | | Figure out how you're going to monitor the external  interested parties that could affect your system. | | | | DO | DN | NA |  |
|  |  | Plan how you're going to monitor your system's internal context. | | | | | DO | DN | NA |  |
|  |  | | Figure out how you're going to monitor the internal  issues and factors that could affect your system. | | | | DO | DN | NA |  |
|  |  | | Figure out how you're going to monitor the internal  interested parties that could affect your system. | | | | DO | DN | NA |  |
| 4.1.3 Figure out who will perform monitoring tasks | | | | | | | | | | |
|  | Allocate responsibility and authority for monitoring system plans. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring system policies. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring system outputs. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring system supplies. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring system materials. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring system hardware. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring system software. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring system services. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring system products. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring system property. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring system providers. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring system objectives. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring system documents. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring system participants. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring system components. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring system technologies. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring system characteristics. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring system requirements. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring system infrastructure. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring system environment. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring system procedures. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring system practices. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring system records. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring system parties. | | | | | | DO | DN | NA |  |
|  | Allocate responsibility and authority for monitoring system inputs. | | | | | | DO | DN | NA |  |
| 4.2 QUALIFY THE RESOURCES NEEDED TO MONITOR SYSTEM | | | | | | | | | | |
| 4.2.1 make sure that resources can monitor your system | | | | | | | | | | |
|  | 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 monitoring resources that can handle your unique circumstances. | | | | | DO | DN | NA |  |
|  |  | Select monitoring resources that will ensure that outputs meet requirements. | | | | | DO | DN | NA |  |
|  |  | Select monitoring resources that are capable of providing the information you need. | | | | | DO | DN | NA |  |
| 4.2.2 make sure that resources are validated before use | | | | | | | | | | |
|  | Validate monitoring resources before you use them. | | | | | | DO | DN | NA |  |
|  |  | Validate tools before they are used to monitor management system. | | | | | DO | DN | NA |  |
|  |  | Validate equipment before it is used to monitor management system. | | | | | DO | DN | NA |  |
|  |  | Validate software before it is used to monitor management system. | | | | | DO | DN | NA |  |
| 4.3 PROVIDE THE RESOURCES NEEDED TO MONITOR SYSTEM | | | | | | | | | | |
| 4.3.1 Provide the expertise needed to monitor your system | | | | | | | | | | |
|  | 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 system. | | | | | DO | DN | NA |  |
|  |  | | Acquire the knowledge that managers need to support  system monitoring and achieve conformity of outputs. | | | | DO | DN | NA |  |
|  |  | | Share the knowledge that managers need so that they can  support system monitoring and achieve conformity of outputs. | | | | DO | DN | NA |  |
|  |  | | | Deliver suitable training and awareness programmes  for managers of system monitoring activities. | | | DO | DN | NA |  |
|  |  | Provide the personnel needed to monitor your system. | | | | | DO | DN | NA |  |
|  |  | | Acquire the knowledge that personnel need to monitor  your system and achieve conformity of outputs. | | | | DO | DN | NA |  |
|  |  | | | Consider internal sources of knowledge about system monitoring. | | | DO | DN | NA |  |
|  |  | | | Consider external sources of knowledge about system monitoring. | | | DO | DN | NA |  |
|  |  | | Share the knowledge that personnel need to monitor  your system and achieve conformity of outputs. | | | | DO | DN | NA |  |
|  |  | | | Deliver suitable training and awareness programmes  for your system monitoring personnel. | | | DO | DN | NA |  |
| 4.3.2 Provide the technology needed to monitor your system | | | | | | | | | | |
|  | 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 system. | | | | | DO | DN | NA |  |
|  |  | | Provide the software needed to support system  monitoring and achieve conformity of outputs. | | | | DO | DN | NA |  |
|  |  | Provide the hardware needed to monitor your system. | | | | | DO | DN | NA |  |
|  |  | | Provide the hardware needed to support system  monitoring and achieve conformity of outputs. | | | | DO | DN | NA |  |
| 4.3.3 Provide the infrastructure needed to monitor your system | | | | | | | | | | |
|  | 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 system monitoring and achieve conformity of outputs. | | | | | DO | DN | NA |  |
| 4.4 USE AUTHORIZED METHODS TO MONITOR YOUR SYSTEM | | | | | | | | | | |
| 4.4.1 Use authorized methods to monitor system activities | | | | | | | | | | |
|  | Use authorized methods to monitor system management activities. | | | | | | DO | DN | NA |  |
|  |  | Monitor how well system management activities meet expectations. | | | | | DO | DN | NA |  |
|  |  | | Monitor how well system management activities apply policies. | | | | DO | DN | NA |  |
|  |  | | Monitor how well system management activities implement plans. | | | | DO | DN | NA |  |
|  |  | | Monitor how well system management activities follow procedures. | | | | DO | DN | NA |  |
|  |  | | Monitor how well system management activities achieve objectives. | | | | DO | DN | NA |  |
|  |  | | Monitor how well system management activities comply with requirements. | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor system operating activities. | | | | | | DO | DN | NA |  |
|  |  | Monitor how well system operating activities meet expectations. | | | | | DO | DN | NA |  |
|  |  | | Monitor how well system operating activities apply policies. | | | | DO | DN | NA |  |
|  |  | | Monitor how well system operating activities implement plans. | | | | DO | DN | NA |  |
|  |  | | Monitor how well system operating activities follow procedures. | | | | DO | DN | NA |  |
|  |  | | Monitor how well system operating activities achieve objectives. | | | | DO | DN | NA |  |
|  |  | | Monitor how well system operating activities comply with requirements. | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor system maintenance activities. | | | | | | DO | DN | NA |  |
|  |  | Monitor how well system maintenance activities meet expectations. | | | | | DO | DN | NA |  |
|  |  | | Monitor how well system maintenance activities apply policies. | | | | DO | DN | NA |  |
|  |  | | Monitor how well system maintenance activities implement plans. | | | | DO | DN | NA |  |
|  |  | | Monitor how well system maintenance activities follow procedures. | | | | DO | DN | NA |  |
|  |  | | Monitor how well system maintenance activities achieve objectives. | | | | DO | DN | NA |  |
|  |  | | Monitor how well system maintenance activities comply with requirements. | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor system measurement activities. | | | | | | DO | DN | NA |  |
|  |  | Monitor how well system measurement activities meet expectations. | | | | | DO | DN | NA |  |
|  |  | | Monitor how well system measurement activities apply policies. | | | | DO | DN | NA |  |
|  |  | | Monitor how well system measurement activities implement plans. | | | | DO | DN | NA |  |
|  |  | | Monitor how well system measurement activities follow procedures. | | | | DO | DN | NA |  |
|  |  | | Monitor how well system measurement activities achieve objectives. | | | | DO | DN | NA |  |
|  |  | | Monitor how well system measurement activities comply with requirements. | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor system monitoring activities. | | | | | | DO | DN | NA |  |
|  |  | Monitor how well system monitoring activities meet expectations. | | | | | DO | DN | NA |  |
|  |  | | Monitor how well system monitoring activities apply policies. | | | | DO | DN | NA |  |
|  |  | | Monitor how well system monitoring activities implement plans. | | | | DO | DN | NA |  |
|  |  | | Monitor how well system monitoring activities follow procedures. | | | | DO | DN | NA |  |
|  |  | | Monitor how well system monitoring activities achieve objectives. | | | | DO | DN | NA |  |
|  |  | | Monitor how well system monitoring activities comply with requirements. | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor system control activities. | | | | | | DO | DN | NA |  |
|  |  | Monitor how well system control activities meet expectations. | | | | | DO | DN | NA |  |
|  |  | | Monitor how well system control activities apply policies. | | | | DO | DN | NA |  |
|  |  | | Monitor how well system control activities implement plans. | | | | DO | DN | NA |  |
|  |  | | Monitor how well system control activities follow procedures. | | | | DO | DN | NA |  |
|  |  | | Monitor how well system control activities achieve objectives. | | | | DO | DN | NA |  |
|  |  | | Monitor how well system control activities comply with requirements. | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor system evaluation activities. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor system audit activities. | | | | | DO | DN | NA |  |
|  |  | | Monitor how well system audit activities meet expectations. | | | | DO | DN | NA |  |
|  |  | | | Monitor how well system audit activities apply policies. | | | DO | DN | NA |  |
|  |  | | | Monitor how well system audit activities implement plans. | | | DO | DN | NA |  |
|  |  | | | Monitor how well system audit activities follow procedures. | | | DO | DN | NA |  |
|  |  | | | Monitor how well system audit activities achieve objectives. | | | DO | DN | NA |  |
|  |  | | | Monitor how well system audit activities comply with requirements. | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor system review activities. | | | | | DO | DN | NA |  |
|  |  | | Monitor how well system review activities meet expectations. | | | | DO | DN | NA |  |
|  |  | | | Monitor how well system review activities apply policies. | | | DO | DN | NA |  |
|  |  | | | Monitor how well system review activities implement plans. | | | DO | DN | NA |  |
|  |  | | | Monitor how well system review activities follow procedures. | | | DO | DN | NA |  |
|  |  | | | Monitor how well system review activities achieve objectives. | | | DO | DN | NA |  |
|  |  | | | Monitor how well system review activities comply with requirements. | | | DO | DN | NA |  |
|  | Use authorized methods to monitor system change activities. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor system correction activities. | | | | | DO | DN | NA |  |
|  |  | | Monitor how well system correction activities meet expectations. | | | | DO | DN | NA |  |
|  |  | | | Monitor how well system correction activities apply policies. | | | DO | DN | NA |  |
|  |  | | | Monitor how well system correction activities implement plans. | | | DO | DN | NA |  |
|  |  | | | Monitor how well system correction activities follow procedures. | | | DO | DN | NA |  |
|  |  | | | Monitor how well system correction activities achieve objectives. | | | DO | DN | NA |  |
|  |  | | | Monitor how well system correction activities comply with requirements. | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor system improvement activities. | | | | | DO | DN | NA |  |
|  |  | | Monitor how well system improvement activities meet expectations. | | | | DO | DN | NA |  |
|  |  | | | Monitor how well system improvement activities apply policies. | | | DO | DN | NA |  |
|  |  | | | Monitor how well system improvement activities implement plans. | | | DO | DN | NA |  |
|  |  | | | Monitor how well system improvement activities follow procedures. | | | DO | DN | NA |  |
|  |  | | | Monitor how well system improvement activities achieve objectives. | | | DO | DN | NA |  |
|  |  | | | Monitor how well system improvement activities comply with requirements. | | | DO | DN | NA |  |
| 4.4.2 Use authorized methods to monitor system outputs | | | | | | | | | | |
|  | Use authorized methods to monitor how well system outputs meet expectations. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor how well system outputs apply policies. | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor how well system outputs implement plans. | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor how well system outputs follow procedures. | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor how well system outputs achieve objectives. | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor how well system outputs comply with requirements. | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to monitor how well outputs meet customer requirements. | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to monitor how well outputs meet regulatory requirements. | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to monitor how well outputs meet corporate requirements. | | | | DO | DN | NA |  |
| 4.4.3 Use authorized methods to monitor system inputs | | | | | | | | | | |
|  | Use authorized methods to monitor supplies that have a major impact on outputs. | | | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor services that have a major impact on outputs. | | | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor materials that have a major impact on outputs. | | | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor products that have a major impact on outputs. | | | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor components that have a major impact on outputs. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor your “critical items” and “key characteristics”. | | | | | DO | DN | NA |  |
| 4.4.4 Use authorized methods to monitor system documents | | | | | | | | | | |
|  | Use authorized methods to monitor documents that specify how system is operated. | | | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor documents that specify how system is maintained. | | | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor documents that specify how system is monitored. | | | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor documents that specify how system is measured. | | | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor documents that specify how system is controlled. | | | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor documents that specify how system is audited. | | | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor documents that specify how system is reviewed. | | | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor documents that specify how system is corrected. | | | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor documents that specify how system is improved. | | | | | | DO | DN | NA |  |
| 4.4.5 Use authorized methods to monitor system records | | | | | | | | | | |
|  | Use authorized methods to monitor records of personnel performance and competence. | | | | | | DO | DN | NA |  |
|  |  | Retain and maintain records of personnel performance and competence. | | | | | DO | DN | NA |  |
|  |  | | Use records to show that personnel know how to perform system tasks. | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor records that track the performance of your system. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor records that keep track of system operations. | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to monitor records that keep track of system outputs. | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to monitor records that keep track of system activities. | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to monitor records that keep track of system inputs. | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor records that keep track of system maintenance. | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor records that keep track of system measurement. | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor records that keep track of system monitoring. | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor records that keep track of system control. | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor records that keep track of system audits. | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor records that keep track of system reviews. | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor records that keep track of system corrections. | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor records that keep track of system improvements. | | | | | DO | DN | NA |  |
| 4.4.6 Use authorized methods to monitor system property | | | | | | | | | | |
|  | Use authorized methods to monitor system property owned by your  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 |  |
|  | Use authorized methods to monitor system property owned by  your organization that is needed to achieve conformity of outputs. | | | | | | DO | DN | NA |  |
| 4.4.7 Use authorized methods to monitor system participants | | | | | | | | | | |
|  | Use authorized methods to monitor system personnel. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor objectives that system personnel must achieve. | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to monitor safety objectives that personnel must achieve. | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to monitor quality objectives that personnel must achieve. | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to monitor privacy objectives that personnel must achieve. | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to monitor security objectives that personnel must achieve. | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to monitor business objectives that personnel must achieve. | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to monitor technical objectives that personnel must achieve. | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to monitor continuity objectives that personnel must achieve. | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor competence and performance of system personnel. | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to monitor system knowledge and skill that has been acquired. | | | | DO | DN | NA |  |
|  |  | | | Consider the need to protect and preserve system lessons learned. | | | DO | DN | NA |  |
|  |  | | | Consider the need to protect and preserve your intellectual property. | | | DO | DN | NA |  |
|  |  | | Use authorized methods to monitor changes and trends in knowledge and information. | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor system management. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor system management personnel. | | | | | 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 |  |
|  |  | | Use authorized criteria to monitor verification activities delegated to external providers. | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor interested parties. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor external parties that could influence system. | | | | | DO | DN | NA |  |
|  |  | | Monitor the performance of external system, product, and service providers. | | | | DO | DN | NA |  |
|  |  | | | Expect system managers to use data and criteria to  monitor the performance of their external providers. | | | DO | DN | NA |  |
|  |  | | | | Expect system managers to document performance  monitoring activities and retain these documents. | | DO | DN | NA |  |
|  |  | | | | | Expect system managers to control documents  that describe their performance monitoring activities. | DO | DN | NA |  |
|  |  | | Monitor external system, product, and service verification activities. | | | | DO | DN | NA |  |
|  |  | | | Monitor verifications whenever they are delegated to external providers. | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor internal parties that could influence system. | | | | | DO | DN | NA |  |
| 4.4.8 Use authorized methods to monitor system technologies | | | | | | | | | | |
|  | Use authorized methods to monitor technology used to perform system operations. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor software used to perform system operations. | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor hardware used to perform system operations. | | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor technology used to automate system operations. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor software used to automate system operations. | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor hardware used to automate system operations. | | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor technology used to maintain system operations. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor software used to maintain system operations. | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor hardware used to maintain system operations. | | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor technology used to monitor system operations. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor software used to monitor system operations. | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor hardware used to monitor system operations. | | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor technology used to measure system operations. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor software used to measure system operations. | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor hardware used to measure system operations. | | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor technology used to control system operations. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor software used to control system operations. | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor hardware used to control system operations. | | | | | DO | DN | NA |  |
| 4.4.9 Use authorized methods to monitor system environment | | | | | | | | | | |
|  | Use authorized methods to monitor your system'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 system's internal environment. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor internal interested parties and their requirements. | | | | | DO | DN | NA |  |
| 4.4.10 Use authorized methods to monitor system infrastructure | | | | | | | | | | |
|  | Use authorized methods to monitor system networks and communications. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor internal system networks and communications. | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to monitor external system networks and communications. | | | | | DO | DN | NA |  |
|  | Use authorized methods to monitor system utilities and support services. | | | | | | DO | DN | NA |  |
| 4.5 CONTROL THE RESOURCES NEEDED TO MONITOR SYSTEM | | | | | | | | | | |
| 4.5.1 CONTROL THE TECHNOLOGIES NEEDED TO MONITOR SYSTEM | | | | | | | | | | |
|  | Control the technology needed to monitor your system. | | | | | | DO | DN | NA |  |
|  |  | Control the tools needed to monitor your system. | | | | | DO | DN | NA |  |
|  |  | Control the software needed to monitor your system. | | | | | DO | DN | NA |  |
|  |  | Control the equipment needed to monitor your system. | | | | | DO | DN | NA |  |
| 4.5.2 CONTROL THE RECORDS NEEDED TO MONITOR SYSTEM | | | | | | | | | | |
|  | Control the records needed to monitor your system. | | | | | | DO | DN | NA |  |
|  |  | Establish a register of your system 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 system 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. | | | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 5.1 PLAN HOW YOU'RE GOING TO CONTROL SYSTEM | | | | | | | | | | | |
| 5.1.1 Consider how to control your system outputs | | | | | | | | | | | |
|  | Figure out how you're going to control your system outputs. | | | | | | | DO | DN | NA |  |
|  |  | Consider output requirements as you develop output controls. | | | | | | DO | DN | NA |  |
|  |  | | Consider privacy requirements as you develop output controls. | | | | | DO | DN | NA |  |
|  |  | | Consider safety requirements as you develop output controls. | | | | | DO | DN | NA |  |
|  |  | | | Consider personnel safety requirements as you develop output controls. | | | | DO | DN | NA |  |
|  |  | | Consider quality requirements as you develop output controls. | | | | | DO | DN | NA |  |
|  |  | | | Consider reliability requirements as you develop output controls. | | | | DO | DN | NA |  |
|  |  | | | Consider 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 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 maintenance requirements as you develop output controls. | | | | DO | DN | NA |  |
|  |  | | | | Consider maintainability requirements as you develop output controls. | | | DO | DN | NA |  |
|  |  | | Consider security requirements as you develop output controls. | | | | | DO | DN | NA |  |
|  |  | | | Consider handling requirements as you develop output controls. | | | | DO | DN | NA |  |
|  |  | | | Consider packaging requirements as you develop output controls. | | | | DO | DN | NA |  |
|  |  | | | Consider availability requirements as you develop output controls. | | | | DO | DN | NA |  |
|  |  | | | Consider preservation requirements as you develop output controls. | | | | DO | DN | NA |  |
|  |  | | | Consider obsolescence requirements as you develop output controls. | | | | DO | DN | NA |  |
|  |  | | | | Consider recycling requirements as you develop output controls. | | | DO | DN | NA |  |
|  |  | | | | Consider disposal requirements as you develop output controls. | | | DO | DN | NA |  |
|  |  | | | | | Consider final disposal requirements as you develop output controls. | | DO | DN | NA |  |
|  |  | | Consider production requirements as you develop output controls. | | | | | DO | DN | NA |  |
|  |  | | | Consider producibility requirements as you develop output controls. | | | | DO | DN | NA |  |
|  |  | | Consider measurement requirements as you develop output controls. | | | | | DO | DN | NA |  |
|  |  | | Consider monitoring requirements as you develop output controls. | | | | | DO | DN | NA |  |
|  |  | | | Consider inspectability requirements as you develop output controls. | | | | DO | DN | NA |  |
| 5.1.2 Consider how to control your system inputs | | | | | | | | | | | |
|  | Figure out how you're going to control your system inputs. | | | | | | | DO | DN | NA |  |
|  |  | Consider system input requirements as you develop input controls. | | | | | | DO | DN | NA |  |
|  |  | | Consider input privacy 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 system. | | | | DO | DN | NA |  |
|  |  | | | Consider suitability requirements for software programmes to be used by system. | | | | 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 |  |
| 5.1.3 Consider how to control your system activities | | | | | | | | | | | |
|  | Figure out how you're going to control your system activities. | | | | | | | DO | DN | NA |  |
|  |  | Consider system safety requirements as you develop system controls. | | | | | | DO | DN | NA |  |
|  |  | Consider system privacy requirements as you develop system controls. | | | | | | DO | DN | NA |  |
|  |  | Consider system quality requirements as you develop system controls. | | | | | | DO | DN | NA |  |
|  |  | Consider system security requirements as you develop system controls. | | | | | | DO | DN | NA |  |
|  |  | Consider system reliability requirements as you develop system controls. | | | | | | DO | DN | NA |  |
|  |  | Consider system monitoring requirements as you develop system controls. | | | | | | DO | DN | NA |  |
|  |  | Consider system measurement requirements as you develop system controls. | | | | | | DO | DN | NA |  |
|  |  | Consider system improvement requirements as you develop system controls. | | | | | | DO | DN | NA |  |
|  |  | Consider system maintenance requirements as you develop system controls. | | | | | | DO | DN | NA |  |
|  |  | Consider system evaluation requirements as you develop system controls. | | | | | | DO | DN | NA |  |
|  |  | Consider system correction requirements as you develop system controls. | | | | | | DO | DN | NA |  |
|  |  | Consider system reporting requirements as you develop system controls. | | | | | | DO | DN | NA |  |
|  |  | Consider system review requirements as you develop system controls. | | | | | | DO | DN | NA |  |
|  |  | Consider system audit requirements as you develop system controls. | | | | | | DO | DN | NA |  |
| 5.1.4 Consider how to control your system 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 |  |
| 5.2 DEVELOP WAYS OF CONTROLLING YOUR SYSTEM | | | | | | | | | | | |
| 5.2.1 Develop ways of controlling system elements | | | | | | | | | | | |
|  | Develop controlled conditions for system outputs. | | | | | | | DO | DN | NA |  |
|  |  | Develop ways of controlling your system outputs. | | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling the quality of system outputs. | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of controlling the reliability of system outputs. | | | | DO | DN | NA |  |
|  |  | | | Develop ways of controlling the suitability of system 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 system 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 system inputs. | | | | | | | DO | DN | NA |  |
|  |  | Develop ways of controlling your system inputs. | | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling the quality of system inputs. | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of controlling the purity of system 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 system 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 system inputs. | | | | DO | DN | NA |  |
|  |  | | | | Develop acceptance criteria for your system inputs. | | | DO | DN | NA |  |
|  |  | | | | | Develop methods and procedures for testing system inputs. | | DO | DN | NA |  |
|  |  | | | | | Develop methods and procedures for inspecting system inputs. | | DO | DN | NA |  |
|  |  | | | | | Develop methods and procedures for monitoring system inputs. | | DO | DN | NA |  |
|  |  | | | | | Develop methods and procedures for measuring system inputs. | | DO | DN | NA |  |
|  |  | | | | | Develop methods and procedures for evaluating system inputs. | | DO | DN | NA |  |
|  |  | | Develop ways of controlling the security of system inputs. | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling the safety of system inputs. | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling the privacy of system inputs. | | | | | DO | DN | NA |  |
|  | Develop controlled conditions for system activities. | | | | | | | DO | DN | NA |  |
|  |  | Develop ways of controlling your system activities. | | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling system testing activities. | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling system control activities. | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling system inspection activities. | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling system management activities. | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling system measurement activities. | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling system maintenance activities. | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling system production activities. | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling system monitoring activities. | | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling system evaluation activities. | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of controlling system audit activities. | | | | DO | DN | NA |  |
|  |  | | | Develop ways of controlling system review activities. | | | | DO | DN | NA |  |
|  |  | | Develop ways of controlling system change activities. | | | | | DO | DN | NA |  |
|  |  | | | Develop ways of controlling system correction activities. | | | | DO | DN | NA |  |
|  |  | | | Develop ways of controlling system improvement activities. | | | | DO | DN | NA |  |
| 5.2.2 Develop ways of controlling system 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 |  |
|  |  | 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 system control documents and records. | | DO | DN | NA |  |
|  |  | | | | | Examine related conformance documents and records. | | DO | DN | NA |  |
|  |  | | | | | Examine related production documents and records. | | DO | DN | NA |  |
|  |  | | | | | | Review production verification activities and results. | DO | DN | NA |  |
|  |  | | | | | | Review data related to production part approval system. | 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 system, 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 |  |
| 5.3 PROVIDE RESOURCES NEEDED TO CONTROL SYSTEM | | | | | | | | | | | |
| 5.3.1 PROVIDE HUMAN RESOURCES NEEDED TO CONTROL SYSTEM | | | | | | | | | | | |
|  | Provide the people that are needed in order to control your system. | | | | | | | DO | DN | NA |  |
|  | Provide the training that is needed in order to control your system. | | | | | | | DO | DN | NA |  |
|  | Provide the knowledge that is needed in order to control your system. | | | | | | | DO | DN | NA |  |
|  | Provide the expertise that is needed in order to control your system. | | | | | | | DO | DN | NA |  |
| 5.3.2 PROVIDE TECHNICAL RESOURCES NEEDED TO CONTROL SYSTEM | | | | | | | | | | | |
|  | Provide the policies that are needed in order to control your system. | | | | | | | DO | DN | NA |  |
|  | Provide the procedures that are needed in order to control your system. | | | | | | | DO | DN | NA |  |
|  | Provide the technologies that are needed in order to control your system. | | | | | | | DO | DN | NA |  |
|  | Provide the methodologies that are needed in order to control your system. | | | | | | | DO | DN | NA |  |
|  | Provide the infrastructure that is needed in order to control your system. | | | | | | | DO | DN | NA |  |
| 5.4 USE AUTHORIZED METHODS TO CONTROL SYSTEM | | | | | | | | | | | |
| 5.4.1 Use authorized methods to control system inputs | | | | | | | | | | | |
|  | Use authorized methods to control the identity of system inputs. | | | | | | | DO | DN | NA |  |
|  |  | Establish suitable means for identifying your system 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 |  |
|  | 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 management system are being controlled. | | | | | | DO | DN | NA |  |
|  |  | | Identify and record purchased products (inputs) that are released for use in  your system 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 |  |
| 5.4.2 Use authorized methods to control system outputs | | | | | | | | | | | |
|  | Use authorized methods to 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 being documented. | | | | | | DO | DN | NA |  |
|  |  | | Control output design and development documents and records. | | | | | DO | DN | NA |  |
|  | Use authorized methods to control outputs while system is operating. | | | | | | | DO | DN | NA |  |
|  |  | Establish suitable means and methods for identifying system 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 system outputs. | | | | | 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 management system are being controlled. | | | | | DO | DN | NA |  |
|  |  | | | Identify and record purchased products (inputs) that are released for use in  your system 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 |  |
|  | Use authorized methods to control how outputs are released. | | | | | | | DO | DN | NA |  |
|  |  | Verify acceptance before outputs are officially released. | | | | | | DO | DN | NA |  |
|  |  | | Implement arrangements to verify your system outputs. | | | | | DO | DN | NA |  |
|  |  | | | Verify that output requirements are 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 system 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 system 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 |  |
|  |  | | 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 |  |
| 5.4.3 Use authorized methods to control system activities | | | | | | | | | | | |
|  | Use authorized methods to control normal system activities. | | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to control system control activities. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to control system management activities. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to control system maintenance activities. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to control system measurement activities. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to control system monitoring activities. | | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to control system evaluation activities. | | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to control system audit activities. | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to control system review activities. | | | | | DO | DN | NA |  |
|  |  | Use authorized methods to control system change activities. | | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to control system correction activities. | | | | | DO | DN | NA |  |
|  |  | | Use authorized methods to control system 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 all special activities are approved. | 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 |  |
| 5.4.4 Use authorized methods to control system technology | | | | | | | | | | | |
|  | Use authorized methods to control system equipment, tools, and software. | | | | | | | DO | DN | NA |  |
|  |  | Validate technology prior to final release for system operations. | | | | | | DO | DN | NA |  |
|  |  | | Validate technology that is used to perform system operations. | | | | | DO | DN | NA |  |
|  |  | | | Validate tools before they are used to perform system operations. | | | | DO | DN | NA |  |
|  |  | | | Validate equipment before it is used to perform system operations. | | | | DO | DN | NA |  |
|  |  | | | Validate software before it is used to perform system operations. | | | | DO | DN | NA |  |
|  |  | | Validate technology that is used to automate system operations. | | | | | DO | DN | NA |  |
|  |  | | | Validate tools before they are used to automate system operations. | | | | DO | DN | NA |  |
|  |  | | | Validate equipment before it is used to automate system operations. | | | | DO | DN | NA |  |
|  |  | | | Validate software before it is used to automate system operations. | | | | DO | DN | NA |  |
|  |  | | Validate technology that is used to maintain system operations. | | | | | DO | DN | NA |  |
|  |  | | | Validate tools before they are used to maintain system operations. | | | | DO | DN | NA |  |
|  |  | | | Validate equipment before it is used to maintain system operations. | | | | DO | DN | NA |  |
|  |  | | | Validate software before it is used to maintain system operations. | | | | DO | DN | NA |  |
|  |  | | Validate technology that is used to monitor system operations. | | | | | DO | DN | NA |  |
|  |  | | | Validate tools before they are used to monitor system operations. | | | | DO | DN | NA |  |
|  |  | | | Validate equipment before it is used to monitor system operations. | | | | DO | DN | NA |  |
|  |  | | | Validate software before it is used to monitor system operations. | | | | DO | DN | NA |  |
|  |  | | Validate technology that is used to measure system operations. | | | | | DO | DN | NA |  |
|  |  | | | Validate tools before they are used to measure system operations. | | | | DO | DN | NA |  |
|  |  | | | Validate equipment before it is used to measure system operations. | | | | DO | DN | NA |  |
|  |  | | | Validate software before it is used to measure system operations. | | | | DO | DN | NA |  |
|  |  | | Validate technology that is used to control system operations. | | | | | DO | DN | NA |  |
|  |  | | | Validate tools before they are used to control system operations. | | | | DO | DN | NA |  |
|  |  | | | Validate equipment before it is used to control system operations. | | | | DO | DN | NA |  |
|  |  | | | Validate software before it is used to control system operations. | | | | DO | DN | NA |  |
| 5.4.5 Use authorized methods to control system performance | | | | | | | | | | | |
|  | Use authorized methods to control internal personnel. | | | | | | | DO | DN | NA |  |
|  |  | Identify the people who can affect system performance. | | | | | | DO | DN | NA |  |
|  |  | Qualify the people who can affect system 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 system 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 system outputs. | | | | DO | DN | NA |  |
|  |  | | | | Ensure that externally provided products and services meet requirements  if external providers deliver them directly to your system 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 system 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 |  |
| 5.4.6 Use authorized methods to control system documentation | | | | | | | | | | | |
|  | Use authorized methods to control how documented information is controlled. | | | | | | | DO | DN | NA |  |
|  |  | Control how management system documents and records are created. | | | | | | DO | DN | NA |  |
|  |  | | Make sure that system documents and records are suitable for use. | | | | | DO | DN | NA |  |
|  |  | | | Make sure that documents and records are properly identified. | | | | 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. | | | | DO | DN | NA |  |
|  |  | | | | Make sure that system documents and records use the appropriate media. | | | DO | DN | NA |  |
|  |  | | | | Make sure that system documents and records use the appropriate graphics. | | | DO | DN | NA |  |
|  |  | | | | Make sure that system documents and records use the appropriate language. | | | DO | DN | NA |  |
|  |  | | | | Make sure that system documents and records use the appropriate software. | | | DO | DN | NA |  |
|  |  | Control how system documents and records are identified and described. | | | | | | 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 system documents and records are distributed. | | | | | | DO | DN | NA |  |
|  |  | Control how system documents and records are stored. | | | | | | DO | DN | NA |  |
|  |  | Control how system documents and records are retrieved. | | | | | | DO | DN | NA |  |
|  |  | Control how system documents and records are accessed. | | | | | | DO | DN | NA |  |
|  |  | | Prevent unauthorized access to system 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 system documents and records are used. | | | | | | DO | DN | NA |  |
|  |  | | Control how active system documents and records are used. | | | | | DO | DN | NA |  |
|  |  | | | Control how documents and records are used to plan your system. | | | | DO | DN | NA |  |
|  |  | | | | Control how internal documents and records are used to plan your system. | | | DO | DN | NA |  |
|  |  | | | | Control how external documents and records are used to plan your system. | | | DO | DN | NA |  |
|  |  | | | Control how documents and records are used to operate your system. | | | | DO | DN | NA |  |
|  |  | | | | Control how internal documents and records are used to operate system. | | | DO | DN | NA |  |
|  |  | | | | Control how external documents and records are used to operate system. | | | DO | DN | NA |  |
|  |  | | | Control how documents and records are used to implement your system. | | | | DO | DN | NA |  |
|  |  | | | | Control how internal documents and records are used to implement system. | | | DO | DN | NA |  |
|  |  | | | | Control how external documents and records are used to implement system. | | | DO | DN | NA |  |
|  |  | | | Control how documents and records are used to maintain your system. | | | | DO | DN | NA |  |
|  |  | | | | Control how internal documents and records are used to maintain system. | | | DO | DN | NA |  |
|  |  | | | | Control how external documents and records are used to maintain system. | | | DO | DN | NA |  |
|  |  | | | Control how documents and records are used to monitor your system. | | | | DO | DN | NA |  |
|  |  | | | | Control how internal documents and records are used to monitor system. | | | DO | DN | NA |  |
|  |  | | | | Control how external documents and records are used to monitor system. | | | DO | DN | NA |  |
|  |  | | | Control how documents and records are used to measure your system. | | | | DO | DN | NA |  |
|  |  | | | | Control how internal documents and records are used to measure system. | | | DO | DN | NA |  |
|  |  | | | | Control how external documents and records are used to measure system. | | | DO | DN | NA |  |
|  |  | | | Control how documents and records are used to control your system. | | | | DO | DN | NA |  |
|  |  | | | | Control how internal documents and records are used to control system. | | | DO | DN | NA |  |
|  |  | | | | Control how external documents and records are used to control system. | | | DO | DN | NA |  |
|  |  | | | Control how documents and records are used to evaluate your system. | | | | DO | DN | NA |  |
|  |  | | | | Control how documents and records are used to audit your system. | | | DO | DN | NA |  |
|  |  | | | | | Control how internal documents and records are used to audit system. | | DO | DN | NA |  |
|  |  | | | | | Control how external documents and records are used to audit system. | | DO | DN | NA |  |
|  |  | | | | Control how documents and records are used to review your system. | | | DO | DN | NA |  |
|  |  | | | | | Control how internal documents and records are used to review system. | | DO | DN | NA |  |
|  |  | | | | | Control how external documents and records are used to review system. | | DO | DN | NA |  |
|  |  | | | Control how documents and records are used to change your system. | | | | DO | DN | NA |  |
|  |  | | | | Control how documents and records are used to correct your system. | | | DO | DN | NA |  |
|  |  | | | | | Control how internal documents and records are used to correct system. | | DO | DN | NA |  |
|  |  | | | | | Control how external documents and records are used to correct system. | | DO | DN | NA |  |
|  |  | | | | Control how documents and records are used to improve your system. | | | DO | DN | NA |  |
|  |  | | | | | Control how internal documents and records are used to improve system. | | DO | DN | NA |  |
|  |  | | | | | Control how external documents and records are used to improve system. | | DO | DN | NA |  |
|  |  | | Control how inactive system documents and records are used. | | | | | DO | DN | NA |  |
|  |  | | | Control how obsolete system documents and records are used. | | | | DO | DN | NA |  |
|  |  | | | | Prevent the unintended use of obsolete documents and records. | | | DO | DN | NA |  |
|  |  | | | | | Identify obsolete management system documents and records. | | DO | DN | NA |  |
|  |  | | | | | Control obsolete management system documents and records. | | DO | DN | NA |  |
|  |  | | | | | Remove obsolete management system documents and records. | | DO | DN | NA |  |
|  |  | Control how system 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 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 system documents and records from loss. | | DO | DN | NA |  |
|  |  | | | | | Protect system documents and records from corruption. | | DO | DN | NA |  |
|  |  | | | | | Protect system documents and records from physical damage. | | DO | DN | NA |  |
|  |  | | | | | Protect system documents and records from unauthorized access. | | DO | DN | NA |  |
|  |  | | | | | Protect system documents and records from unintended alteration. | | DO | DN | NA |  |
|  |  | | | | | Protect system documents and records from inappropriate changes. | | DO | DN | NA |  |
|  |  | Control how system documents and records are changed. | | | | | | DO | DN | NA |  |
|  |  | | Control how paper documents and records are changed. | | | | | DO | DN | NA |  |
|  |  | | Control how electronic documents and records are changed. | | | | | DO | DN | NA |  |
|  |  | Control how system 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 |  |
|  | Use authorized methods to control system documents and records. | | | | | | | DO | DN | NA |  |
|  |  | Control all the internal documents and records that your system needs. | | | | | | DO | DN | NA |  |
|  |  | | Control information that your system needs in order to be effective. | | | | | DO | DN | NA |  |
|  |  | | | Control all the documents and records needed to operate your system. | | | | DO | DN | NA |  |
|  |  | | | | Control all the documents and records used to facilitate system 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 system. | | | | DO | DN | NA |  |
|  |  | | | | Control all the documents and records used to maintain system 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 system. | | | | DO | DN | NA |  |
|  |  | | | | Control all the documents and records used to monitor system 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 system. | | | | DO | DN | NA |  |
|  |  | | | | Control all the documents and records used to measure system 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 system. | | | | DO | DN | NA |  |
|  |  | | | | Control all the documents and records used to control system 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 system. | | | | DO | DN | NA |  |
|  |  | | | | Control all the documents and records needed to audit your system. | | | DO | DN | NA |  |
|  |  | | | | | Control all the documents and records used to audit system 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 system. | | | DO | DN | NA |  |
|  |  | | | | | Control all the documents and records used to review system 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 system. | | | | DO | DN | NA |  |
|  |  | | | | Control all the documents and records needed to correct your system. | | | DO | DN | NA |  |
|  |  | | | | | Control all the documents and records used to correct system 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 system. | | | DO | DN | NA |  |
|  |  | | | | | Control all the documents and records used to improve system 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 system needs. | | | | | | DO | DN | NA |  |
|  |  | | Control all external documented information needed in order to plan system. | | | | | DO | DN | NA |  |
|  |  | | Control all external documented information needed in order to operate system. | | | | | 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. | | | | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 6.1 PLAN HOW YOU'RE GOING TO EVALUATE SYSTEM | | | | | | | | | | | |
| 6.1.1 Plan how you're going to audit your system | | | | | | | | | | | |
|  | Develop an internal audit programme. | | | | | | | DO | DN | NA |  |
|  |  | Develop a programme that can find out if your system meets requirements. | | | | | | DO | DN | NA |  |
|  |  | | Make sure it can determine how well your system meets corporate expectations. | | | | | DO | DN | NA |  |
|  |  | | Make sure it can determine how well your system meets international standards. | | | | | DO | DN | NA |  |
|  |  | Develop a programme that can determine if your system 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 |  |
| 6.1.2 Plan how you're going to analyze your system | | | | | | | | | | | |
|  | Plan how you're going to analyze the opinions and satisfaction of system 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 system 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 system 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 system. | | | | | | | 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 management system outputs. | | | | | DO | DN | NA |  |
|  |  | | | Plan how you're going to analyze your management system 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 system 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 system 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 |  |
| 6.1.3 Plan how you're going to review your system | | | | | | | | | | | |
|  | Consider how you're going to review your management system. | | | | | | | DO | DN | NA |  |
|  |  | Consider how you're going to review the suitability of your system. | | | | | | DO | DN | NA |  |
|  |  | Consider how you're going to review the adequacy of your system. | | | | | | DO | DN | NA |  |
|  |  | Consider how you're going to review the effectiveness of your system. | | | | | | DO | DN | NA |  |
|  | Consider the issues that are relevant to your management system. | | | | | | | DO | DN | NA |  |
|  |  | Consider changes in the external issues that influence your system. | | | | | | DO | DN | NA |  |
|  |  | Consider changes in the internal issues that influence your system. | | | | | | 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 |  |
| 6.2 PROVIDE RESOURCES NEEDED TO EVALUATE SYSTEM | | | | | | | | | | | |
| 6.2.1 Provide the people that you need to evalaute your system | | | | | | | | | | | |
|  | Provide the people that you need in order to audit your system. | | | | | | | DO | DN | NA |  |
|  | Provide the people that you need in order to analyze your system. | | | | | | | DO | DN | NA |  |
|  | Provide the people that you need in order to review your system. | | | | | | | DO | DN | NA |  |
| 6.2.2 Provide the knowledge that YOU need to evaluate your system | | | | | | | | | | | |
|  | Provide the knowledge that you need in order to audit your system. | | | | | | | DO | DN | NA |  |
|  | Provide the knowledge that you need in order to analyze your system. | | | | | | | DO | DN | NA |  |
|  | Provide the knowledge that you need in order to review your system. | | | | | | | DO | DN | NA |  |
| 6.2.3 Provide the technology that YOU need to evaluate your system | | | | | | | | | | | |
|  | Provide the technology that you need in order to audit your system. | | | | | | | DO | DN | NA |  |
|  | Provide the technology that you need in order to analyze your system. | | | | | | | DO | DN | NA |  |
|  | Provide the technology that you need in order to review your system. | | | | | | | DO | DN | NA |  |
| 6.2.4 Provide the infrastructure that you need to evaluate your system | | | | | | | | | | | |
|  | Provide the infrastructure that you need in order to audit your system. | | | | | | | DO | DN | NA |  |
|  | Provide the infrastructure that you need in order to analyze your system. | | | | | | | DO | DN | NA |  |
|  | Provide the infrastructure that you need in order to review your system. | | | | | | | DO | DN | NA |  |
| 6.3 USE AUTHORIZED METHODS TO EVALUATE SYSTEM | | | | | | | | | | | |
| 6.3.1 Use authorized methods to audit your system | | | | | | | | | | | |
|  | Use authorized methods to plan your internal audit activities. | | | | | | | DO | DN | NA |  |
|  |  | Define the scope for each internal management system audit. | | | | | | DO | DN | NA |  |
|  |  | Specify audit criteria for each internal management system audit. | | | | | | DO | DN | NA |  |
|  |  | Clarify internal management system audit methods and techniques. | | | | | | DO | DN | NA |  |
|  |  | Select impartial and objective internal management system auditors. | | | | | | DO | DN | NA |  |
|  |  | Schedule internal management system audits at planned intervals. | | | | | | DO | DN | NA |  |
|  | Use authorized methods to carry out audits at planned intervals. | | | | | | | DO | DN | NA |  |
|  |  | Conduct internal conformance audits of management system. | | | | | | DO | DN | NA |  |
|  |  | | Determine if your system meets relevant requirements. | | | | | DO | DN | NA |  |
|  |  | | | Determine if your system meets internal requirements. | | | | DO | DN | NA |  |
|  |  | | | Determine if your system meets external requirements. | | | | DO | DN | NA |  |
|  |  | | | | Determine if your system meets external customer requirements. | | | DO | DN | NA |  |
|  |  | | | | Determine if your system meets external statutory requirements. | | | DO | DN | NA |  |
|  |  | | | | Determine if your system meets external regulatory requirements. | | | DO | DN | NA |  |
|  |  | | | | | Determine if your system complies with government regulations. | | DO | DN | NA |  |
|  |  | | | | | Determine if your system complies with international standards. | | DO | DN | NA |  |
|  |  | | | | | | Determine how well system meets safety management requirements. | DO | DN | NA |  |
|  |  | | | | | | Determine how well system meets privacy management requirements. | DO | DN | NA |  |
|  |  | | | | | | Determine how well system meets security management requirements. | DO | DN | NA |  |
|  |  | | | | | | Determine how well system meets quality management requirements. | DO | DN | NA |  |
|  |  | | | | | | Determine how well system meets business continuity management requirements. | DO | DN | NA |  |
|  |  | Conduct internal effectiveness audits of your management system. | | | | | | DO | DN | NA |  |
|  |  | | Determine how effective management system implementation was. | | | | | DO | DN | NA |  |
|  |  | | | Use performance indicators to see if system was effectively implemented. | | | | DO | DN | NA |  |
|  |  | | Determine how effective management system operations are. | | | | | DO | DN | NA |  |
|  |  | | | Use performance indicators to see if system is being effectively operated. | | | | DO | DN | NA |  |
|  |  | | Determine how effective management system controls are. | | | | | DO | DN | NA |  |
|  |  | | | Use performance indicators to see if system is being effectively controlled. | | | | DO | DN | NA |  |
|  |  | | Determine how effective management system maintenance is. | | | | | DO | DN | NA |  |
|  |  | | | Use performance indicators to see if system is being effectively maintained. | | | | DO | DN | NA |  |
|  |  | | Determine how effective management system monitoring is. | | | | | DO | DN | NA |  |
|  |  | | | Use performance indicators to see if system is being effectively monitored. | | | | DO | DN | NA |  |
|  |  | | Determine how effective management system measurement is. | | | | | DO | DN | NA |  |
|  |  | | | Use performance indicators to see if system is being effectively measured. | | | | DO | DN | NA |  |
|  |  | | Determine how effective management system evaluations are. | | | | | DO | DN | NA |  |
|  |  | | | Use performance indicators to see if system is being effectively evaluated. | | | | DO | DN | NA |  |
|  |  | | | | Use performance indicators to see if system is being effectively audited. | | | DO | DN | NA |  |
|  |  | | | | Use performance indicators to see if system is being effectively reviewed. | | | DO | DN | NA |  |
|  |  | | Determine how effective management system changes are. | | | | | DO | DN | NA |  |
|  |  | | | Use performance indicators to see if system is being effectively modified. | | | | DO | DN | NA |  |
|  |  | | | | Use performance indicators to see if system corrections are effective. | | | DO | DN | NA |  |
|  |  | | | | Use performance indicators to see if system improvements are effective. | | | DO | DN | NA |  |
|  | Use authorized methods to report management system audit results to management. | | | | | | | DO | DN | NA |  |
|  | Use authorized methods to maintain your management system audit programme. | | | | | | | DO | DN | NA |  |
|  |  | Retain documented information about your audit programme. | | | | | | DO | DN | NA |  |
|  |  | | Retain your internal audit results and control these results. | | | | | DO | DN | NA |  |
| 6.3.2 Use authorized methods to analyze your system | | | | | | | | | | | |
|  | Use authorized methods to analyze the opinions of customers. | | | | | | | DO | DN | NA |  |
|  |  | Use your analytical results to evaluate customer satisfaction. | | | | | | DO | DN | NA |  |
|  |  | | Evaluate the degree of customer satisfaction. | | | | | DO | DN | NA |  |
|  | Use authorized methods to analyze system performance. | | | | | | | DO | DN | NA |  |
|  |  | Use your results to analyze conformance. | | | | | | DO | DN | NA |  |
|  |  | | Analyze the conformity of system outputs. | | | | | DO | DN | NA |  |
|  |  | | | Analyze management system 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 management system operations. | | | | | DO | DN | NA |  |
|  |  | | | Determine if you need to improve its system effectiveness. | | | | DO | DN | NA |  |
|  | Use authorized methods to analyze the effectiveness of your system. | | | | | | | DO | DN | NA |  |
|  |  | Use your results to analyze management system effectiveness. | | | | | | DO | DN | NA |  |
|  |  | | Analyze the effectiveness of management system operations. | | | | | DO | DN | NA |  |
|  |  | | | Determine if you need to improve management system operations. | | | | DO | DN | NA |  |
|  |  | | Analyze the effectiveness of management system maintenance. | | | | | DO | DN | NA |  |
|  |  | | | Determine if you need to improve management system maintenance. | | | | DO | DN | NA |  |
|  |  | | Analyze the effectiveness of management system monitoring. | | | | | DO | DN | NA |  |
|  |  | | | Determine if you need to improve management system monitoring. | | | | DO | DN | NA |  |
|  |  | | Analyze the effectiveness of management system measurement. | | | | | DO | DN | NA |  |
|  |  | | | Determine if you need to improve management system measurement. | | | | DO | DN | NA |  |
|  |  | | Analyze the effectiveness of management system evaluations. | | | | | DO | DN | NA |  |
|  |  | | | Analyze the effectiveness of management system audits. | | | | DO | DN | NA |  |
|  |  | | | | Determine if you need to improve management system audits. | | | DO | DN | NA |  |
|  |  | | | Analyze the effectiveness of management system reviews. | | | | DO | DN | NA |  |
|  |  | | | | Determine if you need to improve management system reviews. | | | DO | DN | NA |  |
|  |  | | Analyze the effectiveness of management system changes. | | | | | DO | DN | NA |  |
|  |  | | | Analyze the effectiveness of management system corrections. | | | | DO | DN | NA |  |
|  |  | | | | Determine if you need to improve system correction activities. | | | DO | DN | NA |  |
|  |  | | | Analyze the effectiveness of management system improvements. | | | | DO | DN | NA |  |
|  |  | | | | Determine if you need to improve system improvement activities. | | | DO | DN | NA |  |
|  |  | Use your results to analyze management system management. | | | | | | DO | DN | NA |  |
|  |  | | Analyze the effectiveness of actions taken by managers. | | | | | DO | DN | NA |  |
|  |  | | | Analyze the effectiveness of actions taken to address system risks. | | | | DO | DN | NA |  |
|  |  | | | Analyze the effectiveness of actions taken to address system opportunities. | | | | DO | DN | NA |  |
|  |  | | | Analyze the effectiveness of actions taken to address system nonconformities. | | | | DO | DN | NA |  |
|  |  | | | Analyze the effectiveness of actions taken to address system performance problems. | | | | DO | DN | NA |  |
|  | Use authorized methods to analyze the competence of system participants. | | | | | | | DO | DN | NA |  |
|  |  | Analyze the competence and performance of system 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 system, 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 |  |
| 6.3.3 Use authorized methods to review your system | | | | | | | | | | | |
|  | Use authorized methods to review the performance of your system. | | | | | | | DO | DN | NA |  |
|  |  | Review your management system nonconformities. | | | | | | DO | DN | NA |  |
|  |  | Review management system 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 management system personnel. | | | | | | DO | DN | NA |  |
|  |  | | Review how well objectives are being met. | | | | | DO | DN | NA |  |
|  |  | | Review the competence of system personnel. | | | | | DO | DN | NA |  |
|  |  | Review system management activities and results. | | | | | | DO | DN | NA |  |
|  |  | | Review system control methods and results. | | | | | DO | DN | NA |  |
|  |  | | Review system operations methods and results. | | | | | DO | DN | NA |  |
|  |  | | Review system monitoring methods and results. | | | | | DO | DN | NA |  |
|  |  | | Review system measurement methods and results. | | | | | DO | DN | NA |  |
|  |  | | Review system maintenance methods and results. | | | | | DO | DN | NA |  |
|  |  | | Review system evaluation methods and results. | | | | | DO | DN | NA |  |
|  |  | | | Review system audit activities and results. | | | | DO | DN | NA |  |
|  |  | | | Review system analysis activities and results. | | | | DO | DN | NA |  |
|  |  | | Review system modification methods and results. | | | | | DO | DN | NA |  |
|  |  | | | Review actual management system modifications. | | | | DO | DN | NA |  |
|  |  | | | | Review actions taken to modify management system. | | | DO | DN | NA |  |
|  |  | | | | | Review the effectiveness of actions taken to improve system. | | DO | DN | NA |  |
|  |  | | | | | Review the effectiveness of corrective and preventive actions. | | DO | DN | NA |  |
|  |  | | | | | | Review corrective actions taken to address system nonconformities. | DO | DN | NA |  |
|  |  | | | | | | Review preventive actions taken to address system nonconformities. | DO | DN | NA |  |
|  |  | | | Review potential management system changes. | | | | DO | DN | NA |  |
|  |  | | | | Review potential improvement opportunities. | | | DO | DN | NA |  |
|  |  | | | | Review potential corrective and preventive actions. | | | DO | DN | NA |  |
|  |  | Review management system 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 management system 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 management system 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 management system resources. | | | | | | DO | DN | NA |  |
|  | Generate suitable management system review outputs. | | | | | | | DO | DN | NA |  |
| 6.4 RECORD THE RESULTS OF SYSTEM EVALUATIONS | | | | | | | | | | | |
| 6.4.1 record the results of management system audits | | | | | | | | | | | |
|  | Record your management system audit activities and results. | | | | | | | DO | DN | NA |  |
|  |  | Maintain your quality management system audit records. | | | | | | DO | DN | NA |  |
|  |  | Control your quality management system audit records. | | | | | | DO | DN | NA |  |
| 6.4.2 record the results of management system analyses | | | | | | | | | | | |
|  | Record your management system analysis activities and results. | | | | | | | DO | DN | NA |  |
|  |  | Maintain your quality management system analysis records. | | | | | | DO | DN | NA |  |
|  |  | Control your quality management system analysis records. | | | | | | DO | DN | NA |  |
| 6.4.3 record the results of management system reviews | | | | | | | | | | | |
|  | Record your management system review activities and results. | | | | | | | DO | DN | NA |  |
|  |  | Maintain your quality management system review records. | | | | | | DO | DN | NA |  |
|  |  | Control your quality management system 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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| 7.1 ESTABLISH CHANGE MANAGEMENT METHODS | | | | | | | | | | |
| 7.1.1 Establish methods for correcting system and outputs | | | | | | | | | | |
|  | Establish appropriate corrective action methods and procedures. | | | | | | DO | DN | NA |  |
|  |  | Document your system’s corrective action methods and procedures. | | | | | DO | DN | NA |  |
|  |  | | Maintain documents that describe corrective action methods and procedures. | | | | DO | DN | NA |  |
|  | Establish appropriate corrective action record keeping methods and procedures. | | | | | | DO | DN | NA |  |
|  |  | Figure out how you're going to record the actions taken to correct system and outputs. | | | | | DO | DN | NA |  |
|  |  | Figure out how you're going to record the system and output corrections that are made. | | | | | DO | DN | NA |  |
| 7.1.2 Establish methods for improving system and outputs | | | | | | | | | | |
|  | Establish appropriate system and output improvement methods and procedures. | | | | | | DO | DN | NA |  |
|  |  | Document your system and output improvement methods and procedures. | | | | | DO | DN | NA |  |
|  |  | | Maintain documents describing system and output improvement methods and procedures. | | | | DO | DN | NA |  |
|  | Establish appropriate system and output improvement record keeping methods. | | | | | | DO | DN | NA |  |
|  |  | Figure out how you're going to record the actions taken to improve system and outputs. | | | | | DO | DN | NA |  |
|  |  | Figure out how you're going to record the system and output improvements that are made. | | | | | DO | DN | NA |  |
| 7.2 GENERATE OPPORTUNITIES TO CHANGE SYSTEM | | | | | | | | | | |
| 7.2.1 DISCOVER opportunities to CHANGE system and outputs | | | | | | | | | | |
|  | Discover opportunities to correct your management system and 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 management system and outputs. | | | | | | DO | DN | NA |  |
|  |  | Discover systemic improvement opportunities by examining audit reports. | | | | | DO | DN | NA |  |
|  |  | Discover systemic improvement opportunities by examining review results. | | | | | DO | DN | NA |  |
|  |  | Discover systemic improvement opportunities by examining best practices. | | | | | DO | DN | NA |  |
|  |  | Discover systemic improvement opportunities by examining lessons learned. | | | | | DO | DN | NA |  |
|  |  | Discover systemic improvement opportunities by examining nonconformities. | | | | | DO | DN | NA |  |
|  |  | Discover systemic improvement opportunities by examining customer feedback. | | | | | DO | DN | NA |  |
| 7.2.2 Confirm that system and output CHANGES are needed | | | | | | | | | | |
|  | Confirm that proposed management system modifications are necessary. | | | | | | DO | DN | NA |  |
|  |  | Confirm that proposed management system modifications would be feasible. | | | | | DO | DN | NA |  |
|  |  | Confirm that proposed management system modifications would be appropriate. | | | | | DO | DN | NA |  |
|  |  | Confirm that proposed management system modifications would be effective. | | | | | DO | DN | NA |  |
|  |  | | Confirm that proposed management system modifications would be cost-effective. | | | | DO | DN | NA |  |
|  | Confirm that proposed management system output modifications would be necessary. | | | | | | DO | DN | NA |  |
|  |  | Confirm that proposed management system output modifications would be feasible. | | | | | DO | DN | NA |  |
|  |  | Confirm that proposed management system output modifications would be appropriate. | | | | | DO | DN | NA |  |
|  |  | Confirm that proposed management system output modifications would be effective. | | | | | DO | DN | NA |  |
|  |  | | Confirm that proposed management system output modifications would be cost-effective. | | | | DO | DN | NA |  |
| 7.2.3 Approve opportunities to CHANGE system and outputs | | | | | | | | | | |
|  | Authorize proposed management system corrections and improvements. | | | | | | DO | DN | NA |  |
|  | Authorize proposed management output corrections and improvements. | | | | | | DO | DN | NA |  |
| 7.3 PLAN CHANGES TO YOUR MANAGEMENT SYSTEM | | | | | | | | | | |
| 7.3.1 Plan how you're going to correct system and 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 system and output nonconformities. | | | | | DO | DN | NA |  |
|  |  | Plan how you're going to control and correct system 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 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 system 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 system and output risks. | | | | | | DO | DN | NA |  |
| 7.3.2 Plan how you're going to improve system and outputs | | | | | | | | | | |
|  | Plan improvements and other changes to your management system. | | | | | | DO | DN | NA |  |
|  |  | Identify people authorized to approve changes in your system. | | | | | DO | DN | NA |  |
|  |  | Use your system purpose and scope to guide system improvements. | | | | | DO | DN | NA |  |
|  |  | | Use system policy statements to guide system improvements. | | | | DO | DN | NA |  |
|  |  | | | Use your quality policy to guide your system improvements. | | | DO | DN | NA |  |
|  |  | | | | Use your quality objectives to guide system improvements. | | DO | DN | NA |  |
|  |  | | | Use your privacy policy to guide your system improvements. | | | DO | DN | NA |  |
|  |  | | | | Use your privacy objectives to guide system improvements. | | DO | DN | NA |  |
|  |  | | | Use your safety policy to guide your system improvements. | | | DO | DN | NA |  |
|  |  | | | | Use your safety objectives to guide system improvements. | | DO | DN | NA |  |
|  |  | | | Use your security policy to guide your system improvements. | | | DO | DN | NA |  |
|  |  | | | | Use your security objectives to guide system improvements. | | DO | DN | NA |  |
|  |  | | | Use your business continuity policy to guide your system improvements. | | | DO | DN | NA |  |
|  |  | | | | Use your business continuity objectives to guide system improvements. | | DO | DN | NA |  |
|  |  | Consider improvements and other changes to your management system. | | | | | 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 system whenever you make changes. | | | | DO | DN | NA |  |
|  |  | Figure out how you're going to control changes in your management system. | | | | | DO | DN | NA |  |
|  |  | | Ensure that system continues to meet requirements even though changes are being made. | | | | DO | DN | NA |  |
|  | Plan improvements and other changes to management system outputs. | | | | | | DO | DN | NA |  |
|  |  | Identify people authorized to approve changes in system outputs. | | | | | DO | DN | NA |  |
|  |  | Use your system purpose and scope to guide output improvements. | | | | | DO | DN | NA |  |
|  |  | | Use system policy statements to guide system 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 privacy policy to guide your output improvements. | | | DO | DN | NA |  |
|  |  | | | | Use your privacy 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 business continuity policy to guide your output improvements. | | | DO | DN | NA |  |
|  |  | | | | Use your business continuity objectives to guide output improvements. | | DO | DN | NA |  |
|  |  | Consider improvements and other changes to management system 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 system’s outputs. | | | | | DO | DN | NA |  |
|  |  | | Ensure that outputs continue to meet requirements even though changes are being made. | | | | DO | DN | NA |  |
| 7.4 USE APPROVED METHODS TO CHANGE SYSTEM | | | | | | | | | | |
| 7.4.1 Use APPROVED methods to correct system 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 system and output nonconformities. | | | | DO | DN | NA |  |
|  |  | | | Determine the causes of system 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 system 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 system and outputs. | | | | | | DO | DN | NA |  |
|  |  | Provide suitable resources needed to correct system outputs. | | | | | DO | DN | NA |  |
|  |  | Provide suitable resources needed to correct system 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 |  |
| 7.4.2 Use APPROVED methods to improve system and outputs | | | | | | | | | | |
|  | Apply system and output improvement methods and procedures. | | | | | | DO | DN | NA |  |
|  |  | Evaluate the need to make system and output improvements. | | | | | DO | DN | NA |  |
|  | Provide the resources needed to make system and output improvements. | | | | | | DO | DN | NA |  |
|  |  | Provide suitable resources needed to improve your system outputs. | | | | | DO | DN | NA |  |
|  |  | Provide suitable resources needed to improve your system activities. | | | | | DO | DN | NA |  |
|  | Develop improvements to your system and system outputs. | | | | | | DO | DN | NA |  |
|  |  | Make sure that your system and output improvements are feasible. | | | | | DO | DN | NA |  |
|  |  | Make sure that your system and output improvements are appropriate. | | | | | DO | DN | NA |  |
|  |  | | Make sure that system and output improvements also consider effects. | | | | DO | DN | NA |  |
|  |  | Make sure that your system and output improvements are effective. | | | | | DO | DN | NA |  |
|  |  | | Make sure that your system and output improvements are cost-effective. | | | | DO | DN | NA |  |
|  | Implement improvements to your management system and system outputs. | | | | | | DO | DN | NA |  |
|  |  | Improve the suitability, adequacy, and effectiveness of your management system. | | | | | DO | DN | NA |  |
|  |  | Improve the quality, safety, privacy, and security of management system outputs. | | | | | DO | DN | NA |  |
|  | Control improvements to your management system and system outputs. | | | | | | DO | DN | NA |  |
|  |  | Control improvements and other changes affecting system software. | | | | | DO | DN | NA |  |
|  |  | Control improvements and other changes affecting system operations. | | | | | DO | DN | NA |  |
|  |  | Control improvements and other changes affecting system equipment. | | | | | DO | DN | NA |  |
|  |  | Control improvements and other changes affecting system tools. | | | | | DO | DN | NA |  |
|  | Monitor improvements to your management system and system outputs. | | | | | | DO | DN | NA |  |
|  |  | Monitor the implementation of system and output improvement activities. | | | | | DO | DN | NA |  |
|  | Record improvements to your management system and system outputs. | | | | | | DO | DN | NA |  |
| 7.5 REVIEW AND EVALUATE CHANGES TO SYSTEM | | | | | | | | | | |
| 7.5.1 Review and evaluate system and output corrections | | | | | | | | | | |
|  | Review and evaluate actions taken to correct your management system. | | | | | | DO | DN | NA |  |
|  |  | Document your system correction reviews and the actions that are taken. | | | | | DO | DN | NA |  |
|  |  | Establish a record of system correction reviews and actions taken. | | | | | DO | DN | NA |  |
|  | Review and evaluate actions taken to correct system 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 |  |
| 7.5.2 Review and evaluate system and output improvements | | | | | | | | | | |
|  | Review and evaluate improvements and changes to management system. | | | | | | DO | DN | NA |  |
|  |  | Document management system improvement reviews and the actions that are taken. | | | | | DO | DN | NA |  |
|  |  | Establish a record of management system improvement reviews and the actions taken. | | | | | DO | DN | NA |  |
|  | Review and evaluate improvements and changes to management system 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. | | | | | | | | | | |

