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|  | **ISO’S PROCESS  BASED STANDARDS** | Almost all ISO management standards now expect organizations  to use a process approach. These include:   * ISO 9001 Quality Management Standard. * ISO 14001 Environmental Management Standard. * ISO 45001 Occupational Health and Safety Standard. * ISO 27001 Information Security Management Standard. * ISO 13485 Quality Management Standard for Medical Devices. * AS9100 Quality Management Standard for Aerospace and Defense. * IATF 16949 Quality Management Standard for Automotive Sector. * ISO 17025 Standard for Testing and Calibration Laboratories. * ISO 22301 Business Continuity Management Standard. * ISO 50001 Energy Management Standard. * ISO 31000 Risk Management Standard. |
|  |  | Because of this, organizations have been asking us to develop a generic process audit  tool that is based on and consistent with the process approach advocated by the above management standards. So that's what we've done.  However, before we could create such an audit tool, we needed to first develop a generic process management framework that is consistent with all of the above standards, one that could be used to establish process audit criteria and to develop process audit questions. Now that this generic process management framework has been finalized (see Title 7), we've used it to develop our plain English process management audit tool (our Title 8). |
|  | **OUR PROCESS AUDIT METHODOLOGY** | Start your process audit by first selecting a process. Then enter the name of your process  at the top of each process audit questionnaire (Parts 1 to 9). This will help to focus your audit and keep it on track. Then prepare your audit profile (Part B). First record the name of the organization and the process being audited and a brief description of the scope or focus of the audit. Also record the names of your audit team members and your start date. Once you've completed your audit, use the same form to record when the audit was finished, who reviewed it, and when, and any review comments you may have.  Our process audit consists of nine questionnaires, one for each of the nine sections  that make up our Plain English Process Management Framework (our Title 7). For each question, three answers are possible: YES, NO, or N/A (to save space we use Y, N, X).  A YES answer means you’re in compliance with the framework, a NO answer means  you’re not in compliance, while an N/A answer means that a question is not  applicable in your case. NO answers identify gaps that exist between our process  framework and your process activities, gaps that probably should be filled. |
|  |  | Once you've completed all nine questionnaires, study your NO answers, your own notes and comments, and our questions, and then use this information to formulate actions or steps that need to be taken in order to bring your organization's processes into compliance with our Plain English Process Management Standard (which is based on and is consistent with ISO's many management standards).  Use this information to develop your own unique process improvement plan. And once you've implemented this plan, your process will not only perform better but it will also comply with our process management standard and ISO's management standards.  We've also provided a mini audit questionnaire (Part C) that you can use to carry out  a quick process audit or to decide what general areas need more detailed attention.  If you're not clear about what one of these general questions is talking about, simply  go to our more detailed audit tool and study the relevant section. |
|  | **OTHER RESOURCES** | Process management library: <https://www.praxiom.com/process.htm>  Process definitions: <https://www.praxiom.com/process-definitions.htm> |
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| **PROCESS AUDIT SCOPE** | |
| **NAME OF ORGANIZATION BEING AUDITED** | **ADDRESS OF ORGANIZATION BEING AUDITED** |
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| **PROCESS BEING AUDITED** | **ADDRESS OF PROCESS AUDIT** |
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| **PROCESS AUDIT SCOPE** | |
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| **AUDITORS** | |
| **AUDIT MANAGER** | **AUDIT STAFF** |
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| **AUDIT SCHEDULE** | |
| **AUDIT START DATE** | **AUDIT FINISH DATE** |
|  |  |
| **AUDIT REVIEWER** | |
| **AUDIT REVIEWED BY** | **DATE AUDIT REVIEWED** |
|  |  |
| **REVIEW COMMENTS** | |
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| 1. ASSESS Process Development ACTIVITIES | | | | | | |
| 1.1 | Did you study the context of your process? | | Y | N | X |  |
| 1.1.1 | | Did you consider process participants? | Y | N | X |  |
| 1.1.2 | | Did you consider process environment? | Y | N | X |  |
| 1.1.3 | | Did you consider process risks and threats? | Y | N | X |  |
| 1.1.4 | | Did you consider process opportunities? | Y | N | X |  |
| 1.2 | Did you clarify the purpose of your process? | | Y | N | X |  |
| 1.2.1 | | Did you define process scope and boundaries? | Y | N | X |  |
| 1.2.2 | | Did you establish your process objectives? | Y | N | X |  |
| 1.3 | Did you consider your process requirements? | | Y | N | X |  |
| 1.3.1 | | Did you clarify process output requirements? | Y | N | X |  |
| 1.3.2 | | Did you clarify process knowledge requirements? | Y | N | X |  |
| 1.3.3 | | Did you clarify process competence requirements? | Y | N | X |  |
| 1.3.4 | | Did you clarify process management requirements? | Y | N | X |  |
| 1.3.5 | | Did you clarify process communication requirements? | Y | N | X |  |
| 1.3.6 | | Did you clarify process infrastructure requirements? | Y | N | X |  |
| 1.3.7 | | Did you clarify process environment requirements? | Y | N | X |  |
| 1.3.8 | | Did you clarify process resource requirements? | Y | N | X |  |
| 1.4 | Did you plan process design and development? | | Y | N | X |  |
| 1.4.1 | | Did you carry out output planning? | Y | N | X |  |
| 1.4.2 | | Did you carry out process planning? | Y | N | X |  |
| 1.4.3 | | Did you carry out input planning? | Y | N | X |  |
| 1.5 | Did you design process support programmes? | | Y | N | X |  |
| 1.5.1 | | Did you design risk management programme? | Y | N | X |  |
| 1.5.2 | | Did you design safety management programme? | Y | N | X |  |
| 1.5.3 | | Did you design quality management programme? | Y | N | X |  |
| 1.5.4 | | Did you design security management programme? | Y | N | X |  |
| 1.5.5 | | Did you design supplier management programme? | Y | N | X |  |
| 1.5.6 | | Did you design environmental management programme? | Y | N | X |  |
| 1.5.7 | | Did you design business continuity management programme? | Y | N | X |  |
| 1.6 | Did you identify process documents and records? | | Y | N | X |  |
| 1.6.1 | | Did you evaluate documentation requirements? | Y | N | X |  |
| 1.6.2 | | Did you select process documents and records? | Y | N | X |  |
| 1.6.3 | | Did you develop process documents and records? | Y | N | X |  |
| 1.7 | Did you establish process roles and responsibilities? | | Y | N | X |  |
| 1.7.1 | | Did you assign process responsibilities and authorities? | Y | N | X |  |
| 1.7.2 | | Did you document process responsibilities and authorities? | Y | N | X |  |
| 2. ASSESS Process Implementation ACTIVITIES | | | | | | |
| 2.1 | Did you provide resources needed to implement process? | | Y | N | X |  |
| 2.2 | Did you create the environment that your process needs? | | Y | N | X |  |
| 2.3 | Did you verify that process can produce required outputs? | | Y | N | X |  |
| 2.4 | Did you establish plans to achieve your process objectives? | | Y | N | X |  |
| 2.5 | Did you explain process policies, procedures, and objectives? | | Y | N | X |  |
| 2.6 | Did you communicate process management expectations? | | Y | N | X |  |
| 2.7 | Did you expect all process managers to be accountable? | | Y | N | X |  |
| 2.8 | Did you establish process management programmes? | | Y | N | X |  |
| 2.9 | Did you retain implementation documentation? | | Y | N | X |  |
| 3. ASSESS Process Operation ACTIVITIES | | | | | | |
| 3.1 | Do you provide resources to facilitate process operations? | | Y | N | X |  |
| 3.1.1 | | Do you provide the expertise needed to operate your process? | Y | N | X |  |
| 3.1.2 | | Do you provide the technology needed to operate your process? | Y | N | X |  |
| 3.1.3 | | Do you provide the infrastructure needed to operate your process? | Y | N | X |  |
| 3.2 | Do you ask process owners to manage process operations? | | Y | N | X |  |
| 3.2.1 | | Do you expect process managers to address risks and opportunities? | Y | N | X |  |
| 3.2.2 | | Do you expect process managers to implement policies and procedures? | Y | N | X |  |
| 3.2.3 | | Do you expect process managers to specify output requirements and capabilities? | Y | N | X |  |
| 3.2.4 | | Do you expect process managers to communicate with their process customers? | Y | N | X |  |
| 3.2.5 | | Do you expect process managers to evaluate and select their external providers? | Y | N | X |  |
| 3.2.6 | | Do you expect process managers to supervise and control all process activities? | Y | N | X |  |
| 3.2.7 | | Do you expect process managers to measure conformance and performance? | Y | N | X |  |
| 3.2.8 | | Do you expect process managers to meet expectations and requirements? | Y | N | X |  |
| 3.2.9 | | Do you expect process managers to be accountable for their process? | Y | N | X |  |
| 3.3 | Do you expect personnel to carry out process operations? | | Y | N | X |  |
| 3.3.1 | | Do you expect personnel to focus on process customers? | Y | N | X |  |
| 3.3.2 | | Do you expect personnel to handle risks and opportunities? | Y | N | X |  |
| 3.3.3 | | Do you expect personnel to implement policies and procedures? | Y | N | X |  |
| 3.3.4 | | Do you expect personnel to comply with all relevant requirements? | Y | N | X |  |
| 3.3.5 | | Do you expect personnel to take appropriate action when necessary? | Y | N | X |  |
| 3.3.6 | | Do you expect personnel to control process documents and records? | Y | N | X |  |
| 4. ASSESS Process Maintenance ACTIVITIES | | | | | | |
| 4.1 | Do you provide the resources needed to maintain process? | | Y | N | X |  |
| 4.1.1 | | Do you provide the expertise needed to maintain your process? | Y | N | X |  |
| 4.1.2 | | Do you provide the technology needed to maintain your process? | Y | N | X |  |
| 4.1.3 | | Do you provide the infrastructure needed to maintain your process? | Y | N | X |  |
| 4.2 | Do you use authorized methods to maintain your process? | | Y | N | X |  |
| 4.2.1 | | Do you use authorized methods to maintain process documents? | Y | N | X |  |
| 4.2.2 | | Do you use authorized methods to maintain process records? | Y | N | X |  |
| 4.2.3 | | Do you use authorized methods to maintain process property? | Y | N | X |  |
| 4.2.4 | | Do you use authorized methods to maintain process procedures? | Y | N | X |  |
| 4.2.5 | | Do you use authorized methods to maintain process programmes? | Y | N | X |  |
| 4.2.6 | | Do you use authorized methods to maintain process competence? | Y | N | X |  |
| 4.2.7 | | Do you use authorized methods to maintain process technologies? | Y | N | X |  |
| 4.2.8 | | Do you use authorized methods to maintain process infrastructure? | Y | N | X |  |
| 4.2.9 | | Do you use authorized methods to maintain process communications? | Y | N | X |  |
| 5. ASSESS Process Measurement ACTIVITIES | | | | | | |
| 5.1 | Do you plan how you're going to measure your process? | | Y | N | X |  |
| 5.1.1 | | Do you figure out what needs to be measured? | Y | N | X |  |
| 5.1.2 | | Do you figure out how measurements will be done? | Y | N | X |  |
| 5.1.3 | | Do you figure out who will perform measurement tasks? | Y | N | X |  |
| 5.2 | Do you qualify the resources needed to measure process? | | Y | N | X |  |
| 5.3 | Do you provide the resources needed to measure process? | | Y | N | X |  |
| 5.3.1 | | Do you provide the expertise needed to measure your process? | Y | N | X |  |
| 5.3.2 | | Do you provide the technology needed to measure your process? | Y | N | X |  |
| 5.3.3 | | Do you provide the infrastructure needed to measure your process? | Y | N | X |  |
| 5.4 | Do you use authorized methods to measure your process? | | Y | N | X |  |
| 5.4.1 | | Do you use authorized methods to measure process elements? | Y | N | X |  |
| 5.4.2 | | Do you use authorized methods to measure process performance? | Y | N | X |  |
| 5.5 | Do you control the resources needed to measure process? | | Y | N | X |  |
| 5.5.1 | | Do you control the documents needed to measure your process? | Y | N | X |  |
| 5.5.2 | | Do you control the technology needed to measure your process? | Y | N | X |  |
| 5.5.3 | | Do you control the records needed to measure your process? | Y | N | X |  |
| 6. ASSESS Process Monitoring ACTIVITIES | | | | | | |
| 6.1 | Do you plan how you're going to monitor your process? | | Y | N | X |  |
| 6.1.1 | | Do you figure out what needs to be monitored? | Y | N | X |  |
| 6.1.2 | | Do you figure out how monitoring will be done? | Y | N | X |  |
| 6.1.3 | | Do you figure out who will perform monitoring tasks? | Y | N | X |  |
| 6.2 | Do you qualify the resources needed to monitor process? | | Y | N | X |  |
| 6.3 | Do you provide the resources needed to monitor process? | | Y | N | X |  |
| 6.3.1 | | Do you provide the expertise needed to monitor your process? | Y | N | X |  |
| 6.3.2 | | Do you provide the technology needed to monitor your process? | Y | N | X |  |
| 6.3.3 | | Do you provide the infrastructure needed to monitor your process? | Y | N | X |  |
| 6.4 | Do you use authorized methods to monitor your process? | | Y | N | X |  |
| 6.4.1 | | Do you use authorized methods to monitor process activities? | Y | N | X |  |
| 6.4.2 | | Do you use authorized methods to monitor process outputs? | Y | N | X |  |
| 6.4.3 | | Do you use authorized methods to monitor process inputs? | Y | N | X |  |
| 6.4.4 | | Do you use authorized methods to monitor process documents? | Y | N | X |  |
| 6.4.5 | | Do you use authorized methods to monitor process records? | Y | N | X |  |
| 6.4.6 | | Do you use authorized methods to monitor process property? | Y | N | X |  |
| 6.4.7 | | Do you use authorized methods to monitor process participants? | Y | N | X |  |
| 6.4.8 | | Do you use authorized methods to monitor process technologies? | Y | N | X |  |
| 6.4.9 | | Do you use authorized methods to monitor process environment? | Y | N | X |  |
| 6.4.10 | | Do you use authorized methods to monitor process infrastructure? | Y | N | X |  |
| 6.5 | Do you control the resources needed to monitor process? | | Y | N | X |  |
| 7. ASSESS Process Control ACTIVITIES | | | | | | |
| 7.1 | Do you plan how you're going to control process? | | Y | N | X |  |
| 7.1.1 | | Do you consider how to control your process outputs? | Y | N | X |  |
| 7.1.2 | | Do you consider how to control your process inputs? | Y | N | X |  |
| 7.1.3 | | Do you consider how to control your process activities? | Y | N | X |  |
| 7.1.4 | | Do you consider how to control your process providers? | Y | N | X |  |
| 7.2 | Do you develop ways of controlling your process? | | Y | N | X |  |
| 7.2.1 | | Do you develop ways of controlling process elements? | Y | N | X |  |
| 7.2.2 | | Do you develop ways of controlling process providers? | Y | N | X |  |
| 7.3 | Do you provide resources needed to control process? | | Y | N | X |  |
| 7.4 | Do you use authorized methods to control process? | | Y | N | X |  |
| 7.4.1 | | Do you use authorized methods to control process inputs? | Y | N | X |  |
| 7.4.2 | | Do you use authorized methods to control process outputs? | Y | N | X |  |
| 7.4.3 | | Do you use authorized methods to control process activities? | Y | N | X |  |
| 7.4.4 | | Do you use authorized methods to control process technology? | Y | N | X |  |
| 7.4.5 | | Do you use authorized methods to control process programmes? | Y | N | X |  |
| 7.4.6 | | Do you use authorized methods to control process performance? | Y | N | X |  |
| 7.4.7 | | Do you use authorized methods to control process documentation? | Y | N | X |  |
| 8. ASSESS Process Evaluation ACTIVITIES | | | | | | |
| 8.1 | Do you plan how you're going to evaluate process? | | Y | N | X |  |
| 8.1.1 | | Do you plan how you're going to audit your process? | Y | N | X |  |
| 8.1.2 | | Do you plan how you're going to analyze your process? | Y | N | X |  |
| 8.1.3 | | Do you plan how you're going to review your process? | Y | N | X |  |
| 8.2 | Do you provide resources needed to evaluate process? | | Y | N | X |  |
| 8.2.1 | | Do you provide the people that you need to evaluate your process? | Y | N | X |  |
| 8.2.2 | | Do you provide the knowledge that you need to evaluate your process? | Y | N | X |  |
| 8.2.3 | | Do you provide the technology that you need to evaluate your process? | Y | N | X |  |
| 8.2.4 | | Do you provide the infrastructure that you need to evaluate your process? | Y | N | X |  |
| 8.3 | Do you use authorized methods to evaluate process? | | Y | N | X |  |
| 8.3.1 | | Do you use authorized methods to audit your process? | Y | N | X |  |
| 8.3.2 | | Do you use authorized methods to analyze your process? | Y | N | X |  |
| 8.3.3 | | Do you use authorized methods to review your process? | Y | N | X |  |
| 8.4 | Do you record the results of process evaluations? | | Y | N | X |  |
| 9. ASSESS Process Modification ACTIVITIES | | | | | | |
| 9.1 | Do you establish process modification methods? | | Y | N | X |  |
| 9.1.1 | | Do you establish methods for correcting process and outputs? | Y | N | X |  |
| 9.1.2 | | Do you establish methods for improving process and outputs? | Y | N | X |  |
| 9.2 | Do you identify opportunities to modify your process? | | Y | N | X |  |
| 9.2.1 | | Do you discover opportunities to modify process and outputs? | Y | N | X |  |
| 9.2.2 | | Do you define opportunities to modify your process and outputs? | Y | N | X |  |
| 9.2.3 | | Do you confirm that process and output modifications are needed? | Y | N | X |  |
| 9.2.4 | | Do you approve opportunities to modify your process and outputs? | Y | N | X |  |
| 9.3 | Do you plan how you're going to modify your process? | | Y | N | X |  |
| 9.3.1 | | Do you plan how you're going to correct process and its outputs? | Y | N | X |  |
| 9.3.2 | | Do you plan how you're going to improve process and its outputs? | Y | N | X |  |
| 9.4 | Do you use authorized methods to modify your process? | | Y | N | X |  |
| 9.4.1 | | Do you use authorized methods to correct process and outputs? | Y | N | X |  |
| 9.4.2 | | Do you use authorized methods to improve process and outputs? | Y | N | X |  |
| 9.5 | Do you review and evaluate process modifications? | | Y | N | X |  |
| 9.5.1 | | Do you review and evaluate process and output corrections? | Y | N | X |  |
| 9.5.2 | | Do you review and evaluate process and output improvements? | Y | N | X |  |

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| Answer each of the above questions. Three answers are possible: Y (yes), N (no), and X (eXclude). Y means you're in compliance,  N means you're not in compliance, while X means that this question can be excluded because it’s not applicable in your situation.  Y answers and X answers require no further action, while N answers point to things that need to be done to improve the  overall performance of your process. Also, please use the column on the right to record your notes, and in the spaces  below, enter the name and location of your organization, who completed this page, who reviewed it, and the dates. |

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| 1.1 STUDY THE CONTEXT OF YOUR PROCESS | | | | | | | | | | | | | |
| 1.1.1 CONSIDER PROCESS PARTICIPANTS | | | | | | | | | | | | | |
|  | Have you identified the parties that have an interest in your process? | | | | | | | | | Y | N | X |  |
|  |  | Have you identified the internal parties that have an interest in your process? | | | | | | | | Y | N | X |  |
|  |  | | Have you identified the internal parties that could influence your process? | | | | | | | Y | N | X |  |
|  |  | | | Do you clarify the needs and expectations of interested internal parties? | | | | | | Y | N | X |  |
|  |  | | | Do you clarify the issues and concerns that interested internal parties have? | | | | | | Y | N | X |  |
|  |  | Have you identified the external parties that have an interest in your process? | | | | | | | | Y | N | X |  |
|  |  | | Have you identified the external parties that could influence your process? | | | | | | | Y | N | X |  |
|  |  | | | Do you clarify the needs and expectations of interested external parties? | | | | | | Y | N | X |  |
|  |  | | | Do you clarify the issues and concerns that interested external parties have? | | | | | | Y | N | X |  |
| 1.1.2 consider process environment | | | | | | | | | | | | | |
|  | Do you consider your internal process environment? | | | | | | | | | Y | N | X |  |
|  |  | Do you consider the impact it could have on process performance? | | | | | | | | Y | N | X |  |
|  |  | | Do you consider the impact your organization's culture could have? | | | | | | | Y | N | X |  |
|  |  | | Do you consider the impact your organization's expertise could have? | | | | | | | Y | N | X |  |
|  |  | | Do you consider the impact your organization's technology could have? | | | | | | | Y | N | X |  |
|  |  | | Do you consider the impact your organization's infrastructure could have? | | | | | | | Y | N | X |  |
|  | Do you consider your external process environment? | | | | | | | | | Y | N | X |  |
|  |  | Do you consider the impact it could have on process performance? | | | | | | | | Y | N | X |  |
|  |  | | Do you consider the impact your legal environment could have? | | | | | | | Y | N | X |  |
|  |  | | | Have you identified statutory process output requirements? | | | | | | Y | N | X |  |
|  |  | | | Have you identified regulatory process output requirements? | | | | | | Y | N | X |  |
|  |  | | Do you consider the impact your social environment could have? | | | | | | | Y | N | X |  |
|  |  | | Do you consider the impact your market environment could have? | | | | | | | Y | N | X |  |
|  |  | | | Have you identified your customers' process output requirements? | | | | | | Y | N | X |  |
|  |  | | Do you consider the impact your economic environment could have? | | | | | | | Y | N | X |  |
|  |  | | Do you consider the impact your competitive environment could have? | | | | | | | Y | N | X |  |
|  |  | | Do you consider the impact your technological environment could have? | | | | | | | Y | N | X |  |
| 1.1.3 CONSIDER PROCESS RISKS AND THREATS | | | | | | | | | | | | | |
|  | Do you consider how your context could weaken process performance? | | | | | | | | | Y | N | X |  |
|  |  | Do you consider how interested parties could threaten  process performance or disrupt process operations? | | | | | | | | Y | N | X |  |
|  |  | | Do you consider how interested parties could weaken your  ability to provide outputs that meet customer requirements? | | | | | | | Y | N | X |  |
|  |  | | Do you consider how interested parties could weaken your  ability to provide outputs that meet legal requirements? | | | | | | | Y | N | X |  |
|  |  | Do you consider how problems could threaten process performance or disrupt operations? | | | | | | | | Y | N | X |  |
|  |  | | Do you consider how internal problems could affect your ability to achieve process objectives? | | | | | | | Y | N | X |  |
|  |  | | | Do you consider how your values could weaken your ability to achieve objectives? | | | | | | Y | N | X |  |
|  |  | | | Do you consider how your culture could weaken your ability to achieve objectives? | | | | | | Y | N | X |  |
|  |  | | | Do you consider how your knowledge could weaken your ability to achieve objectives? | | | | | | Y | N | X |  |
|  |  | | | Do you consider how your infrastructure could weaken your ability to achieve objectives? | | | | | | Y | N | X |  |
|  |  | | | Do you consider how your performance could weaken your ability to achieve objectives? | | | | | | Y | N | X |  |
|  |  | | Do you consider how external problems could affect your ability to achieve process objectives? | | | | | | | Y | N | X |  |
|  |  | | | Do you consider how legal problems could weaken your ability to achieve objectives? | | | | | | Y | N | X |  |
|  |  | | | Do you consider how social problems could weaken your ability to achieve objectives? | | | | | | Y | N | X |  |
|  |  | | | Do you consider how cultural problems could weaken your ability to achieve objectives? | | | | | | Y | N | X |  |
|  |  | | | Do you consider how market problems could weaken your ability to achieve objectives? | | | | | | Y | N | X |  |
|  |  | | | Do you consider how economic problems could weaken your ability to achieve objectives? | | | | | | Y | N | X |  |
|  |  | | | Do you consider how competitive problems could weaken your ability to achieve objectives? | | | | | | Y | N | X |  |
|  |  | | | Do you consider how technological problems could weaken your ability to achieve objectives? | | | | | | Y | N | X |  |
|  | Do you consider how to address the risks that could weaken process performance? | | | | | | | | | Y | N | X |  |
|  |  | Do you figure out what needs to be done to ensure that process achieves process objectives? | | | | | | | | Y | N | X |  |
|  |  | | Do you figure out how to prevent or reduce undesired affects that process could cause? | | | | | | | Y | N | X |  |
| 1.1.4 CONSIDER PROCESS OPPORTUNITIES | | | | | | | | | | | | | |
|  | Do you consider opportunities to enhance process operations? | | | | | | | | | Y | N | X |  |
|  |  | Do you consider how your organization's context could  reveal opportunities to enhance process operations? | | | | | | | | Y | N | X |  |
|  |  | | Do you consider how interested parties could represent  opportunities to enhance process performance? | | | | | | | Y | N | X |  |
|  |  | | | Do you consider how interested parties could represent opportunities to enhance  your ability to provide outputs that meet customer requirements? | | | | | | Y | N | X |  |
|  |  | | | Do you consider how interested parties could represent opportunities  to enhance your ability to provide outputs that meet legal requirements? | | | | | | Y | N | X |  |
|  |  | | Do you consider how potential challenges could represent  opportunities to enhance process performance? | | | | | | | Y | N | X |  |
|  |  | | | Do you consider how internal challenges could create opportunities  to improve your ability to achieve process objectives? | | | | | | Y | N | X |  |
|  |  | | | | Do you consider how your values could generate opportunities  to enhance your ability to achieve process objectives? | | | | | Y | N | X |  |
|  |  | | | | Do you consider how your culture could generate opportunities  to enhance your ability to achieve process objectives? | | | | | Y | N | X |  |
|  |  | | | | Do you consider how your knowledge could generate opportunities  to enhance your ability to achieve process objectives? | | | | | Y | N | X |  |
|  |  | | | | Do you consider how your infrastructure could generate opportunities  to enhance your ability to achieve process objectives? | | | | | Y | N | X |  |
|  |  | | | | Do you consider how your performance could generate opportunities  to enhance your ability to achieve process objectives? | | | | | Y | N | X |  |
|  |  | | | Do you consider how external challenges could create opportunities  to improve your ability to achieve process objectives? | | | | | | Y | N | X |  |
|  |  | | | | Do you consider how your legal environment could create opportunities  to enhance your ability to achieve process objectives? | | | | | Y | N | X |  |
|  |  | | | | Do you consider how your social environment could create opportunities  to enhance your ability to achieve process objectives? | | | | | Y | N | X |  |
|  |  | | | | Do you consider how your cultural environment could create opportunities  to enhance your ability to achieve process objectives? | | | | | Y | N | X |  |
|  |  | | | | Do you consider how your market environment could create opportunities  to enhance your ability to achieve process objectives? | | | | | Y | N | X |  |
|  |  | | | | Do you consider how your economic environment could create opportunities  to enhance your ability to achieve process objectives? | | | | | Y | N | X |  |
|  |  | | | | Do you consider how your competitive environment could create opportunities  to enhance your ability to achieve process objectives? | | | | | Y | N | X |  |
|  |  | | | | Do you consider how your technological environment could create opportunities  to enhance your ability to achieve process objectives? | | | | | Y | N | X |  |
|  | Do you figure out what you could do to exploit process opportunities? | | | | | | | | | Y | N | X |  |
|  |  | Do you figure out what you could do to improve process performance? | | | | | | | | Y | N | X |  |
| 1.2 CLARIFY THE PURPOSE OF YOUR PROCESS | | | | | | | | | | | | | |
| 1.2.1 DEFINE PROCESS SCOPE AND BOUNDARIES | | | | | | | | | | | | | |
|  | Do you clarify the scope and boundaries of your process? | | | | | | | | | Y | N | X |  |
|  |  | Do you consider how your context could influence your process? | | | | | | | | Y | N | X |  |
|  |  | | Do you consider how internal issues could influence your process? | | | | | | | Y | N | X |  |
|  |  | | | Do you consider the impact your organization's values could have? | | | | | | Y | N | X |  |
|  |  | | | Do you consider the impact your organization's culture could have? | | | | | | Y | N | X |  |
|  |  | | | Do you consider the impact your organization's services could have? | | | | | | Y | N | X |  |
|  |  | | | Do you consider the impact your organization's products could have? | | | | | | Y | N | X |  |
|  |  | | | Do you consider the impact your organization's knowledge could have? | | | | | | Y | N | X |  |
|  |  | | | Do you consider the impact your organization's infrastructure could have? | | | | | | Y | N | X |  |
|  |  | | | Do you consider the impact your organization's performance could have? | | | | | | Y | N | X |  |
|  |  | | Do you consider how external issues could influence your process? | | | | | | | Y | N | X |  |
|  |  | | | Do you consider the impact legal issues and factors could have? | | | | | | Y | N | X |  |
|  |  | | | Do you consider the impact social issues and factors could have? | | | | | | Y | N | X |  |
|  |  | | | Do you consider the impact cultural issues and factors could have? | | | | | | Y | N | X |  |
|  |  | | | Do you consider the impact market issues and factors could have? | | | | | | Y | N | X |  |
|  |  | | | Do you consider the impact economic issues and factors could have? | | | | | | Y | N | X |  |
|  |  | | | Do you consider the impact competitive issues and factors could have? | | | | | | Y | N | X |  |
|  |  | | | Do you consider the impact technological issues and factors could have? | | | | | | Y | N | X |  |
|  | Have you documented the scope and boundaries of your process? | | | | | | | | | Y | N | X |  |
|  |  | Do you retain the documents that describe the scope and boundaries of your process? | | | | | | | | Y | N | X |  |
|  |  | Do you control the documents that describe the scope and boundaries of your process? | | | | | | | | Y | N | X |  |
| 1.2.2 establish your process objectives | | | | | | | | | | | | | |
|  | Do you establish business objectives for your process? | | | | | | | | | Y | N | X |  |
|  | Do you establish technical objectives for your process? | | | | | | | | | Y | N | X |  |
|  | Do you establish safety objectives for your process? | | | | | | | | | Y | N | X |  |
|  | Do you establish quality objectives for your process? | | | | | | | | | Y | N | X |  |
|  | Do you establish security objectives for your process? | | | | | | | | | Y | N | X |  |
|  | Do you establish continuity objectives for your process? | | | | | | | | | Y | N | X |  |
|  | Do you establish environmental objectives for your process? | | | | | | | | | Y | N | X |  |
| 1.3 CONSIDER YOUR PROCESS REQUIREMENTS | | | | | | | | | | | | | |
| 1.3.1 CLARIFY PROCESS OUTPUT REQUIREMENTS | | | | | | | | | | | | | |
|  | Do you consider output quality requirements? | | | | | | | | | Y | N | X |  |
|  |  | Do you consider output reliability requirements? | | | | | | | | Y | N | X |  |
|  |  | Do you consider output consistency requirements? | | | | | | | | Y | N | X |  |
|  |  | Do you consider output availability requirements? | | | | | | | | Y | N | X |  |
|  |  | Do you consider output suitability requirements? | | | | | | | | Y | N | X |  |
|  |  | | Do you consider suitability requirements for parts and materials to be used in outputs? | | | | | | | Y | N | X |  |
|  |  | | Do you consider suitability requirements for software to be embedded in outputs? | | | | | | | Y | N | X |  |
|  |  | | | Do you consider suitability requirements for software that you plan to purchase? | | | | | | Y | N | X |  |
|  |  | | | Do you consider suitability requirements for software that you plan to develop? | | | | | | Y | N | X |  |
|  |  | Do you consider output purity requirements? | | | | | | | | Y | N | X |  |
|  |  | | Do you consider the need to control foreign objects? | | | | | | | Y | N | X |  |
|  |  | | Do you consider the need to detect foreign objects? | | | | | | | Y | N | X |  |
|  |  | | Do you consider the need to remove foreign objects? | | | | | | | Y | N | X |  |
|  |  | | Do you consider the need to prevent foreign objects? | | | | | | | Y | N | X |  |
|  |  | Do you consider output verification requirements? | | | | | | | | Y | N | X |  |
|  |  | | Do you consider how to verify that output requirements are being met? | | | | | | | Y | N | X |  |
|  |  | | | Do you consider how verifications will be done at all appropriate stages? | | | | | | Y | N | X |  |
|  |  | Do you consider output validation requirements? | | | | | | | | Y | N | X |  |
|  |  | | Do you consider how to confirm that intended use requirements are being met? | | | | | | | Y | N | X |  |
|  |  | | | Do you consider how validations will be done at all appropriate stages? | | | | | | Y | N | X |  |
|  |  | Do you consider output control requirements? | | | | | | | | Y | N | X |  |
|  |  | | Do you consider how nonconforming outputs will be controlled? | | | | | | | Y | N | X |  |
|  | Do you consider output safety requirements? | | | | | | | | | Y | N | X |  |
|  |  | Do you consider personal safety requirements? | | | | | | | | Y | N | X |  |
|  | Do you consider output security requirements? | | | | | | | | | Y | N | X |  |
|  |  | Do you consider personnel security requirements? | | | | | | | | Y | N | X |  |
|  |  | Do you consider information security requirements? | | | | | | | | Y | N | X |  |
|  | Do you consider output production requirements? | | | | | | | | | Y | N | X |  |
|  |  | Do you consider output producibility requirements? | | | | | | | | Y | N | X |  |
|  |  | Do you consider output inspectability requirements? | | | | | | | | Y | N | X |  |
|  | Do you consider output maintenance requirements? | | | | | | | | | Y | N | X |  |
|  |  | Do you consider output maintainability requirements? | | | | | | | | Y | N | X |  |
|  | Do you consider output handling requirements? | | | | | | | | | Y | N | X |  |
|  | Do you consider output packaging requirements? | | | | | | | | | Y | N | X |  |
|  | Do you consider output preservation requirements? | | | | | | | | | Y | N | X |  |
|  | Do you consider output obsolescence requirements? | | | | | | | | | Y | N | X |  |
|  |  | Do you consider output recycling requirements? | | | | | | | | Y | N | X |  |
|  |  | Do you consider output disposal requirements? | | | | | | | | Y | N | X |  |
|  |  | | Do you consider final disposal requirements? | | | | | | | Y | N | X |  |
| 1.3.2 clarify process knowledge requirements | | | | | | | | | | | | | |
|  | Do you determine the knowledge that process personnel need to have? | | | | | | | | | Y | N | X |  |
|  |  | Do you determine the knowledge that process personnel need in order  to support process operations and achieve conformity of outputs? | | | | | | | | Y | N | X |  |
|  |  | | Do you consider internal sources of process knowledge? | | | | | | | Y | N | X |  |
|  |  | | | Do you consider the need to learn from failures and successes? | | | | | | Y | N | X |  |
|  |  | | | Do you consider the need to gather knowledge about processes? | | | | | | Y | N | X |  |
|  |  | | | | Do you consider the need to gather knowledge about process outputs? | | | | | Y | N | X |  |
|  |  | | | Do you consider the need to capture undocumented knowledge? | | | | | | Y | N | X |  |
|  |  | | | | Do you consider the need to capture the knowledge, expertise,  and experience that your own people have accumulated? | | | | | Y | N | X |  |
|  |  | | Do you consider external sources of process knowledge? | | | | | | | Y | N | X |  |
|  |  | | | Do you consider the knowledge that suppliers can provide? | | | | | | Y | N | X |  |
|  |  | | | Do you consider the knowledge that customers can share with you? | | | | | | Y | N | X |  |
|  |  | | | Do you consider the knowledge that can be gathered at conferences? | | | | | | Y | N | X |  |
|  |  | | | Do you consider the knowledge that can be acquired from academia? | | | | | | Y | N | X |  |
| 1.3.3 clarify process competence requirements | | | | | | | | | | | | | |
|  | Have you identified the people under your control who have an  impact on the performance and effectiveness of your process? | | | | | | | | | Y | N | X |  |
|  |  | Do you establish competence requirements for your process? | | | | | | | | Y | N | X |  |
|  |  | | Do you make sure that process personnel have the appropriate training? | | | | | | | Y | N | X |  |
|  |  | | Do you make sure that process personnel have the appropriate education? | | | | | | | Y | N | X |  |
|  |  | | Do you make sure that process personnel have the appropriate experience? | | | | | | | Y | N | X |  |
|  |  | | Do you make sure that process personnel have the appropriate knowledge? | | | | | | | Y | N | X |  |
|  |  | Do you implement competence requirements for your process? | | | | | | | | Y | N | X |  |
|  |  | | Do you define the knowledge and skill required to implement this process? | | | | | | | Y | N | X |  |
|  |  | | Do you define the knowledge and skill required to operate this process? | | | | | | | Y | N | X |  |
|  |  | | Do you define the knowledge and skill required to maintain this process? | | | | | | | Y | N | X |  |
|  |  | | Do you define the knowledge and skill required to monitor this process? | | | | | | | Y | N | X |  |
|  |  | | Do you define the knowledge and skill required to measure this process? | | | | | | | Y | N | X |  |
|  |  | | Do you define the knowledge and skill required to control this process? | | | | | | | Y | N | X |  |
|  |  | | Do you define the knowledge and skill required to evaluate this process? | | | | | | | Y | N | X |  |
|  |  | | | Do you define the knowledge and skill required to audit this process? | | | | | | Y | N | X |  |
|  |  | | | Do you define the knowledge and skill required to review this process? | | | | | | Y | N | X |  |
|  |  | | Do you define the knowledge and skill required to modify this process? | | | | | | | Y | N | X |  |
|  |  | | | Do you define the knowledge and skill required to correct this process? | | | | | | Y | N | X |  |
|  |  | | | Do you define the knowledge and skill required to improve this process? | | | | | | Y | N | X |  |
| 1.3.4 clarify process MANAGEMENT requirements | | | | | | | | | | | | | |
|  | Do you specify risk management requirements for your process? | | | | | | | | | Y | N | X |  |
|  | Do you specify legal management requirements for your process? | | | | | | | | | Y | N | X |  |
|  |  | Do you specify legal management requirements for process outputs? | | | | | | | | Y | N | X |  |
|  |  | | Do you specify statutory management requirements for process outputs? | | | | | | | Y | N | X |  |
|  |  | | Do you specify regulatory management requirements for process outputs? | | | | | | | Y | N | X |  |
|  | Do you specify business management requirements for your process? | | | | | | | | | Y | N | X |  |
|  | Do you specify technical management requirements for your process? | | | | | | | | | Y | N | X |  |
|  | Do you specify quality management requirements for your process? | | | | | | | | | Y | N | X |  |
|  |  | Do you derive quality requirements from your quality policy? | | | | | | | | Y | N | X |  |
|  |  | Do you derive quality requirements from customer expectations? | | | | | | | | Y | N | X |  |
|  | Do you specify safety management requirements for your process? | | | | | | | | | Y | N | X |  |
|  |  | Do you specify safety management requirements for process personnel? | | | | | | | | Y | N | X |  |
|  | Do you specify security management requirements for your process? | | | | | | | | | Y | N | X |  |
|  |  | Do you specify personnel security management requirements? | | | | | | | | Y | N | X |  |
|  |  | Do you specify information security management requirements? | | | | | | | | Y | N | X |  |
|  |  | Do you specify component security management requirements? | | | | | | | | Y | N | X |  |
|  |  | | Do you specify counterfeit parts management requirements? | | | | | | | Y | N | X |  |
|  | Do you specify supplier management requirements for your process? | | | | | | | | | Y | N | X |  |
|  | Do you specify configuration management requirements for your process? | | | | | | | | | Y | N | X |  |
|  | Do you specify environmental management requirements for your process? | | | | | | | | | Y | N | X |  |
|  | Do you specify business continuity management requirements for your process? | | | | | | | | | Y | N | X |  |
| 1.3.5 clarify process communication requirements | | | | | | | | | | | | | |
|  | Do you figure out how internal process communications will be handled? | | | | | | | | | Y | N | X |  |
|  |  | Do you figure out what internal process communications need to say? | | | | | | | | Y | N | X |  |
|  |  | Do you figure out when internal process communications should be done? | | | | | | | | Y | N | X |  |
|  |  | Do you figure out who should carry out internal process communications? | | | | | | | | Y | N | X |  |
|  |  | | Do you figure out who should receive internal process communications? | | | | | | | Y | N | X |  |
|  | Do you figure out how external process communications will be handled? | | | | | | | | | Y | N | X |  |
|  |  | Do you figure out what external process communications need to say? | | | | | | | | Y | N | X |  |
|  |  | Do you figure out when external process communications should be done? | | | | | | | | Y | N | X |  |
|  |  | Do you figure out who should carry out external process communications? | | | | | | | | Y | N | X |  |
| 1.3.6 clarify process INFRASTRUCTURE requirements | | | | | | | | | | | | | |
|  | Have you identified the infrastructure that your process needs in  order to support operations and achieve conformity of outputs? | | | | | | | | | Y | N | X |  |
|  |  | Do you consider the buildings that your process needs? | | | | | | | | Y | N | X |  |
|  |  | Do you consider the utilities that your process needs? | | | | | | | | Y | N | X |  |
|  |  | Do you consider the equipment that your process needs? | | | | | | | | Y | N | X |  |
|  |  | | Do you consider the hardware that your process needs? | | | | | | | Y | N | X |  |
|  |  | | Do you consider the software that your process needs? | | | | | | | Y | N | X |  |
|  |  | Do you consider the technology that your process need? | | | | | | | | Y | N | X |  |
|  |  | | Do you consider your information technology needs? | | | | | | | Y | N | X |  |
|  |  | | Do you consider your communication technology needs? | | | | | | | Y | N | X |  |
|  |  | | Do you consider your transportation technology needs? | | | | | | | Y | N | X |  |
| 1.3.7 clarify process ENVIRONMENT requirements | | | | | | | | | | | | | |
|  | Have you identified the environment that your process  needs in order to achieve conformity of outputs? | | | | | | | | | Y | N | X |  |
|  |  | Do you consider the social factors that could affect your process? | | | | | | | | Y | N | X |  |
|  |  | Do you consider the cultural factors that could affect your process? | | | | | | | | Y | N | X |  |
|  |  | Do you consider the psychological factors that could affect your process? | | | | | | | | Y | N | X |  |
|  |  | Do you consider the ergonomic factors that could affect your process? | | | | | | | | Y | N | X |  |
|  |  | Do you consider the climatic factors that could affect your process? | | | | | | | | Y | N | X |  |
|  |  | | Do you consider whether humidity could affect process? | | | | | | | Y | N | X |  |
|  |  | | Do you consider whether temperature could affect process? | | | | | | | Y | N | X |  |
|  |  | | Do you consider whether pollution could affect your process? | | | | | | | Y | N | X |  |
|  |  | Do you consider the physical factors that could affect your process? | | | | | | | | Y | N | X |  |
|  |  | | Do you consider the sanitation factors that could affect your process? | | | | | | | Y | N | X |  |
|  |  | | | Do you consider whether cleanliness is an important factor? | | | | | | Y | N | X |  |
| 1.3.8 clarify process RESOURCE requirements | | | | | | | | | | | | | |
|  | Do you consider internal capabilities and external sources? | | | | | | | | | Y | N | X |  |
|  |  | Do you consider your organization's internal capabilities and constraints? | | | | | | | | Y | N | X |  |
|  |  | Do you consider what needs to be obtained from external resource providers? | | | | | | | | Y | N | X |  |
|  | Do you determine the resources that your process needs? | | | | | | | | | Y | N | X |  |
|  |  | Have you identified the resources needed to implement your process? | | | | | | | | Y | N | X |  |
|  |  | Have you identified the resources needed to operate your process? | | | | | | | | Y | N | X |  |
|  |  | Have you identified the resources needed to monitor your process? | | | | | | | | Y | N | X |  |
|  |  | Have you identified the resources needed to measure your process? | | | | | | | | Y | N | X |  |
|  |  | Have you identified the resources needed to control your process? | | | | | | | | Y | N | X |  |
|  |  | Have you identified the resources needed to maintain your process? | | | | | | | | Y | N | X |  |
|  |  | Have you identified the resources needed to evaluate your process? | | | | | | | | Y | N | X |  |
|  |  | | Have you identified the resources needed to audit your process? | | | | | | | Y | N | X |  |
|  |  | | Have you identified the resources needed to review your process? | | | | | | | Y | N | X |  |
|  |  | Have you identified the resources needed to modify your process? | | | | | | | | Y | N | X |  |
|  |  | | Have you identified the resources needed to correct your process? | | | | | | | Y | N | X |  |
|  |  | | Have you identified the resources needed to improve your process? | | | | | | | Y | N | X |  |
| 1.4 PLAN PROCESS DESIGN AND DEVELOPMENT | | | | | | | | | | | | | |
| 1.4.1 CARRY OUT OUTPUT PLANNING | | | | | | | | | | | | | |
|  | Do you determine criteria for your outputs? | | | | | | | | | Y | N | X |  |
|  |  | Do you establish acceptance criteria for outputs? | | | | | | | | Y | N | X |  |
|  |  | | Do you use statistical techniques to support outputs? | | | | | | | Y | N | X |  |
|  |  | | | Do you use statistical techniques to verify output designs? | | | | | | Y | N | X |  |
|  |  | | | | Do you use statistical techniques to verify output safety? | | | | | Y | N | X |  |
|  |  | | | | Do you use statistical techniques to verify output quality? | | | | | Y | N | X |  |
|  | Do you determine the outputs that are needed? | | | | | | | | | Y | N | X |  |
|  |  | Do you plan output design and development activities? | | | | | | | | Y | N | X |  |
|  |  | | Do you consider your output needs and complexities? | | | | | | | Y | N | X |  |
|  |  | | | Do you consider your ability to meet output requirements? | | | | | | Y | N | X |  |
|  |  | | | | Do you consider how you're going to meet output safety requirements? | | | | | Y | N | X |  |
|  |  | | | | Do you consider how you're going to meet output quality requirements? | | | | | Y | N | X |  |
|  |  | | | | Do you consider how you're going to meet output control requirements? | | | | | Y | N | X |  |
|  |  | | | | Do you consider how you're going to meet output testing requirements? | | | | | Y | N | X |  |
|  |  | | | | Do you consider how you're going to meet output suitability requirements? | | | | | Y | N | X |  |
|  |  | | | | Do you consider how you're going to meet output availability requirements? | | | | | Y | N | X |  |
|  |  | | | | Do you consider how you're going to meet output reliability requirements? | | | | | Y | N | X |  |
|  |  | | | | Do you consider how you're going to meet output monitoring requirements? | | | | | Y | N | X |  |
|  |  | | | | Do you consider how you're going to meet output measurement requirements? | | | | | Y | N | X |  |
|  |  | | | | Do you consider how you're going to meet output production requirements? | | | | | Y | N | X |  |
|  |  | | | | Do you consider how you're going to meet output preservation requirements? | | | | | Y | N | X |  |
|  |  | | | | Do you consider how you're going to meet output maintenance requirements? | | | | | Y | N | X |  |
|  |  | | | | Do you consider how you're going to meet output obsolescence requirements? | | | | | Y | N | X |  |
|  |  | | | | Do you consider how you're going to meet output delivery requirements? | | | | | Y | N | X |  |
|  |  | | Do you consider output design and development complexities? | | | | | | | Y | N | X |  |
|  |  | | | Do you consider your output design and development activities? | | | | | | Y | N | X |  |
|  |  | | | | Do you consider dividing output design and development into distinct activities? | | | | | Y | N | X |  |
|  |  | | | | | Do you define content for each set of output design and development activities? | | | | Y | N | X |  |
|  |  | | | | | Do you define tasks for each set of output design and development activities? | | | | Y | N | X |  |
|  |  | | | | | Do you define inputs for each set of output design and development activities? | | | | Y | N | X |  |
|  |  | | | | | Do you define outputs for each set of output design and development activities? | | | | Y | N | X |  |
|  |  | | | | | Do you define resources for each set of output design and development activities? | | | | Y | N | X |  |
|  |  | | | | | Do you define responsibilities for each set of output design and development activities? | | | | Y | N | X |  |
|  |  | | | Do you consider output design and development requirements? | | | | | | Y | N | X |  |
|  |  | | | | Do you consider your output evaluation requirements? | | | | | Y | N | X |  |
|  |  | | | | | Do you consider output review requirements? | | | | Y | N | X |  |
|  |  | | | | | Do you consider output verification requirements? | | | | Y | N | X |  |
|  |  | | | | | Do you consider output validation requirements? | | | | Y | N | X |  |
|  |  | | | | Do you consider design and development output requirements? | | | | | Y | N | X |  |
|  |  | | | Do you consider output design and development expectations? | | | | | | Y | N | X |  |
|  |  | | | | Do you consider output control expectations? | | | | | Y | N | X |  |
|  |  | | | | | Do you consider the level of control expected by your customers? | | | | Y | N | X |  |
|  |  | | | | | Do you consider the level of control expected by interested parties? | | | | Y | N | X |  |
|  |  | | | Do you consider output design and development relationships? | | | | | | Y | N | X |  |
|  |  | | | | Do you consider the need to control interactions between people? | | | | | Y | N | X |  |
|  |  | | | | Do you consider the need to control interactions between groups? | | | | | Y | N | X |  |
|  |  | | | Do you consider output design and development responsibilities? | | | | | | Y | N | X |  |
|  |  | | | | Do you consider design and development authorities? | | | | | Y | N | X |  |
|  |  | | | Do you consider output design and development documentation? | | | | | | Y | N | X |  |
|  |  | | | | Do you consider the need to control and maintain documentation? | | | | | Y | N | X |  |
|  |  | | | | | Do you consider the need to confirm that requirements are being met? | | | | Y | N | X |  |
|  |  | | | Do you consider output design and development resources? | | | | | | Y | N | X |  |
|  |  | | | | Do you consider internal design and development resource needs? | | | | | Y | N | X |  |
|  |  | | | | Do you consider external design and development resource needs? | | | | | Y | N | X |  |
|  |  | | Do you consider output verification and validation activities? | | | | | | | Y | N | X |  |
|  |  | | | Do you plan your design verification and validation testing activities? | | | | | | Y | N | X |  |
|  |  | | | | Do you make sure that test plans and specifications specify test items? | | | | | Y | N | X |  |
|  |  | | | | Do you make sure that test plans and specifications specify test requirements? | | | | | Y | N | X |  |
|  |  | | | | | Do you make sure that plans and specifications specify testing objectives? | | | | Y | N | X |  |
|  |  | | | | | Do you make sure that plans and specifications specify testing conditions? | | | | Y | N | X |  |
|  |  | | | | | Do you make sure that plans and specifications specify testing parameters? | | | | Y | N | X |  |
|  |  | | | | | Do you make sure that plans and specifications specify testing resources? | | | | Y | N | X |  |
|  |  | | | | Do you make sure that plans and specifications specify acceptance criteria? | | | | | Y | N | X |  |
|  |  | | | Do you control your design verification and validation testing activities? | | | | | | Y | N | X |  |
|  |  | | | | Do you make sure that test procedures describe how testing is performed? | | | | | Y | N | X |  |
|  |  | | | | | Do you make sure that test procedures describe testing methods and techniques? | | | | Y | N | X |  |
|  |  | | | | Do you make sure that test procedures describe how testing results are recorded? | | | | | Y | N | X |  |
|  |  | | | Do you review your design verification and validation testing activities? | | | | | | Y | N | X |  |
|  |  | | | | Do you make sure that the correct items were used for testing? | | | | | Y | N | X |  |
|  |  | | | | | Do you make sure that the right configuration was submitted? | | | | Y | N | X |  |
|  |  | | | | Do you make sure that your testing procedures were followed? | | | | | Y | N | X |  |
|  |  | | | | Do you make sure that all testing objectives were achieved? | | | | | Y | N | X |  |
|  |  | | | | Do you make sure that test plan requirements were met? | | | | | Y | N | X |  |
|  |  | | | | Do you make sure that acceptance criteria were met? | | | | | Y | N | X |  |
|  |  | | | Do you document your design verification and validation testing activities? | | | | | | Y | N | X |  |
|  |  | | | | Do you make sure that records show that test items were identified? | | | | | Y | N | X |  |
|  |  | | | | Do you make sure that records show that test requirements were met? | | | | | Y | N | X |  |
|  |  | | | | | Do you make sure that records show that testing objectives were set? | | | | Y | N | X |  |
|  |  | | | | | Do you make sure that records show that testing resources were allocated? | | | | Y | N | X |  |
|  |  | | | | | Do you make sure that records show that testing conditions were specified? | | | | Y | N | X |  |
|  |  | | | | | Do you make sure that records show that testing procedures were followed? | | | | Y | N | X |  |
|  |  | | | | | Do you make sure that records show that testing parameters were recorded? | | | | Y | N | X |  |
|  |  | | | | | Do you make sure that records show that testing reviews were carried out? | | | | Y | N | X |  |
|  |  | | | | | Do you make sure that records show that acceptance criteria were used? | | | | Y | N | X |  |
|  |  | | | | Do you make sure that records show that operational conditions were examined? | | | | | Y | N | X |  |
|  |  | | | | | Do you make sure that reports show that the design for output meets specification requirements for all identified operational conditions? | | | | Y | N | X |  |
|  |  | | | | | Do you make sure that calculations show that the design for output meets specification requirements for all identified operational conditions? | | | | Y | N | X |  |
|  |  | | | | | Do you make sure that test results show that the design for output meets specification requirements for all identified operational conditions? | | | | Y | N | X |  |
|  | Do you determine how outputs will be controlled? | | | | | | | | | Y | N | X |  |
|  |  | Do you define your configuration management requirements? | | | | | | | | Y | N | X |  |
|  |  | | Do you make sure that your configuration management methods can be used to identify  and control physical and functional attributes throughout the lifecycle of your outputs? | | | | | | | Y | N | X |  |
|  |  | | | Do you make sure that your configuration management methods are  appropriate for your organization and the outputs it produces? | | | | | | Y | N | X |  |
|  |  | Do you define how you intend to control nonconforming outputs? | | | | | | | | Y | N | X |  |
|  |  | | Do you document your output nonconformity control methods? | | | | | | | Y | N | X |  |
|  |  | | | Do you define responsibility and authority for handling nonconforming outputs? | | | | | | Y | N | X |  |
|  |  | | | | Do you define responsibility and authority for review of nonconforming outputs? | | | | | Y | N | X |  |
|  |  | | | | | Do you define the process that will be used to approve personnel  who will make all output nonconformity review decisions? | | | | Y | N | X |  |
|  |  | | | | Do you define responsibility and authority for disposition of nonconforming outputs? | | | | | Y | N | X |  |
|  |  | | | | | Do you define the process that will be used to approve personnel  who will make output nonconformity disposition decisions? | | | | Y | N | X |  |
|  |  | | | Do you define how you plan to manage and control your nonconforming outputs? | | | | | | Y | N | X |  |
|  |  | | | | Do you define how you're going to contain the impact of nonconformities? | | | | | Y | N | X |  |
|  |  | | | | | Do you define how you intend to contain the effect on other processes? | | | | Y | N | X |  |
|  |  | | | | | Do you define how you intend to contain the effect on other outputs? | | | | Y | N | X |  |
|  |  | | | | | Do you define how you intend to contain the effect on other parties? | | | | Y | N | X |  |
|  |  | | | | | | Do you define how you intend to contain the effect on customers? | | | Y | N | X |  |
|  |  | | | | Do you define how you intend to report your nonconforming outputs? | | | | | Y | N | X |  |
|  |  | | | | | Do you define how nonconformities affecting products and services are reported? | | | | Y | N | X |  |
|  |  | | | | | | Do you define how you intend to notify interested parties about nonconformities? | | | Y | N | X |  |
|  |  | | | | | | | Do you define how internal parties will be notified about nonconformities? | | Y | N | X |  |
|  |  | | | | | | | | Do you define how you plan to notify internal organizations about nonconformities? | Y | N | X |  |
|  |  | | | | | | | Do you define how external parties will be notified about nonconformities? | | Y | N | X |  |
|  |  | | | | | | | | Do you define how you plan to notify customers about nonconformities? | Y | N | X |  |
|  |  | | | | | | | | Do you define how you plan to notify distributors about nonconformities? | Y | N | X |  |
|  |  | | | | | | | | Do you define how you plan to notify regulators about nonconformities? | Y | N | X |  |
|  |  | | | | | | | | Do you define how you plan to notify suppliers about nonconformities? | Y | N | X |  |
|  |  | | | | Do you define how appropriate corrective actions will be implemented? | | | | | Y | N | X |  |
|  |  | | | | | Do you define how corrective action will be developed and taken  whenever nonconforming outputs are detected after delivery? | | | | Y | N | X |  |
|  |  | | | | | | Do you define how you intend to ensure that actions will deal with impacts? | | | Y | N | X |  |
| 1.4.2 CARRY OUT PROCESS PLANNING | | | | | | | | | | | | | |
|  | Do you select the people that should be involved in process planning? | | | | | | | | | Y | N | X |  |
|  |  | Do you ask people from affected organizational functions to participate? | | | | | | | | Y | N | X |  |
|  | Do you establish performance criteria that your process should meet? | | | | | | | | | Y | N | X |  |
|  |  | Do you establish performance criteria that process outputs should meet? | | | | | | | | Y | N | X |  |
|  | Do you determine the activities that should make up your process? | | | | | | | | | Y | N | X |  |
|  |  | Do you determine the activities needed to generate your outputs? | | | | | | | | Y | N | X |  |
|  |  | Do you determine the activities needed to control your “critical items”? | | | | | | | | Y | N | X |  |
|  |  | Do you determine the activities needed to prevent unintended deliveries? | | | | | | | | Y | N | X |  |
|  | Do you develop suitable process verification methods? | | | | | | | | | Y | N | X |  |
|  |  | Do you consider using risk assessments to help ensure that your  process is able to produce outputs that meet requirements? | | | | | | | | Y | N | X |  |
|  |  | Do you consider using capacity studies to help ensure that your  process is able to produce outputs that meet requirements? | | | | | | | | Y | N | X |  |
|  |  | Do you consider using capability studies to help ensure that your  process is able to produce outputs that meet requirements? | | | | | | | | Y | N | X |  |
|  |  | Do you consider using control plans to help ensure that your  process is able to produce outputs that meet requirements? | | | | | | | | Y | N | X |  |
|  | Do you clarify process interactions and interconnections? | | | | | | | | | Y | N | X |  |
|  |  | Have you identified downstream processes? | | | | | | | | Y | N | X |  |
|  |  | Have you identified upstream processes? | | | | | | | | Y | N | X |  |
|  | Do you allocate the resources needed to support process? | | | | | | | | | Y | N | X |  |
|  |  | Do you allocate the resources needed to manage process? | | | | | | | | Y | N | X |  |
|  |  | Do you allocate the resources needed to manage projects? | | | | | | | | Y | N | X |  |
|  |  | Do you allocate the resources needed to manage “critical items”? | | | | | | | | Y | N | X |  |
| 1.4.3 carry out input planning | | | | | | | | | | | | | |
|  | Have you identified your process input requirements? | | | | | | | | | Y | N | X |  |
|  |  | Have you identified the products that your process will need to have? | | | | | | | | Y | N | X |  |
|  |  | | Have you identified the product providers that will be needed? | | | | | | | Y | N | X |  |
|  |  | Have you identified the services that your process will need to have? | | | | | | | | Y | N | X |  |
|  |  | | Have you identified the service providers that will be needed? | | | | | | | Y | N | X |  |
|  |  | Have you identified the technologies that your process will need to have? | | | | | | | | Y | N | X |  |
|  |  | | Have you identified the hardware that your process will need to have? | | | | | | | Y | N | X |  |
|  |  | | Have you identified the software that your process will need to have? | | | | | | | Y | N | X |  |
|  |  | Have you identified the information that your process will need to have? | | | | | | | | Y | N | X |  |
|  |  | Have you identified the materials that your process will need to have? | | | | | | | | Y | N | X |  |
|  |  | Have you identified the supplies that your process will need to have? | | | | | | | | Y | N | X |  |
|  |  | Have you identified the parts that your process will need to have? | | | | | | | | Y | N | X |  |
|  | Do you document your process input requirements? | | | | | | | | | Y | N | X |  |
| 1.5 DESIGN PROCESS SUPPORT PROGRAMMES | | | | | | | | | | | | | |
| 1.5.1 design risk management programme | | | | | | | | | | | | | |
|  | Do you make sure that your risk management methods are  appropriate for your process and the outputs it generates? | | | | | | | | | Y | N | X |  |
|  |  | Do you plan the assignment of risk management responsibilities? | | | | | | | | Y | N | X |  |
|  |  | Do you clarify and define your operational risk assessment criteria? | | | | | | | | Y | N | X |  |
|  |  | | Do you figure out how you’re going to determine the likelihood of an occurrence? | | | | | | | Y | N | X |  |
|  |  | | Do you figure out how you’re going to evaluate potentially negative consequences? | | | | | | | Y | N | X |  |
|  |  | | Do you figure out how you’re going to make operational risk acceptance decisions? | | | | | | | Y | N | X |  |
|  |  | Do you describe how you intend to manage operational risks? | | | | | | | | Y | N | X |  |
|  |  | | Do you figure out how operational risks will be identified? | | | | | | | Y | N | X |  |
|  |  | | Do you figure out how operational risks will be assessed? | | | | | | | Y | N | X |  |
|  |  | | Do you figure out how operational risks will be communicated? | | | | | | | Y | N | X |  |
|  |  | Do you specify how risk management initiatives will be taken? | | | | | | | | Y | N | X |  |
|  |  | | Do you figure out how to manage the actions that must be taken to mitigate  the operational risks that exceed the limits set by your risk acceptance criteria? | | | | | | | Y | N | X |  |
|  |  | | | Do you figure out how you’re going to formulate the  actions that must be taken to mitigate operational risks? | | | | | | Y | N | X |  |
|  |  | | | Do you figure out how you’re going to implement the  actions that must be taken to mitigate operational risks? | | | | | | Y | N | X |  |
|  |  | Do you define how residual operational risks will be controlled? | | | | | | | | Y | N | X |  |
|  |  | | Do you figure out how you’re going to control the acceptable operational  risks that remain after you’ve taken action to mitigate unacceptable risks? | | | | | | | Y | N | X |  |
| 1.5.2 DESIGN SAFETY MANAGEMENT PROGRAMME | | | | | | | | | | | | | |
|  | Did you plan your safety management programme? | | | | | | | | | Y | N | X |  |
|  |  | Do you make sure that your safety programme is appropriate for your process? | | | | | | | | Y | N | X |  |
|  |  | | Do you make sure that safety programme is appropriate for your outputs? | | | | | | | Y | N | X |  |
|  |  | | | Do you ensure that your programme applies to the entire output life cycle? | | | | | | Y | N | X |  |
|  | Did you develop a safety management programme? | | | | | | | | | Y | N | X |  |
|  |  | Did you develop a way of managing safety hazards and threats? | | | | | | | | Y | N | X |  |
|  |  | | Did you develop a safety hazard and threat assessment process? | | | | | | | Y | N | X |  |
|  |  | | | Did you develop a suitable safety risk management process? | | | | | | Y | N | X |  |
|  |  | Did you develop a way of managing activities that affect safety? | | | | | | | | Y | N | X |  |
|  |  | | Did you develop a way of analyzing activities that affect safety? | | | | | | | Y | N | X |  |
|  |  | | Did you develop a way of reporting activities that affect safety? | | | | | | | Y | N | X |  |
|  |  | Did you develop a way of managing safety training services? | | | | | | | | Y | N | X |  |
|  |  | Did you develop a way of managing safety communications? | | | | | | | | Y | N | X |  |
| 1.5.3 DESIGN QUALITY MANAGEMENT PROGRAMME | | | | | | | | | | | | | |
|  | Do you establish quality expectations for your process? | | | | | | | | | Y | N | X |  |
|  |  | Do you define quality requirements for your process? | | | | | | | | Y | N | X |  |
|  |  | Do you formulate quality policies for your process? | | | | | | | | Y | N | X |  |
|  |  | Do you write quality procedures for your process? | | | | | | | | Y | N | X |  |
|  |  | Do you prepare quality criteria for your process? | | | | | | | | Y | N | X |  |
|  |  | Do you develop quality plans for your process? | | | | | | | | Y | N | X |  |
|  |  | Do you set quality objectives for your process? | | | | | | | | Y | N | X |  |
|  |  | | Do you clarify criteria for setting quality objectives? | | | | | | | Y | N | X |  |
|  |  | | | Do you make sure that quality objectives are measurable? | | | | | | Y | N | X |  |
|  |  | | | Do you make sure that quality objectives consider requirements? | | | | | | Y | N | X |  |
|  |  | | | Do you make sure that quality objectives support your strategic direction? | | | | | | Y | N | X |  |
|  |  | | | Do you make sure that quality objectives are compatible with your context? | | | | | | Y | N | X |  |
|  |  | | | Do you make sure that quality objectives are consistent with your policies? | | | | | | Y | N | X |  |
|  |  | | Do you define quality objectives for your process? | | | | | | | Y | N | X |  |
|  |  | | | Do you set quality objectives in all relevant areas of your process? | | | | | | Y | N | X |  |
|  |  | | | | Do you set quality objectives for all relevant process functions? | | | | | Y | N | X |  |
|  |  | | | | | Do you set objectives that address the need to provide compliant outputs? | | | | Y | N | X |  |
|  |  | | | | | Do you set objectives that address the need to enhance customer satisfaction? | | | | Y | N | X |  |
|  |  | Do you create quality controls for your process? | | | | | | | | Y | N | X |  |
|  |  | | Did you establish a configuration management system? | | | | | | | Y | N | X |  |
|  |  | | | Do you figure out how you're going to identify and control physical  and functional attributes throughout the lifecycle of your outputs? | | | | | | Y | N | X |  |
|  |  | | | | Do you develop configuration management methods that are  appropriate for your organization and the outputs it produces? | | | | | Y | N | X |  |
| 1.5.4 DESIGN SECURITY MANAGEMENT PROGRAMME | | | | | | | | | | | | | |
|  | Did you develop a personnel security management programme? | | | | | | | | | Y | N | X |  |
|  |  | Do you define personnel security requirements for your process? | | | | | | | | Y | N | X |  |
|  |  | Do you formulate personnel security policies for your process? | | | | | | | | Y | N | X |  |
|  |  | Do you write personnel security procedures for your process? | | | | | | | | Y | N | X |  |
|  |  | Do you prepare personnel security criteria for your process? | | | | | | | | Y | N | X |  |
|  |  | Do you develop personnel security plans for your process? | | | | | | | | Y | N | X |  |
|  |  | Do you set personnel security objectives for your process? | | | | | | | | Y | N | X |  |
|  | Did you develop an information security management programme? | | | | | | | | | Y | N | X |  |
|  |  | Do you define information security requirements for your process? | | | | | | | | Y | N | X |  |
|  |  | Do you formulate information security policies for your process? | | | | | | | | Y | N | X |  |
|  |  | Do you write information security procedures for your process? | | | | | | | | Y | N | X |  |
|  |  | Do you prepare information security criteria for your process? | | | | | | | | Y | N | X |  |
|  |  | Do you develop information security plans for your process? | | | | | | | | Y | N | X |  |
|  |  | Do you set information security objectives for your process? | | | | | | | | Y | N | X |  |
|  | Did you develop a component security management programme? | | | | | | | | | Y | N | X |  |
|  |  | Did you develop a counterfeit parts management programme? | | | | | | | | Y | N | X |  |
|  |  | | Did you plan your counterfeit part management programme? | | | | | | | Y | N | X |  |
|  |  | | | Did you ensure that counterfeit part management programme is designed to prevent the use and inclusion of suspicious or counterfeit parts in outputs delivered to customers? | | | | | | Y | N | X |  |
|  |  | | | | Do you make sure that your counterfeit part management programme  is appropriate for your process and the outputs it provides to its customers? | | | | | Y | N | X |  |
|  |  | | Did you develop your counterfeit part management programme? | | | | | | | Y | N | X |  |
|  |  | | | Did you develop a process to teach people about counterfeit parts? | | | | | | Y | N | X |  |
|  |  | | | Did you develop a process to monitor counterfeit parts and components? | | | | | | Y | N | X |  |
|  |  | | | | Did you develop a process to monitor obsolete parts and components? | | | | | Y | N | X |  |
|  |  | | | Did you develop a process to control the acquisition of parts and components? | | | | | | Y | N | X |  |
|  |  | | | | Did you develop a process to detect suspicious and counterfeit parts and components? | | | | | Y | N | X |  |
|  |  | | | | | Do you develop methodologies to test and to verify your parts and components? | | | | Y | N | X |  |
|  |  | | | | | | Do you develop methodologies to detect counterfeit parts and components? | | | Y | N | X |  |
|  |  | | | | Did you develop a process to quarantine suspicious or counterfeit parts and components? | | | | | Y | N | X |  |
|  |  | | | | Did you develop a process to report suspicious or counterfeit parts and components? | | | | | Y | N | X |  |
|  |  | | | Did you develop a process to trace parts and components back to suppliers? | | | | | | Y | N | X |  |
|  |  | | | | Do you ensure that you can trace them back to original or authorized manufacturers? | | | | | Y | N | X |  |
| 1.5.5 DESIGN SUPPLIER MANAGEMENT PROGRAMME | | | | | | | | | | | | | |
|  | Did you develop a programme to manage, monitor, and control the use of external providers? | | | | | | | | | Y | N | X |  |
|  |  | Do you clarify what you expect from external process, product, and service providers? | | | | | | | | Y | N | X |  |
|  |  | | Do you specify your external document and record keeping requirements? | | | | | | | Y | N | X |  |
|  | Did you develop and do you maintain a register of external provider performance and status? | | | | | | | | | Y | N | X |  |
| 1.5.6 DESIGN environmental MANAGEMENT PROGRAMME | | | | | | | | | | | | | |
|  | Did you plan your environmental management programme? | | | | | | | | | Y | N | X |  |
|  |  | Do you make sure that your environmental programme is appropriate for your process? | | | | | | | | Y | N | X |  |
|  |  | | Do you make sure that your environmental programme is appropriate for your outputs? | | | | | | | Y | N | X |  |
|  |  | | | Do you ensure that your programme applies to the entire output life cycle? | | | | | | Y | N | X |  |
|  | Did you develop an environmental management programme? | | | | | | | | | Y | N | X |  |
|  |  | Did you develop ways of analyzing environmental aspects and impacts? | | | | | | | | Y | N | X |  |
|  |  | Did you develop a way of managing environmental aspects and impacts? | | | | | | | | Y | N | X |  |
| 1.5.7 DESIGN BUSINESS CONTINUITY MANAGEMENT PROGRAMME | | | | | | | | | | | | | |
|  | Did you plan your business continuity management programme? | | | | | | | | | Y | N | X |  |
|  |  | Do you make sure that your continuity programme is appropriate for your process? | | | | | | | | Y | N | X |  |
|  |  | | Do you make sure that business continuity programme is appropriate for your outputs? | | | | | | | Y | N | X |  |
|  |  | | | Do you ensure that your continuity programme applies to the entire output life cycle? | | | | | | Y | N | X |  |
|  | Did you develop a business continuity management programme? | | | | | | | | | Y | N | X |  |
|  |  | Do you ensure that operations continue at specified levels? | | | | | | | | Y | N | X |  |
|  |  | | Did you develop ways of identifying potential threats? | | | | | | | Y | N | X |  |
|  |  | | Did you develop ways of analyzing all possible impacts? | | | | | | | Y | N | X |  |
|  |  | | Did you develop ways of responding to disruptive incidents? | | | | | | | Y | N | X |  |
|  |  | | Did you develop ways of resuming prioritized process activities? | | | | | | | Y | N | X |  |
|  |  | | Did you develop ways of restoring operations to acceptable levels? | | | | | | | Y | N | X |  |
| 1.6 IDENTIFY PROCESS DOCUMENTS AND RECORDS | | | | | | | | | | | | | |
| 1.6.1 EVALUATE DOCUMENTATION REQUIREMENTS | | | | | | | | | | | | | |
|  | Do you figure out how extensive documented process information should be? | | | | | | | | | Y | N | X |  |
|  |  | Do you consider process activities when you establish documents and records? | | | | | | | | Y | N | X |  |
|  |  | Do you consider your process outputs when you establish documents and records? | | | | | | | | Y | N | X |  |
|  |  | Do you consider process personnel when you establish documents and records? | | | | | | | | Y | N | X |  |
|  |  | | Do you consider the competence and expertise of your process personnel? | | | | | | | Y | N | X |  |
|  |  | Do you consider your process obligations when you establish documents and records? | | | | | | | | Y | N | X |  |
|  |  | | Do you consider process property and information provided by your customers? | | | | | | | Y | N | X |  |
|  |  | | Do you consider process property and information provided by external providers? | | | | | | | Y | N | X |  |
| 1.6.2 SELECT PROCESS DOCUMENTS AND RECORDS | | | | | | | | | | | | | |
|  | Do you select all the documents and records that your process needs? | | | | | | | | | Y | N | X |  |
|  |  | Do you select all the internal documents and records that your process needs? | | | | | | | | Y | N | X |  |
|  |  | | Do you include documented information that your process needs to be effective? | | | | | | | Y | N | X |  |
|  |  | | | Do you include all the documents and records that you need in  order to be sure that your process is being carried out as planned? | | | | | | Y | N | X |  |
|  |  | | Do you include documented information required by external standards? | | | | | | | Y | N | X |  |
|  |  | | | Do you include information that documents the scope of your process? | | | | | | Y | N | X |  |
|  |  | | | Do you include information that documents your process goals and objectives? | | | | | | Y | N | X |  |
|  |  | | | Do you include information that documents your process policies and procedures? | | | | | | Y | N | X |  |
|  |  | | | Do you include information that documents your monitoring and measuring resources? | | | | | | Y | N | X |  |
|  |  | | | | Do you include documented information that can prove that  your monitoring and measuring resources are fit for purpose? | | | | | Y | N | X |  |
|  |  | | | | | Do you include documented information describing your verification  and calibration methods whenever traceability is required and whenever  national or international measurement standards do not exist? | | | | Y | N | X |  |
|  |  | | | | Do you include information that documents your process  monitoring and measuring activities and results? | | | | | Y | N | X |  |
|  |  | | | Do you include information that documents the competence of process personnel? | | | | | | Y | N | X |  |
|  |  | | | | Do you include documented information that can prove that the people  under your control who do work that affects quality are, in fact, competent? | | | | | Y | N | X |  |
|  |  | | | Do you include information that documents process activities and results? | | | | | | Y | N | X |  |
|  |  | | | | Do you include documented information that can prove  that your process is being carried out as planned? | | | | | Y | N | X |  |
|  |  | | | | Do you include documented information that facilitates the traceability  of process outputs whenever traceability is a requirement? | | | | | Y | N | X |  |
|  |  | | | Do you include information that documents your output characteristics? | | | | | | Y | N | X |  |
|  |  | | | Do you include information that documents your output requirements? | | | | | | Y | N | X |  |
|  |  | | | | Do you include information that documents changes in requirements? | | | | | Y | N | X |  |
|  |  | | | Do you include information that documents your output compliance? | | | | | | Y | N | X |  |
|  |  | | | Do you include information that documents your output reviews? | | | | | | Y | N | X |  |
|  |  | | | | Do you include information that documents results  whenever you review output requirements? | | | | | Y | N | X |  |
|  |  | | | Do you include information that documents process development activities? | | | | | | Y | N | X |  |
|  |  | | | | Do you include information that documents process development inputs? | | | | | Y | N | X |  |
|  |  | | | | | Do you include documented information that describes changes in inputs? | | | | Y | N | X |  |
|  |  | | | | Do you include information that documents process development outputs? | | | | | Y | N | X |  |
|  |  | | | | | Do you include documented information that describes changes in outputs? | | | | Y | N | X |  |
|  |  | | | | Do you include information that documents process development changes? | | | | | Y | N | X |  |
|  |  | | | | | Do you include documents that authorize changes in process development? | | | | Y | N | X |  |
|  |  | | | | | Do you include documents that record reviews of all relevant changes? | | | | Y | N | X |  |
|  |  | | | | Do you include information that records actions taken to prevent adverse impacts? | | | | | Y | N | X |  |
|  |  | | | | Do you include information that records process development requirements? | | | | | Y | N | X |  |
|  |  | | | | | Do you include documents that confirm that requirements were met? | | | | Y | N | X |  |
|  |  | | | Do you include information that documents external provider performance? | | | | | | Y | N | X |  |
|  |  | | | | Do you include documented information that describes  the results of your evaluation of external providers? | | | | | Y | N | X |  |
|  |  | | | | | Do you include information that describes your re-evaluation results? | | | | Y | N | X |  |
|  |  | | | | | | Do you include information that describes your monitoring results? | | | Y | N | X |  |
|  |  | | | Do you include information that documents other people’s property and information? | | | | | | Y | N | X |  |
|  |  | | | | Do you include information that documents the status of property and information supplied by customers and external providers that is lost, damaged, or unsuitable? | | | | | Y | N | X |  |
|  |  | | | Do you include information that documents your process operations and outputs? | | | | | | Y | N | X |  |
|  |  | | | | Do you include documented information that describes the process  activities to be performed and the results to be achieved? | | | | | Y | N | X |  |
|  |  | | | | | Do you include information that documents unplanned changes in process activities? | | | | Y | N | X |  |
|  |  | | | | | | Do you include documented information that describes who authorized changes,  the actions that were taken, and the results of your review of these changes? | | | Y | N | X |  |
|  |  | | | | Do you include documented information that describes output delivery and  post-delivery activities to be performed and the results to be achieved? | | | | | Y | N | X |  |
|  |  | | | Do you include information that documents the release of process outputs? | | | | | | Y | N | X |  |
|  |  | | | Do you include information that documents your process nonconformities? | | | | | | Y | N | X |  |
|  |  | | | | Do you include documented information that describes  the corrective actions taken and the results achieved? | | | | | Y | N | X |  |
|  |  | | | | | Do you include documented information that describes the actions that  are taken whenever nonconforming process outputs are produced? | | | | Y | N | X |  |
|  |  | | | Do you include information that documents your internal process audit results? | | | | | | Y | N | X |  |
|  |  | | | | Do you include documented information that can demonstrate that  you have implemented an internal process audit programme? | | | | | Y | N | X |  |
|  |  | | | Do you include information that documents your management review outputs? | | | | | | Y | N | X |  |
|  |  | Do you select all the external documents and records that your process needs? | | | | | | | | Y | N | X |  |
|  |  | | Do you include all documented information of external  origin that you need in order to plan your process? | | | | | | | Y | N | X |  |
|  |  | | Do you include all documented information of external  origin that you need in order to operate your process? | | | | | | | Y | N | X |  |
|  |  | | Do you include all documented information of external  origin that you need in order to maintain your process? | | | | | | | Y | N | X |  |
|  |  | | Do you include all documented information of external  origin that you need in order to monitor your process? | | | | | | | Y | N | X |  |
|  |  | | Do you include all documented information of external  origin that you need in order to measure your process? | | | | | | | Y | N | X |  |
|  |  | | Do you include all documented information of external  origin that you need in order to control your process? | | | | | | | Y | N | X |  |
|  |  | | Do you include all documented information of external  origin that you need in order to evaluate your process? | | | | | | | Y | N | X |  |
|  |  | | | Do you include all documented information of external  origin that you need in order to audit your process? | | | | | | Y | N | X |  |
|  |  | | | Do you include all documented information of external  origin that you need in order to review your process? | | | | | | Y | N | X |  |
|  |  | | Do you include all documented information of external  origin that you need in order to modify your process? | | | | | | | Y | N | X |  |
|  |  | | | Do you include all documented information of external  origin that you need in order to correct your process? | | | | | | Y | N | X |  |
|  |  | | | Do you include all documented information of external  origin that you need in order to improve your process? | | | | | | Y | N | X |  |
| 1.6.3 DEVELOP PROCESS DOCUMENTS AND RECORDS | | | | | | | | | | | | | |
|  | Do you document your process participants? | | | | | | | | | Y | N | X |  |
|  |  | Do you document the parties that have an interest in your process? | | | | | | | | Y | N | X |  |
|  | Do you document the scope of your process? | | | | | | | | | Y | N | X |  |
|  |  | Do you consider interested party requirements when you document the scope of your process? | | | | | | | | Y | N | X |  |
|  |  | Do you consider your process environment when you document the scope of your process? | | | | | | | | Y | N | X |  |
|  |  | Do you consider your process outputs when you document the scope of your process? | | | | | | | | Y | N | X |  |
|  | Do you document your process outputs? | | | | | | | | | Y | N | X |  |
|  |  | Do you develop documents defining expected output results? | | | | | | | | Y | N | X |  |
|  |  | Do you document characteristics of outputs you plan to produce? | | | | | | | | Y | N | X |  |
|  |  | | Do you develop and document your output definition data? | | | | | | | Y | N | X |  |
|  | Do you document your process activities? | | | | | | | | | Y | N | X |  |
|  |  | Do you document characteristics of process activities to be performed? | | | | | | | | Y | N | X |  |
|  |  | Do you document performance criteria that your process should meet? | | | | | | | | Y | N | X |  |
|  |  | | Do you document performance criteria that process outputs should meet? | | | | | | | Y | N | X |  |
|  |  | Do you document the activities that should make up your process? | | | | | | | | Y | N | X |  |
|  |  | | Do you document the activities needed to generate your outputs? | | | | | | | Y | N | X |  |
|  |  | | Do you document the activities needed to control your “critical items”? | | | | | | | Y | N | X |  |
|  |  | | Do you document the activities needed to prevent unintended deliveries? | | | | | | | Y | N | X |  |
|  |  | Do you document suitable process verification methods? | | | | | | | | Y | N | X |  |
|  |  | Do you document process interactions and interconnections? | | | | | | | | Y | N | X |  |
|  |  | | Do you document your downstream processes? | | | | | | | Y | N | X |  |
|  |  | | Do you document your upstream processes? | | | | | | | Y | N | X |  |
|  |  | Do you document the resources needed to support your process? | | | | | | | | Y | N | X |  |
|  |  | | Do you document the resources needed to manage your process? | | | | | | | Y | N | X |  |
|  |  | | Do you document the resources needed to manage your projects? | | | | | | | Y | N | X |  |
|  |  | | Do you document the resources needed to manage your “critical items”? | | | | | | | Y | N | X |  |
|  | Do you document your process inputs? | | | | | | | | | Y | N | X |  |
|  |  | Do you document the products that your process will need to have? | | | | | | | | Y | N | X |  |
|  |  | | Do you document the product providers that will be needed? | | | | | | | Y | N | X |  |
|  |  | Do you document the services that your process will need to have? | | | | | | | | Y | N | X |  |
|  |  | | Do you document the service providers that will be needed? | | | | | | | Y | N | X |  |
|  |  | Do you document the technologies that your process will need to have? | | | | | | | | Y | N | X |  |
|  |  | | Do you document the hardware that your process will need to have? | | | | | | | Y | N | X |  |
|  |  | | Do you document the software that your process will need to have? | | | | | | | Y | N | X |  |
|  |  | Do you document the information that your process will need to have? | | | | | | | | Y | N | X |  |
|  |  | Do you document the materials that your process will need to have? | | | | | | | | Y | N | X |  |
|  |  | Do you document the supplies that your process will need to have? | | | | | | | | Y | N | X |  |
|  |  | Do you document the parts that your process will need to have? | | | | | | | | Y | N | X |  |
|  | Do you document process assignments? | | | | | | | | | Y | N | X |  |
|  |  | Do you document process authorities? | | | | | | | | Y | N | X |  |
|  |  | Do you document process responsibilities? | | | | | | | | Y | N | X |  |
|  | Do you document the objectives that your process must achieve? | | | | | | | | | Y | N | X |  |
|  |  | Do you control documents that specify process objectives? | | | | | | | | Y | N | X |  |
|  |  | | Do you retain documents that specify process objectives? | | | | | | | Y | N | X |  |
|  | Do you document process policies, procedures, and work instructions? | | | | | | | | | Y | N | X |  |
|  |  | Do you make sure that policies and procedures support your strategic direction? | | | | | | | | Y | N | X |  |
| 1.7 ESTABLISH PROCESS ROLES AND RESPONSIBILITIES | | | | | | | | | | | | | |
| 1.7.1 ASSIGN PROCESS RESPONSIBILITIES AND AUTHORITIES | | | | | | | | | | | | | |
|  | Do you assign responsibility and authority for managing this process? | | | | | | | | | Y | N | X |  |
|  |  | Do you assign responsibility and authority for applying your quality policy and procedures? | | | | | | | | Y | N | X |  |
|  |  | Do you assign responsibility and authority for complying with regulations and standards? | | | | | | | | Y | N | X |  |
|  |  | Do you assign responsibility and authority for maintaining a focus on process customers? | | | | | | | | Y | N | X |  |
|  |  | | Do you assign responsibility and authority for meeting customer requirements? | | | | | | | Y | N | X |  |
|  |  | | Do you assign responsibility and authority for enhancing customer satisfaction? | | | | | | | Y | N | X |  |
|  |  | Do you assign responsibility and authority for interacting with external parties? | | | | | | | | Y | N | X |  |
|  |  | | Do you assign responsibility and authority for interacting  with external parties that have an interest in this process? | | | | | | | Y | N | X |  |
|  |  | | Do you assign responsibility and authority for interacting  with external providers that support this process? | | | | | | | Y | N | X |  |
|  |  | | | Do you assign responsibility and authority for deciding when external providers are used? | | | | | | Y | N | X |  |
|  |  | | | | Do you assign responsibility and authority for granting an approval status to providers? | | | | | Y | N | X |  |
|  |  | | | | | Do you allocate responsibility and authority for changing providers’ approval status? | | | | Y | N | X |  |
|  | Do you assign responsibility and authority for operating this process? | | | | | | | | | Y | N | X |  |
|  |  | Do you assign responsibility and authority for ensuring that process is efficient and effective? | | | | | | | | Y | N | X |  |
|  |  | | Do you make managers accountable for ensuring that process produces intended outputs? | | | | | | | Y | N | X |  |
|  | Do you assign responsibility and authority for maintaining this process? | | | | | | | | | Y | N | X |  |
|  | Do you assign responsibility and authority for monitoring this process? | | | | | | | | | Y | N | X |  |
|  | Do you assign responsibility and authority for measuring this process? | | | | | | | | | Y | N | X |  |
|  | Do you assign responsibility and authority for controlling this process? | | | | | | | | | Y | N | X |  |
|  |  | Do you assign responsibility and authority for controlling process modifications? | | | | | | | | Y | N | X |  |
|  |  | | Do you make managers accountable for protecting process integrity when changes occur? | | | | | | | Y | N | X |  |
|  | Do you assign responsibility and authority for evaluating this process? | | | | | | | | | Y | N | X |  |
|  |  | Do you assign responsibility and authority for auditing process? | | | | | | | | Y | N | X |  |
|  |  | | Do you assign responsibility and authority for preparing audit reports? | | | | | | | Y | N | X |  |
|  |  | Do you assign responsibility and authority for reviewing process? | | | | | | | | Y | N | X |  |
|  |  | | Do you assign responsibility and authority for preparing review reports? | | | | | | | Y | N | X |  |
|  |  | | | Do you assign responsibility and authority for submitting process performance reports? | | | | | | Y | N | X |  |
|  |  | | | Do you assign responsibility and authority for reporting process improvement opportunities? | | | | | | Y | N | X |  |
|  | Do you assign responsibility and authority for modifying this process? | | | | | | | | | Y | N | X |  |
|  |  | Do you assign responsibility and authority for correcting this process? | | | | | | | | Y | N | X |  |
|  |  | Do you assign responsibility and authority for improving this process? | | | | | | | | Y | N | X |  |
| 1.7.2 DOCUMENT PROCESS RESPONSIBILITIES AND AUTHORITIES | | | | | | | | | | | | | |
|  | Do you document responsibility and authority for managing this process? | | | | | | | | | Y | N | X |  |
|  | Do you document responsibility and authority for operating this process? | | | | | | | | | Y | N | X |  |
|  | Do you document responsibility and authority for maintaining this process? | | | | | | | | | Y | N | X |  |
|  | Do you document responsibility and authority for monitoring this process? | | | | | | | | | Y | N | X |  |
|  | Do you document responsibility and authority for measuring this process? | | | | | | | | | Y | N | X |  |
|  | Do you document responsibility and authority for controlling this process? | | | | | | | | | Y | N | X |  |
|  | Do you document responsibility and authority for evaluating this process? | | | | | | | | | Y | N | X |  |
|  |  | Do you document responsibility and authority for auditing this process? | | | | | | | | Y | N | X |  |
|  |  | Do you document responsibility and authority for reviewing this process? | | | | | | | | Y | N | X |  |
|  | Do you document responsibility and authority for modifying this process? | | | | | | | | | Y | N | X |  |
|  |  | Do you document responsibility and authority for correcting this process? | | | | | | | | Y | N | X |  |
|  |  | Do you document responsibility and authority for improving this process? | | | | | | | | Y | N | X |  |
|  | | | | | | | | | | | | | |
| Answer each of the above questions. Three answers are possible: Y (yes), N (no), and X (eXclude). Y means you're in compliance,  N means you're not in compliance, while X means that this question can be excluded because it’s not applicable in your situation.  Y answers and X answers require no further action, while N answers point to things that need to be done to improve the  overall performance of your process. Also, please use the column on the right to record your notes, and in the spaces  below, enter the name and location of your organization, who completed this page, who reviewed it, and the dates. | | | | | | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 2.1 PROVIDE RESOURCES NEEDED TO IMPLEMENT PROCESS | | | | | | | | | | | |
|  | Did you provide the expertise needed to implement your process? | | | | | | | Y | N | X |  |
|  |  | Did you acquire the knowledge needed to implement your process? | | | | | | Y | N | X |  |
|  |  | | Did you consider internal sources of knowledge about process implementation? | | | | | Y | N | X |  |
|  |  | | Did you consider external sources of knowledge about process implementation? | | | | | Y | N | X |  |
|  |  | | | Did you consider the implementation knowledge that suppliers can provide? | | | | Y | N | X |  |
|  |  | | | Did you consider the implementation knowledge that customers can share with you? | | | | Y | N | X |  |
|  |  | | | Did you consider the implementation knowledge that can be gathered at conferences? | | | | Y | N | X |  |
|  |  | | | Did you consider the implementation knowledge that can be gained from training courses? | | | | Y | N | X |  |
|  |  | | | Did you consider the implementation knowledge that can be gained from published materials? | | | | Y | N | X |  |
|  |  | Did you share the knowledge needed to implement your process? | | | | | | Y | N | X |  |
|  |  | | Did you share implementation knowledge with managers? | | | | | Y | N | X |  |
|  |  | | | Did you teach managers how to implement your process? | | | | Y | N | X |  |
|  |  | | Did you share implementation knowledge with personnel? | | | | | Y | N | X |  |
|  |  | | | Did you teach personnel how to implement your process? | | | | Y | N | X |  |
|  | Did you provide the technology needed to implement your process? | | | | | | | Y | N | X |  |
|  |  | Did you provide the software needed to implement your process? | | | | | | Y | N | X |  |
|  |  | Did you provide the hardware needed to implement your process? | | | | | | Y | N | X |  |
|  |  | | Did you provide the tools needed to implement your process? | | | | | Y | N | X |  |
|  |  | | Did you provide the equipment needed to implement your process? | | | | | Y | N | X |  |
|  | Did you provide the infrastructure needed to implement your process? | | | | | | | Y | N | X |  |
| 2.2 CREATE THE ENVIRONMENT THAT YOUR PROCESS NEEDS | | | | | | | | | | | |
|  | Did you establish the environment that process needs in order to achieve conformity of outputs? | | | | | | | Y | N | X |  |
|  |  | Do you create the culture that your process needs to achieve conformity of outputs? | | | | | | Y | N | X |  |
|  |  | Did you get the technology that your process needs in order to achieve conformity of outputs? | | | | | | Y | N | X |  |
|  |  | Do you acquire the knowledge that your process needs in order to achieve conformity of outputs? | | | | | | Y | N | X |  |
|  |  | | Do you acquire the knowledge that process managers need to achieve conformity of outputs? | | | | | Y | N | X |  |
|  |  | | Do you acquire the knowledge that process personnel need to achieve conformity of outputs? | | | | | Y | N | X |  |
|  |  | Do you develop the expertise that your process needs in order to achieve conformity of outputs? | | | | | | Y | N | X |  |
|  |  | | Do you develop the management expertise that your process needs? | | | | | Y | N | X |  |
|  |  | | | Do you deliver training and awareness programmes to managers? | | | | Y | N | X |  |
|  |  | | | | Do you teach process managers how to operate your process? | | | Y | N | X |  |
|  |  | | | | Do you teach process managers how to maintain your process? | | | Y | N | X |  |
|  |  | | | | Do you teach process managers how to monitor your process? | | | Y | N | X |  |
|  |  | | | | Do you teach process managers how to measure your process? | | | Y | N | X |  |
|  |  | | | | Do you teach process managers how to control your process? | | | Y | N | X |  |
|  |  | | Do you develop the process expertise that process personnel needs? | | | | | Y | N | X |  |
|  |  | | | Do you deliver training and awareness programmes to personnel? | | | | Y | N | X |  |
|  |  | | | | Do you teach process personnel how to operate your process? | | | Y | N | X |  |
|  |  | | | | Do you teach process personnel how to maintain your process? | | | Y | N | X |  |
|  |  | | | | Do you teach process personnel how to monitor your process? | | | Y | N | X |  |
|  |  | | | | Do you teach process personnel how to measure your process? | | | Y | N | X |  |
|  |  | | | | Do you teach process personnel how to control your process? | | | Y | N | X |  |
| 2.3 VERIFY THAT PROCESS CAN PRODUCE REQUIRED OUTPUTS | | | | | | | | | | | |
|  | Do you verify that process can produce outputs that meet requirements? | | | | | | | Y | N | X |  |
|  |  | Do you verify that process documentation can produce the required results? | | | | | | Y | N | X |  |
|  |  | Do you verify that your process resources can produce the required results? | | | | | | Y | N | X |  |
|  |  | | Do you validate resources that will be used to perform process? | | | | | Y | N | X |  |
|  |  | | | Do you validate tools before they are used to perform process? | | | | Y | N | X |  |
|  |  | | | Do you validate equipment before it is used to perform process? | | | | Y | N | X |  |
|  |  | | | Do you validate software before it is used to perform process? | | | | Y | N | X |  |
|  |  | | Do you validate resources that will be used to automate process? | | | | | Y | N | X |  |
|  |  | | | Do you validate tools before they are used to automate process? | | | | Y | N | X |  |
|  |  | | | Do you validate equipment before it is used to automate process? | | | | Y | N | X |  |
|  |  | | | Do you validate software before it is used to automate process? | | | | Y | N | X |  |
|  |  | | Do you validate resources that will be used to monitor process? | | | | | Y | N | X |  |
|  |  | | | Do you validate tools before they are used to monitor process? | | | | Y | N | X |  |
|  |  | | | Do you validate equipment before it is used to monitor process? | | | | Y | N | X |  |
|  |  | | | Do you validate software before it is used to monitor process? | | | | Y | N | X |  |
|  |  | | Do you validate resources that will be used to measure process? | | | | | Y | N | X |  |
|  |  | | | Do you validate tools before they are used to measure process? | | | | Y | N | X |  |
|  |  | | | Do you validate equipment before it is used to measure process? | | | | Y | N | X |  |
|  |  | | | Do you validate software before it is used to measure process? | | | | Y | N | X |  |
|  |  | | Do you validate resources that will be used to control process? | | | | | Y | N | X |  |
|  |  | | | Do you validate tools before they are used to control process? | | | | Y | N | X |  |
|  |  | | | Do you validate equipment before it is used to control process? | | | | Y | N | X |  |
|  |  | | | Do you validate software before it is used to control process? | | | | Y | N | X |  |
| 2.4 ESTABLISH PLANS TO ACHIEVE YOUR PROCESS OBJECTIVES | | | | | | | | | | | |
|  | Do you figure out what must be done to achieve process objectives? | | | | | | | Y | N | X |  |
|  |  | Do you figure out what must be done to achieve business objectives? | | | | | | Y | N | X |  |
|  |  | Do you figure out what must be done to achieve technical objectives? | | | | | | Y | N | X |  |
|  |  | Do you figure out what must be done to achieve quality objectives? | | | | | | Y | N | X |  |
|  |  | Do you figure out what must be done to achieve safety objectives? | | | | | | Y | N | X |  |
|  |  | Do you figure out what must be done to achieve security objectives? | | | | | | Y | N | X |  |
|  |  | Do you figure out what must be done to achieve continuity objectives? | | | | | | Y | N | X |  |
|  |  | Do you figure out what must be done to achieve environmental objectives? | | | | | | Y | N | X |  |
|  | Do you figure out who will be responsible for achieving process objectives? | | | | | | | Y | N | X |  |
|  |  | Do you figure out who will be responsible for achieving business objectives? | | | | | | Y | N | X |  |
|  |  | Do you figure out who will be responsible for achieving technical objectives? | | | | | | Y | N | X |  |
|  |  | Do you figure out who will be responsible for achieving quality objectives? | | | | | | Y | N | X |  |
|  |  | Do you figure out who will be responsible for achieving safety objectives? | | | | | | Y | N | X |  |
|  |  | Do you figure out who will be responsible for achieving security objectives? | | | | | | Y | N | X |  |
|  |  | Do you figure out who will be responsible for achieving continuity objectives? | | | | | | Y | N | X |  |
|  |  | Do you figure out who will be responsible for achieving environmental objectives? | | | | | | Y | N | X |  |
|  | Do you figure out what resources will be needed to achieve process objectives? | | | | | | | Y | N | X |  |
|  |  | Do you figure out what resources will be needed to achieve business objectives? | | | | | | Y | N | X |  |
|  |  | Do you figure out what resources will be needed to achieve technical objectives? | | | | | | Y | N | X |  |
|  |  | Do you figure out what resources will be needed to achieve quality objectives? | | | | | | Y | N | X |  |
|  |  | Do you figure out what resources will be needed to achieve safety objectives? | | | | | | Y | N | X |  |
|  |  | Do you figure out what resources will be needed to achieve security objectives? | | | | | | Y | N | X |  |
|  |  | Do you figure out what resources will be needed to achieve continuity objectives? | | | | | | Y | N | X |  |
|  |  | Do you figure out what resources will be needed to achieve environmental objectives? | | | | | | Y | N | X |  |
| 2.5 EXPLAIN PROCESS POLICIES, PROCEDURES, AND OBJECTIVES | | | | | | | | | | | |
|  | Do you ensure that managers understand policies, procedures, and objectives? | | | | | | | Y | N | X |  |
|  |  | Do you make sure that process managers understand your process policies? | | | | | | Y | N | X |  |
|  |  | | Do you make sure that process managers know how to apply process policies? | | | | | Y | N | X |  |
|  |  | Do you make sure that process managers understand your process procedures? | | | | | | Y | N | X |  |
|  |  | | Do you make sure that process managers know how to follow process procedures? | | | | | Y | N | X |  |
|  |  | Do you make sure that process managers understand their process objectives? | | | | | | Y | N | X |  |
|  |  | | Do you make sure that process managers know how to achieve process objectives? | | | | | Y | N | X |  |
|  |  | | | Do you make sure that managers know who is responsible for achieving objectives? | | | | Y | N | X |  |
|  | Do you ensure that personnel understand policies, procedures, and objectives? | | | | | | | Y | N | X |  |
|  |  | Do you make sure that process personnel understand your process policies? | | | | | | Y | N | X |  |
|  |  | | Do you make sure that process personnel know how to apply process policies? | | | | | Y | N | X |  |
|  |  | Do you make sure that process personnel understand your process procedures? | | | | | | Y | N | X |  |
|  |  | | Do you make sure that process personnel know how to follow process procedures? | | | | | Y | N | X |  |
|  |  | Do you make sure that process personnel understand their process objectives? | | | | | | Y | N | X |  |
|  |  | | Do you make sure that process personnel know how to achieve process objectives? | | | | | Y | N | X |  |
|  |  | | | Do you make sure that personnel know who is responsible for achieving objectives? | | | | Y | N | X |  |
| 2.6 COMMUNICATE PROCESS MANAGEMENT EXPECTATIONS | | | | | | | | | | | |
|  | Do you explain why process policies must be applied? | | | | | | | Y | N | X |  |
|  | Do you explain why process procedures must be used? | | | | | | | Y | N | X |  |
|  | Do you explain why process objectives must be achieved? | | | | | | | Y | N | X |  |
|  | Do you explain why process requirements must be met? | | | | | | | Y | N | X |  |
|  |  | Do you explain why output requirements must be met? | | | | | | Y | N | X |  |
|  | Do you explain why process methods must be followed? | | | | | | | Y | N | X |  |
|  |  | Do you explain why the process approach is important? | | | | | | Y | N | X |  |
|  |  | Do you explain why management programmes are important? | | | | | | Y | N | X |  |
|  |  | | Do you explain why risk management is important? | | | | | Y | N | X |  |
|  |  | | Do you explain why safety management is important? | | | | | Y | N | X |  |
|  |  | | | Do you explain why safety policies must be implemented? | | | | Y | N | X |  |
|  |  | | | Do you explain why safety objectives must be achieved? | | | | Y | N | X |  |
|  |  | | | Do you explain why safety requirements must be met? | | | | Y | N | X |  |
|  |  | | Do you explain why quality management is important? | | | | | Y | N | X |  |
|  |  | | | Do you explain why quality policies must be implemented? | | | | Y | N | X |  |
|  |  | | | Do you explain why quality objectives must be achieved? | | | | Y | N | X |  |
|  |  | | | Do you explain why quality requirements must be met? | | | | Y | N | X |  |
|  |  | | Do you explain why environmental management is important? | | | | | Y | N | X |  |
|  |  | | | Do you explain why environmental policies must be implemented? | | | | Y | N | X |  |
|  |  | | | Do you explain why environmental objectives must be achieved? | | | | Y | N | X |  |
|  |  | | | Do you explain why environmental requirements must be met? | | | | Y | N | X |  |
|  |  | | Do you explain why business continuity management is important? | | | | | Y | N | X |  |
|  |  | | | Do you explain why business continuity policies must be implemented? | | | | Y | N | X |  |
|  |  | | | Do you explain why business continuity objectives must be achieved? | | | | Y | N | X |  |
|  |  | | | Do you explain why business continuity requirements must be met? | | | | Y | N | X |  |
|  |  | | Do you explain why security management is important? | | | | | Y | N | X |  |
|  |  | | | Do you explain why personnel security is important? | | | | Y | N | X |  |
|  |  | | | | Do you explain why personnel security policies must be implemented? | | | Y | N | X |  |
|  |  | | | | Do you explain why personnel security objectives must be achieved? | | | Y | N | X |  |
|  |  | | | | Do you explain why personnel security requirements must be met? | | | Y | N | X |  |
|  |  | | | Do you explain why information security is important? | | | | Y | N | X |  |
|  |  | | | | Do you explain why information security policies must be implemented? | | | Y | N | X |  |
|  |  | | | | Do you explain why information security objectives must be achieved? | | | Y | N | X |  |
|  |  | | | | Do you explain why information security requirements must be met? | | | Y | N | X |  |
|  |  | | | Do you explain why component security is important? | | | | Y | N | X |  |
|  |  | | | | Do you explain why counterfeit parts management is important? | | | Y | N | X |  |
|  |  | | | | | Do you explain why counterfeit parts policies must be implemented? | | Y | N | X |  |
|  |  | | | | | Do you explain why counterfeit parts objectives must be achieved? | | Y | N | X |  |
|  |  | | | | | Do you explain why counterfeit parts requirements must be met? | | Y | N | X |  |
| 2.7 EXPECT ALL PROCESS MANAGERS TO BE ACCOUNTABLE | | | | | | | | | | | |
|  | Do you ask managers to accept responsibility for their process? | | | | | | | Y | N | X |  |
|  |  | Do you ask managers to be accountable for ensuring that process is effective? | | | | | | Y | N | X |  |
|  |  | | Do you ask them to be accountable for ensuring that process produces intended outputs? | | | | | Y | N | X |  |
|  |  | Do you ask managers to be accountable for ensuring that process meets requirements? | | | | | | Y | N | X |  |
|  |  | | Do you ask them to be accountable for ensuring that process meets customer requirements? | | | | | Y | N | X |  |
|  |  | | Do you ask them to be accountable for ensuring that process meets technical requirements? | | | | | Y | N | X |  |
|  |  | | Do you ask them to be accountable for ensuring that process meets business requirements? | | | | | Y | N | X |  |
|  |  | | Do you ask them to be accountable for ensuring that process meets security requirements? | | | | | Y | N | X |  |
|  |  | | Do you ask them to be accountable for ensuring that process meets quality requirements? | | | | | Y | N | X |  |
|  |  | | Do you ask them to be accountable for ensuring that process meets safety requirements? | | | | | Y | N | X |  |
|  |  | | Do you ask them to be accountable for ensuring that process meets legal requirements? | | | | | Y | N | X |  |
|  |  | | Do you ask them to be accountable for ensuring that process meets environmental requirements? | | | | | Y | N | X |  |
|  |  | Do you ask managers to be accountable for ensuring that process complies with standards? | | | | | | Y | N | X |  |
|  |  | | Do you ask them to be accountable for ensuring that process complies with audit standards? | | | | | Y | N | X |  |
|  |  | | Do you ask them to be accountable for ensuring that process complies with safety standards? | | | | | Y | N | X |  |
|  |  | | Do you ask them to be accountable for ensuring that process complies with quality standards? | | | | | Y | N | X |  |
|  |  | | Do you ask them to be accountable for ensuring that process complies with service standards? | | | | | Y | N | X |  |
|  |  | | Do you ask them to be accountable for ensuring that process complies with product standards? | | | | | Y | N | X |  |
|  |  | | Do you ask them to be accountable for ensuring that process complies with security standards? | | | | | Y | N | X |  |
|  |  | | Do you ask them to be accountable for ensuring that process complies with environmental standards? | | | | | Y | N | X |  |
|  |  | Do you ask managers to be accountable for ensuring that process implements policies? | | | | | | Y | N | X |  |
|  |  | | Do you ask them to be accountable for ensuring that process implements audit policies? | | | | | Y | N | X |  |
|  |  | | Do you ask them to be accountable for ensuring that process implements safety policies? | | | | | Y | N | X |  |
|  |  | | Do you ask them to be accountable for ensuring that process implements quality policies? | | | | | Y | N | X |  |
|  |  | | Do you ask them to be accountable for ensuring that process implements service policies? | | | | | Y | N | X |  |
|  |  | | Do you ask them to be accountable for ensuring that process implements product policies? | | | | | Y | N | X |  |
|  |  | | Do you ask them to be accountable for ensuring that process implements security policies? | | | | | Y | N | X |  |
|  |  | | Do you ask them to be accountable for ensuring that process implements environmental policies? | | | | | Y | N | X |  |
|  |  | Do you ask managers to be accountable for ensuring that process follows procedures? | | | | | | Y | N | X |  |
|  |  | | Do you ask them to be accountable for ensuring that process follows safety procedures? | | | | | Y | N | X |  |
|  |  | | Do you ask them to be accountable for ensuring that process follows quality procedures? | | | | | Y | N | X |  |
|  |  | | Do you ask them to be accountable for ensuring that process follows service procedures? | | | | | Y | N | X |  |
|  |  | | Do you ask them to be accountable for ensuring that process follows product procedures? | | | | | Y | N | X |  |
|  |  | | Do you ask them to be accountable for ensuring that process follows security procedures? | | | | | Y | N | X |  |
|  |  | | Do you ask them to be accountable for ensuring that process follows environmental procedures? | | | | | Y | N | X |  |
| 2.8 ESTABLISH PROCESS MANAGEMENT PROGRAMMES | | | | | | | | | | | |
|  | Did you establish a suitable quality management programme? | | | | | | | Y | N | X |  |
|  |  | Do you formulate quality management requirements? | | | | | | Y | N | X |  |
|  |  | Do you allocate quality management goals and objectives? | | | | | | Y | N | X |  |
|  |  | Do you assign quality management responsibilities and authorities? | | | | | | Y | N | X |  |
|  |  | Do you implement quality management plans, policies, and procedures? | | | | | | Y | N | X |  |
|  |  | Have you identified suitable quality control points and do you apply quality controls? | | | | | | Y | N | X |  |
|  |  | | Did you establish a suitable configuration management programme? | | | | | Y | N | X |  |
|  |  | | | Did you establish a programme to identify and control the attributes of process outputs? | | | | Y | N | X |  |
|  |  | | | | Did you establish a programme to identify and control output identities and characteristics? | | | Y | N | X |  |
|  |  | | | | Did you establish a programme to identify and control output traceability to requirements? | | | Y | N | X |  |
|  |  | | | | Did you establish a programme to identify and control output changes and modifications? | | | Y | N | X |  |
|  |  | | | | Did you establish a programme to identify and control output documents and records? | | | Y | N | X |  |
|  |  | | | | | Do you make sure that your output documents and records  are consistent with the actual attributes of your outputs? | | Y | N | X |  |
|  |  | | | | | | Do you ensure that requirements documentation is consistent with actual attributes? | Y | N | X |  |
|  |  | | | | | | Do you ensure that your design documentation is consistent with actual attributes? | Y | N | X |  |
|  |  | | | | | | Do you ensure that your validation documentation is consistent with actual attributes? | Y | N | X |  |
|  |  | | | | | | Do you ensure that your verification documentation is consistent with actual attributes? | Y | N | X |  |
|  |  | | | | | | Do you ensure that your acceptance documentation is consistent with actual attributes? | Y | N | X |  |
|  |  | | | Do you assign responsibility for identifying and controlling the attributes of process outputs? | | | | Y | N | X |  |
|  | Did you establish a suitable supplier management programme? | | | | | | | Y | N | X |  |
|  |  | Did you establish a programme to manage and control external providers? | | | | | | Y | N | X |  |
|  |  | | Do you allocate supplier management goals and objectives? | | | | | Y | N | X |  |
|  |  | | Do you assign supplier management responsibilities and authorities? | | | | | Y | N | X |  |
|  |  | | Do you implement supplier management plans, policies, and procedures? | | | | | Y | N | X |  |
|  |  | | Have you identified supplier control points and do you apply supplier controls? | | | | | Y | N | X |  |
|  |  | Did you establish a register of external provider performance and status? | | | | | | Y | N | X |  |
|  | Did you establish a suitable risk management programme? | | | | | | | Y | N | X |  |
|  |  | Do you assign risk management responsibilities? | | | | | | Y | N | X |  |
|  |  | | Do you assign operational risk management tasks? | | | | | Y | N | X |  |
|  |  | Do you manage risks related to process outputs? | | | | | | Y | N | X |  |
|  |  | | Have you identified risks related to process outputs? | | | | | Y | N | X |  |
|  |  | | Do you assess risks related to process outputs? | | | | | Y | N | X |  |
|  |  | | | Do you determine the likelihood that events will occur? | | | | Y | N | X |  |
|  |  | | | | Do you determine the likelihood or probability that an undesirable  occurrence or outcome will actually occur in the future? | | | Y | N | X |  |
|  |  | | | Do you evaluate potentially severe consequences? | | | | Y | N | X |  |
|  |  | | | Do you make operational risk acceptance decisions? | | | | Y | N | X |  |
|  |  | | Do you communicate risks related to process outputs? | | | | | Y | N | X |  |
|  |  | Do you apply the actions that must be taken to mitigate the operational  risks that exceed the limits set by your risk acceptance criteria? | | | | | | Y | N | X |  |
|  |  | | Have you identified the actions that must be taken to mitigate operational risks? | | | | | Y | N | X |  |
|  |  | | Do you implement actions that must be taken to mitigate operational risks? | | | | | Y | N | X |  |
|  |  | Do you control the risks that remain after you’ve implemented  actions to mitigate unacceptable operational risks? | | | | | | Y | N | X |  |
|  | Did you establish a suitable security management programme? | | | | | | | Y | N | X |  |
|  |  | Did you establish a component security management programme? | | | | | | Y | N | X |  |
|  |  | | Did you set up a counterfeit parts management programme? | | | | | Y | N | X |  |
|  |  | | | Do you assign responsibility and authority for counterfeit parts? | | | | Y | N | X |  |
|  |  | | | Do you implement policies and procedures for counterfeit parts? | | | | Y | N | X |  |
|  |  | | | Have you identified counterfeit control points and do you apply controls? | | | | Y | N | X |  |
|  |  | | | Do you teach people about counterfeit parts and components? | | | | Y | N | X |  |
|  |  | | | | Do you explain how counterfeit parts can be prevented? | | | Y | N | X |  |
|  |  | | | | | Do you explain how suspicious parts can be detected? | | Y | N | X |  |
|  |  | | | Do you monitor counterfeit parts reported by external sources? | | | | Y | N | X |  |
|  |  | | | | Do you monitor suspicious and obsolete parts and components? | | | Y | N | X |  |
|  |  | | | Do you control the acquisition and use of parts and components? | | | | Y | N | X |  |
|  |  | | | | Do you acquire parts and components from original or authorized manufacturers? | | | Y | N | X |  |
|  |  | | | | | Do you acquire items from authorized distributors or other approved sources? | | Y | N | X |  |
|  |  | | | | Do you test and verify parts and components and detect all counterfeit items? | | | Y | N | X |  |
|  |  | | | | Do you quarantine and report suspicious or counterfeit parts and components? | | | Y | N | X |  |
|  |  | | | Do you maintain a parts and components traceability programme? | | | | Y | N | X |  |
|  |  | Did you establish an information security management programme? | | | | | | Y | N | X |  |
|  |  | | Do you allocate goals and objectives for information security? | | | | | Y | N | X |  |
|  |  | | Do you assign responsibility and authority for information security? | | | | | Y | N | X |  |
|  |  | | Do you implement plans, policies, and procedures for information security? | | | | | Y | N | X |  |
|  |  | | Have you identified suitable infosec control points and do you apply infosec controls? | | | | | Y | N | X |  |
|  |  | Did you establish a personnel security management programme? | | | | | | Y | N | X |  |
|  |  | | Do you allocate goals and objectives for personnel security? | | | | | Y | N | X |  |
|  |  | | Do you assign responsibility and authority for personnel security? | | | | | Y | N | X |  |
|  |  | | Do you implement plans, policies, and procedures for personnel security? | | | | | Y | N | X |  |
|  |  | | Have you identified suitable personnel control points and do you apply personnel controls? | | | | | Y | N | X |  |
|  | Did you establish a suitable safety management programme? | | | | | | | Y | N | X |  |
|  |  | Do you formulate safety management requirements? | | | | | | Y | N | X |  |
|  |  | Do you allocate safety management goals and objectives? | | | | | | Y | N | X |  |
|  |  | Do you assign safety management responsibilities and authorities? | | | | | | Y | N | X |  |
|  |  | Do you implement safety management plans, policies, and procedures? | | | | | | Y | N | X |  |
|  |  | Have you identified suitable safety control points and do you apply safety controls? | | | | | | Y | N | X |  |
|  | Did you establish a suitable environmental management programme? | | | | | | | Y | N | X |  |
|  |  | Do you formulate environmental management requirements? | | | | | | Y | N | X |  |
|  |  | Do you allocate environmental management goals and objectives? | | | | | | Y | N | X |  |
|  |  | Do you assign environmental management responsibilities and authorities? | | | | | | Y | N | X |  |
|  |  | Do you implement environmental management plans, policies, and procedures? | | | | | | Y | N | X |  |
|  | Did you establish a suitable business continuity management programme? | | | | | | | Y | N | X |  |
|  |  | Do you formulate business continuity management requirements? | | | | | | Y | N | X |  |
|  |  | Do you allocate business continuity management goals and objectives? | | | | | | Y | N | X |  |
|  |  | Do you assign business continuity management responsibilities and authorities? | | | | | | Y | N | X |  |
|  |  | Do you implement business continuity management plans, policies, and procedures? | | | | | | Y | N | X |  |
| 2.9 RETAIN IMPLEMENTATION DOCUMENTATION | | | | | | | | | | | |
|  | Do you retain a record of implementation responsibilities? | | | | | | | Y | N | X |  |
|  | Do you retain a record of implementation plans and procedures? | | | | | | | Y | N | X |  |
|  | Do you retain a record of implementation results and achievements? | | | | | | | Y | N | X |  |
|  | Do you retain a record of process verification and validation activities? | | | | | | | Y | N | X |  |
|  |  | Do you retain a record of process verification and validation results? | | | | | | Y | N | X |  |

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

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| 4.1 PROVIDE THE RESOURCES NEEDED TO MAINTAIN PROCESS | | | | | | | | | | | | |
| 4.1.1 provide the expertise needed to maintain your process | | | | | | | | | | | | |
|  | Do you provide the managers needed to maintain your process? | | | | | | | | Y | N | X |  |
|  |  | Do you acquire the knowledge that managers need in order to  support process maintenance and achieve conformity of outputs? | | | | | | | Y | N | X |  |
|  |  | | Do you consider internal sources of knowledge about managing process maintenance? | | | | | | Y | N | X |  |
|  |  | | Do you consider external sources of knowledge about managing process maintenance? | | | | | | Y | N | X |  |
|  |  | Do you share the knowledge that managers need so that they can  support process maintenance and achieve conformity of outputs? | | | | | | | Y | N | X |  |
|  |  | | Do you deliver suitable training and awareness programmes  to the people that manage process maintenance activities? | | | | | | Y | N | X |  |
|  | Do you provide the personnel needed to maintain your process? | | | | | | | | Y | N | X |  |
|  |  | Do you acquire the knowledge that personnel need in order  to maintain process and achieve conformity of outputs? | | | | | | | Y | N | X |  |
|  |  | | Do you consider internal sources of knowledge about process maintenance? | | | | | | Y | N | X |  |
|  |  | | Do you consider external sources of knowledge about process maintenance? | | | | | | Y | N | X |  |
|  |  | Do you share the knowledge that personnel need in order  to maintain process and achieve conformity of outputs? | | | | | | | Y | N | X |  |
|  |  | | Do you deliver suitable training and awareness programmes  for your process maintenance personnel? | | | | | | Y | N | X |  |
| 4.1.2 provide the technology needed to maintain your process | | | | | | | | | | | | |
|  | Do you provide the software needed to maintain your process? | | | | | | | | Y | N | X |  |
|  |  | Do you provide the software needed to support process  maintenance and achieve conformity of outputs? | | | | | | | Y | N | X |  |
|  | Do you provide the hardware needed to maintain your process? | | | | | | | | Y | N | X |  |
|  |  | Do you provide the hardware needed to support process  maintenance and achieve conformity of outputs? | | | | | | | Y | N | X |  |
| 4.1.3 provide the infrastructure needed to maintain your process | | | | | | | | | | | | |
|  | Do you provide the infrastructure needed to support process  maintenance and achieve conformity of outputs? | | | | | | | | Y | N | X |  |
| 4.2 USE AUTHORIZED METHODS TO MAINTAIN YOUR PROCESS | | | | | | | | | | | | |
| 4.2.1 use authorized methods to maintain process documents | | | | | | | | | | | | |
|  | Do you maintain documents that describe how your process should be carried out? | | | | | | | | Y | N | X |  |
|  |  | Do you maintain documents that show how process operations should be carried out? | | | | | | | Y | N | X |  |
|  |  | Do you maintain documents that show how process maintenance should be carried out? | | | | | | | Y | N | X |  |
|  |  | Do you maintain documents that show how process monitoring should be carried out? | | | | | | | Y | N | X |  |
|  |  | Do you maintain documents that show how process measurement should be carried out? | | | | | | | Y | N | X |  |
|  |  | Do you maintain documents that show how process control should be carried out? | | | | | | | Y | N | X |  |
|  |  | Do you maintain documents that show how process evaluation should be carried out? | | | | | | | Y | N | X |  |
|  |  | | Do you maintain documents that show how process audits should be carried out? | | | | | | Y | N | X |  |
|  |  | | Do you maintain documents that show how process reviews should be carried out? | | | | | | Y | N | X |  |
|  |  | Do you maintain documents that show how process modification should be carried out? | | | | | | | Y | N | X |  |
|  |  | | Do you maintain documents that show how process correction should be carried out? | | | | | | Y | N | X |  |
|  |  | | Do you maintain documents that show how process improvement should be carried out? | | | | | | Y | N | X |  |
| 4.2.2 use authorized methods to maintain process records | | | | | | | | | | | | |
|  | Do you maintain a record that describes the scope of your process? | | | | | | | | Y | N | X |  |
|  | Do you maintain a record of process responsibilities and authorities? | | | | | | | | Y | N | X |  |
|  | Do you maintain a record of personnel performance and competence? | | | | | | | | Y | N | X |  |
|  |  | Do you retain your documentation and use it as evidence to  show that your process personnel are in fact competent? | | | | | | | Y | N | X |  |
|  | Do you maintain a record showing that process is performing as planned? | | | | | | | | Y | N | X |  |
|  |  | Do you maintain records that show that process operations are carried out as planned? | | | | | | | Y | N | X |  |
|  |  | Do you maintain records that show that process maintenance is carried out as planned? | | | | | | | Y | N | X |  |
|  |  | Do you maintain records that show that process monitoring is carried out as planned? | | | | | | | Y | N | X |  |
|  |  | Do you maintain records that show that process measurement is carried out as planned? | | | | | | | Y | N | X |  |
|  |  | Do you maintain records that show that process control is carried out as planned? | | | | | | | Y | N | X |  |
|  |  | Do you maintain records that show that process evaluation is carried out as planned? | | | | | | | Y | N | X |  |
|  |  | | Do you maintain records that show that process audits are carried out as planned? | | | | | | Y | N | X |  |
|  |  | | Do you maintain records that show that process reviews are carried out as planned? | | | | | | Y | N | X |  |
|  |  | Do you maintain records that show that process modification is carried out as planned? | | | | | | | Y | N | X |  |
|  |  | | Do you maintain records that show that process corrections are carried out as planned? | | | | | | Y | N | X |  |
|  |  | | Do you maintain records that show that process improvements are carried out as planned? | | | | | | Y | N | X |  |
| 4.2.3 use authorized methods to maintain process property | | | | | | | | | | | | |
|  | Do you maintain process property owned by your customers and  suppliers that is needed to achieve conformity of outputs? | | | | | | | | Y | N | X |  |
|  |  | Have you identified property belonging to customers and external providers? | | | | | | | Y | N | X |  |
|  |  | Do you verify property belonging to customers and external providers? | | | | | | | Y | N | X |  |
|  |  | Do you protect property belonging to customers and external providers? | | | | | | | Y | N | X |  |
|  |  | | Are you careful with other people's property while it is being  used by your organization or while it is under its control? | | | | | | Y | N | X |  |
|  |  | | | Do you safeguard other people's property whenever your  process intends to use or incorporate it into its outputs? | | | | | Y | N | X |  |
|  |  | Do you report property belonging to your customers and external providers? | | | | | | | Y | N | X |  |
|  |  | | Do you report lost or damaged property to customers and external providers? | | | | | | Y | N | X |  |
|  |  | | Do you report unsuitable property to customers and external providers? | | | | | | Y | N | X |  |
|  |  | Do you document property belonging to your customers and external providers? | | | | | | | Y | N | X |  |
|  |  | | Do you document the status of external property that is lost, damaged, or unsuitable? | | | | | | Y | N | X |  |
|  |  | | | Do you control and retain records documenting lost, damaged, or unsuitable property? | | | | | Y | N | X |  |
|  | Do you maintain process property owned by your process  that is needed to achieve conformity of process outputs? | | | | | | | | Y | N | X |  |
|  |  | Do you maintain equipment that process needs in order to achieve conformity of outputs? | | | | | | | Y | N | X |  |
|  |  | Do you maintain software that process needs in order to achieve conformity of outputs? | | | | | | | Y | N | X |  |
|  |  | Do you maintain tools that process needs in order to achieve conformity of outputs? | | | | | | | Y | N | X |  |
| 4.2.4 use authorized methods to maintain process procedures | | | | | | | | | | | | |
|  | Do you use authorized methods to maintain process management procedures? | | | | | | | | Y | N | X |  |
|  |  | Do you use authorized methods to maintain process control procedures? | | | | | | | Y | N | X |  |
|  |  | Do you use authorized methods to maintain process operation procedures? | | | | | | | Y | N | X |  |
|  |  | Do you use authorized methods to maintain process maintenance procedures? | | | | | | | Y | N | X |  |
|  |  | Do you use authorized methods to maintain process monitoring procedures? | | | | | | | Y | N | X |  |
|  |  | | Do you use authorized methods to maintain process feedback procedures? | | | | | | Y | N | X |  |
|  |  | Do you use authorized methods to maintain process measurement procedures? | | | | | | | Y | N | X |  |
|  |  | | Do you use authorized methods to maintain equipment calibration procedures? | | | | | | Y | N | X |  |
|  |  | Do you use authorized methods to maintain process evaluation procedures? | | | | | | | Y | N | X |  |
|  |  | | Do you use authorized methods to maintain process audit procedures? | | | | | | Y | N | X |  |
|  |  | | Do you use authorized methods to maintain process review procedures? | | | | | | Y | N | X |  |
|  |  | Do you use authorized methods to maintain process modification procedures? | | | | | | | Y | N | X |  |
|  |  | | Do you use authorized methods to maintain process correction procedures? | | | | | | Y | N | X |  |
|  |  | | Do you use authorized methods to maintain process improvement procedures? | | | | | | Y | N | X |  |
| 4.2.5 use authorized methods to maintain process programmes | | | | | | | | | | | | |
|  | Do you use authorized methods to maintain process management programmes? | | | | | | | | Y | N | X |  |
|  |  | Do you use authorized methods to maintain risk management programme? | | | | | | | Y | N | X |  |
|  |  | Do you use authorized methods to maintain safety management programme? | | | | | | | Y | N | X |  |
|  |  | Do you use authorized methods to maintain quality management programme? | | | | | | | Y | N | X |  |
|  |  | | Do you use authorized methods to maintain configuration management programme? | | | | | | Y | N | X |  |
|  |  | Do you use authorized methods to maintain security management programme? | | | | | | | Y | N | X |  |
|  |  | | Do you use authorized methods to maintain personnel security management programme? | | | | | | Y | N | X |  |
|  |  | | Do you use authorized methods to maintain information security management programme? | | | | | | Y | N | X |  |
|  |  | | Do you use authorized methods to maintain component security management programme? | | | | | | Y | N | X |  |
|  |  | | | Do you use authorized methods to maintain counterfeit parts management programme? | | | | | Y | N | X |  |
|  |  | Do you use authorized methods to maintain supplier management programme? | | | | | | | Y | N | X |  |
|  |  | Do you use authorized methods to maintain environmental management programme? | | | | | | | Y | N | X |  |
|  |  | Do you use authorized methods to maintain business continuity management programme? | | | | | | | Y | N | X |  |
| 4.2.6 use authorized methods to maintain process competence | | | | | | | | | | | | |
|  | Do you share information and knowledge with process personnel? | | | | | | | | Y | N | X |  |
|  |  | Do you make sure that they are aware of process policies? | | | | | | | Y | N | X |  |
|  |  | Do you make sure that they are aware of process objectives? | | | | | | | Y | N | X |  |
|  |  | Do you make sure that they are aware of process procedures? | | | | | | | Y | N | X |  |
|  |  | Do you make sure that they are aware of process documents and records? | | | | | | | Y | N | X |  |
|  |  | | Do you make sure that personnel stay abreast of all relevant changes? | | | | | | Y | N | X |  |
|  |  | Do you make sure that they are aware of the contribution they make? | | | | | | | Y | N | X |  |
|  |  | | Do you make sure that they understand how they affect process performance? | | | | | | Y | N | X |  |
|  |  | | Do you make sure that they understand how they influence process outputs? | | | | | | Y | N | X |  |
|  |  | | | Do you make sure that they understand how they affect output quality? | | | | | Y | N | X |  |
|  |  | | | Do you make sure that they understand how they affect output safety? | | | | | Y | N | X |  |
|  |  | | | Do you make sure that they understand how they affect output security? | | | | | Y | N | X |  |
|  |  | Do you make sure that they are aware of all relevant requirements? | | | | | | | Y | N | X |  |
|  |  | | Do you explain why compliance is important to your process? | | | | | | Y | N | X |  |
|  |  | | | Do you explain why they need to meet all relevant requirements? | | | | | Y | N | X |  |
|  |  | | | | Do you explain why they need to meet all output requirements? | | | | Y | N | X |  |
|  |  | | | | Do you explain why they need to meet all process requirements? | | | | Y | N | X |  |
|  |  | Do you make sure that they are aware of how they can help? | | | | | | | Y | N | X |  |
|  |  | | Do you explain how they can help enhance process effectiveness? | | | | | | Y | N | X |  |
|  |  | | | Do you explain why it's important to improve process performance? | | | | | Y | N | X |  |
|  | Do you acquire competence whenever shortcomings are discovered? | | | | | | | | Y | N | X |  |
|  |  | Do you acquire the necessary competence whenever process  personnel fail to meet process competence requirements? | | | | | | | Y | N | X |  |
|  |  | | Do you consider helping your personnel to improve? | | | | | | Y | N | X |  |
|  |  | | | Do you consider providing suitable training? | | | | | Y | N | X |  |
|  |  | | | Do you consider offering mentoring services? | | | | | Y | N | X |  |
|  |  | | Do you consider hiring competent people? | | | | | | Y | N | X |  |
|  |  | | | Do you consider hiring competent employees? | | | | | Y | N | X |  |
|  |  | | | Do you consider hiring competent contractors? | | | | | Y | N | X |  |
|  |  | | Do you consider reassigning unsuitable personnel? | | | | | | Y | N | X |  |
|  | Do you maintain the process knowledge that has been acquired? | | | | | | | | Y | N | X |  |
|  |  | Do you consider the need to protect and preserve lessons learned? | | | | | | | Y | N | X |  |
|  |  | Do you consider the need to protect and preserve intellectual property? | | | | | | | Y | N | X |  |
| 4.2.7 use authorized methods to maintain process technologies | | | | | | | | | | | | |
|  | Do you maintain technology used to perform process operations? | | | | | | | | Y | N | X |  |
|  |  | Do you maintain tools used to perform process operations? | | | | | | | Y | N | X |  |
|  |  | | Do you define storage requirements for tools used for process operations? | | | | | | Y | N | X |  |
|  |  | | | Do you define how and when to check the status of tools used for process operations? | | | | | Y | N | X |  |
|  |  | Do you maintain equipment used to perform process operations? | | | | | | | Y | N | X |  |
|  |  | | Do you define storage requirements for equipment used for process operations? | | | | | | Y | N | X |  |
|  |  | | | Do you define how and when to check the status of equipment used for process operations? | | | | | Y | N | X |  |
|  |  | Do you maintain software used to perform process operations? | | | | | | | Y | N | X |  |
|  |  | | Do you define how and when to check the status of software used for process operations? | | | | | | Y | N | X |  |
|  | Do you maintain technology used to automate process operations? | | | | | | | | Y | N | X |  |
|  |  | Do you maintain tools used to automate process operations? | | | | | | | Y | N | X |  |
|  |  | | Do you define storage requirements for tools used to automate process operations? | | | | | | Y | N | X |  |
|  |  | | | Do you define how and when to check the status of tools used to automate operations? | | | | | Y | N | X |  |
|  |  | Do you maintain equipment used to automate process operations? | | | | | | | Y | N | X |  |
|  |  | | Do you define storage requirements for equipment used to automate process operations? | | | | | | Y | N | X |  |
|  |  | | | Do you define how and when to check the status of equipment used for automation? | | | | | Y | N | X |  |
|  |  | Do you maintain software used to automate process operations? | | | | | | | Y | N | X |  |
|  |  | | Do you define how and when to check the status of software used for automation? | | | | | | Y | N | X |  |
|  | Do you maintain technology used to control process operations? | | | | | | | | Y | N | X |  |
|  |  | Do you maintain tools used to control process operations? | | | | | | | Y | N | X |  |
|  |  | | Do you define storage requirements for tools used to control process operations? | | | | | | Y | N | X |  |
|  |  | | | Do you define how and when to check status of tools used to control process operations? | | | | | Y | N | X |  |
|  |  | Do you maintain equipment used to control process operations? | | | | | | | Y | N | X |  |
|  |  | | Do you define storage requirements for equipment used to control process operations? | | | | | | Y | N | X |  |
|  |  | | | Do you define how and when to check the status of process control equipment? | | | | | Y | N | X |  |
|  |  | Do you maintain software used to control process operations? | | | | | | | Y | N | X |  |
|  |  | | Do you define how and when to check status of software used to control process operations? | | | | | | Y | N | X |  |
|  | Do you maintain technology used to monitor process operations? | | | | | | | | Y | N | X |  |
|  |  | Do you maintain tools used to monitor process operations? | | | | | | | Y | N | X |  |
|  |  | | Do you define storage requirements for tools used to monitor process operations? | | | | | | Y | N | X |  |
|  |  | | | Do you define how and when to check status of tools used to monitor process operations? | | | | | Y | N | X |  |
|  |  | Do you maintain equipment used to monitor process operations? | | | | | | | Y | N | X |  |
|  |  | | Do you define storage requirements for equipment used to monitor process operations? | | | | | | Y | N | X |  |
|  |  | | | Do you define how and when to check the status of process monitoring equipment? | | | | | Y | N | X |  |
|  |  | Do you maintain software used to monitor process operations? | | | | | | | Y | N | X |  |
|  |  | | Do you define how and when to check status of software used to monitor operations? | | | | | | Y | N | X |  |
|  | Do you maintain technology used to measure process operations? | | | | | | | | Y | N | X |  |
|  |  | Do you maintain software used to measure process operations? | | | | | | | Y | N | X |  |
|  |  | | Do you define how and when to check the status of software used to measure operations? | | | | | | Y | N | X |  |
|  |  | Do you maintain tools used to measure process operations? | | | | | | | Y | N | X |  |
|  |  | | Do you define storage requirements for tools used to measure process operations? | | | | | | Y | N | X |  |
|  |  | | | Do you define how and when to check the status of tools used to measure operations? | | | | | Y | N | X |  |
|  |  | Do you maintain equipment used to measure process operations? | | | | | | | Y | N | X |  |
|  |  | | Do you define storage requirements for equipment used to measure process operations? | | | | | | Y | N | X |  |
|  |  | | | Do you define how and when to check the status of process measuring equipment? | | | | | Y | N | X |  |
|  |  | | Did you establish an identification system for measurement equipment? | | | | | | Y | N | X |  |
|  |  | | | Do you use it to ensure that your equipment calibration status is always clear? | | | | | Y | N | X |  |
|  |  | | Do you verify or calibrate your process measurement equipment? | | | | | | Y | N | X |  |
|  |  | | | Do you verify or calibrate equipment under suitable conditions? | | | | | Y | N | X |  |
|  |  | | | | Do you verify or calibrate your equipment at planned intervals or prior to use? | | | | Y | N | X |  |
|  |  | | | | | Do you verify or calibrate your equipment against measurement standards  that are traceable to national or international measurement standards? | | | Y | N | X |  |
|  |  | | | | | | Do you document your verification and calibration methods whenever  national or international measurement standards do not exist? | | Y | N | X |  |
|  |  | | | | | | | Do you control your verification and calibration documents? | Y | N | X |  |
|  |  | | | | | | | Do you retain your verification and calibration documents? | Y | N | X |  |
|  |  | | Do you safeguard your process measurement equipment? | | | | | | Y | N | X |  |
|  |  | | | Do you protect your calibration status and measurement results? | | | | | Y | N | X |  |
|  |  | | | | Do you protect measurement equipment from damage or deterioration? | | | | Y | N | X |  |
|  |  | | | | Do you protect measurement equipment from unauthorized adjustment? | | | | Y | N | X |  |
|  |  | | | Do you evaluate the validity of previous measurement results whenever you  discover that measurement equipment is unfit for its intended purpose? | | | | | Y | N | X |  |
|  |  | | | | Do you take corrective action whenever you discover that your  measurement equipment is unfit for its intended purpose? | | | | Y | N | X |  |
| 4.2.8 use authorized methods to maintain process infrastructure | | | | | | | | | | | | |
|  | Do you maintain the infrastructure that process needs in order to achieve conformity of outputs? | | | | | | | | Y | N | X |  |
|  |  | Do you maintain the facilities that process needs in order to achieve conformity of outputs? | | | | | | | Y | N | X |  |
|  |  | Do you maintain the utilities that process needs in order to achieve conformity of outputs? | | | | | | | Y | N | X |  |
|  |  | Do you maintain the services that process needs in order to achieve conformity of outputs? | | | | | | | Y | N | X |  |
|  |  | Do you maintain the technologies that process needs in order to achieve conformity of outputs? | | | | | | | Y | N | X |  |
|  |  | | Do you maintain the hardware that process needs in order to achieve conformity of outputs? | | | | | | Y | N | X |  |
|  |  | | Do you maintain the software that process needs in order to achieve conformity of outputs? | | | | | | Y | N | X |  |
| 4.2.9 use authorized methods to maintain process communications | | | | | | | | | | | | |
|  | Do you use authorized methods to maintain internal process communications? | | | | | | | | Y | N | X |  |
|  | Do you use authorized methods to maintain external process communications? | | | | | | | | Y | N | X |  |
|  | | | | | | | | | | | | |
|  | | | | | | | | | | | | |
|  | | | | | | | | | | | | |
| Answer each of the above questions. Three answers are possible: Y (yes), N (no), and X (eXclude). Y means you're in compliance,  N means you're not in compliance, while X means that this question can be excluded because it’s not applicable in your situation.  Y answers and X answers require no further action, while N answers point to things that need to be done to improve the  overall performance of your process. Also, please use the column on the right to record your notes, and in the spaces  below, enter the name and location of your organization, who completed this page, who reviewed it, and the dates. | | | | | | | | | | | | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 5.1 PLAN HOW YOU'RE GOING TO MEASURE YOUR PROCESS | | | | | | | | | | | |
| 5.1.1 figure out what needs to be measured | | | | | | | | | | | |
|  | Do you figure out what kind of process activities need to be measured? | | | | | | | Y | N | X |  |
|  |  | Do you figure out what kind of process characteristics need to be measured? | | | | | | Y | N | X |  |
|  | Do you figure out what kind of inputs and outputs need to be measured? | | | | | | | Y | N | X |  |
|  |  | Do you figure out what kind of output characteristics need to be measured? | | | | | | Y | N | X |  |
|  |  | Do you figure out what kind of input characteristics need to be measured? | | | | | | Y | N | X |  |
| 5.1.2 figure out how measurements will be done | | | | | | | | | | | |
|  | Do you plan how you're going to measure process elements? | | | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to measure your process outputs? | | | | | | Y | N | X |  |
|  |  | | Do you plan how you're going to measure your outputs against expectations? | | | | | Y | N | X |  |
|  |  | | | Do you plan how you're going to measure how well outputs implement plans? | | | | Y | N | X |  |
|  |  | | | Do you plan how you're going to measure how well outputs achieve objectives? | | | | Y | N | X |  |
|  |  | | | Do you plan how you're going to measure how well outputs meet requirements? | | | | Y | N | X |  |
|  |  | | | Do you plan how you're going to measure how well outputs comply with policies? | | | | Y | N | X |  |
|  |  | Do you plan how you're going to measure your process inputs? | | | | | | Y | N | X |  |
|  |  | | Do you plan how you're going to measure your inputs against expectations? | | | | | Y | N | X |  |
|  |  | | | Do you plan how you're going to measure how well inputs implement plans? | | | | Y | N | X |  |
|  |  | | | Do you plan how you're going to measure how well inputs achieve objectives? | | | | Y | N | X |  |
|  |  | | | Do you plan how you're going to measure how well inputs meet requirements? | | | | Y | N | X |  |
|  |  | | | Do you plan how you're going to measure how well inputs comply with policies? | | | | Y | N | X |  |
|  |  | Do you plan how you're going to measure your process activities? | | | | | | Y | N | X |  |
|  |  | | Do you plan how you're going to measure process management activities? | | | | | Y | N | X |  |
|  |  | | | Do you plan how to measure how well process management activities meet expectations? | | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process management activities apply policies? | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process management activities implement plans? | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process management activities follow procedures? | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process management activities achieve objectives? | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process management activities meet requirements? | | | Y | N | X |  |
|  |  | | Do you plan how you're going to measure process operating activities? | | | | | Y | N | X |  |
|  |  | | | Do you plan how to measure how well process operating activities meet expectations? | | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process operating activities apply policies? | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process operating activities implement plans? | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process operating activities follow procedures? | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process operating activities achieve objectives? | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process operating activities meet requirements? | | | Y | N | X |  |
|  |  | | Do you plan how you're going to measure process maintenance activities? | | | | | Y | N | X |  |
|  |  | | | Do you plan how to measure how well process maintenance activities meet expectations? | | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process maintenance activities apply policies? | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process maintenance activities implement plans? | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process maintenance activities follow procedures? | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process maintenance activities achieve objectives? | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process maintenance activities meet requirements? | | | Y | N | X |  |
|  |  | | Do you plan how you're going to measure process monitoring activities? | | | | | Y | N | X |  |
|  |  | | | Do you plan how to measure how well process monitoring activities meet expectations? | | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process monitoring activities apply policies? | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process monitoring activities implement plans? | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process monitoring activities follow procedures? | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process monitoring activities achieve objectives? | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process monitoring activities meet requirements? | | | Y | N | X |  |
|  |  | | Do you plan how you're going to measure process measurement activities? | | | | | Y | N | X |  |
|  |  | | | Do you plan how to measure how well process measurement activities meet expectations? | | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process measurement activities apply policies? | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process measurement activities implement plans? | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process measurement activities follow procedures? | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process measurement activities achieve objectives? | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process measurement activities meet requirements? | | | Y | N | X |  |
|  |  | | Do you plan how you're going to measure process control activities? | | | | | Y | N | X |  |
|  |  | | | Do you plan how to measure how well process control activities meet expectations? | | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process control activities apply policies? | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process control activities implement plans? | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process control activities follow procedures? | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process control activities achieve objectives? | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process control activities meet requirements? | | | Y | N | X |  |
|  |  | | Do you plan how you're going to measure process evaluation activities? | | | | | Y | N | X |  |
|  |  | | | Do you plan how you're going to measure process audit activities? | | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process audit activities meet expectations? | | | Y | N | X |  |
|  |  | | | | | Do you plan how to measure how well process audit activities apply policies? | | Y | N | X |  |
|  |  | | | | | Do you plan how to measure how well process audit activities implement plans? | | Y | N | X |  |
|  |  | | | | | Do you plan how to measure how well process audit activities follow procedures? | | Y | N | X |  |
|  |  | | | | | Do you plan how to measure how well process audit activities achieve objectives? | | Y | N | X |  |
|  |  | | | | | Do you plan how to measure how well process audit activities meet requirements? | | Y | N | X |  |
|  |  | | | Do you plan how you're going to measure process review activities? | | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process review activities meet expectations? | | | Y | N | X |  |
|  |  | | | | | Do you plan how to measure how well process review activities apply policies? | | Y | N | X |  |
|  |  | | | | | Do you plan how to measure how well process review activities implement plans? | | Y | N | X |  |
|  |  | | | | | Do you plan how to measure how well process review activities follow procedures? | | Y | N | X |  |
|  |  | | | | | Do you plan how to measure how well process review activities achieve objectives? | | Y | N | X |  |
|  |  | | | | | Do you plan how to measure how well process review activities meet requirements? | | Y | N | X |  |
|  |  | | Do you plan how you're going to measure process modification activities? | | | | | Y | N | X |  |
|  |  | | | Do you plan how you're going to measure process correction activities? | | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process correction activities meet expectations? | | | Y | N | X |  |
|  |  | | | | | Do you plan how to measure how well process correction activities apply policies? | | Y | N | X |  |
|  |  | | | | | Do you plan how to measure how well process correction activities implement plans? | | Y | N | X |  |
|  |  | | | | | Do you plan how to measure how well process correction activities follow procedures? | | Y | N | X |  |
|  |  | | | | | Do you plan how to measure how well process correction activities achieve objectives? | | Y | N | X |  |
|  |  | | | | | Do you plan how to measure how well process correction activities meet requirements? | | Y | N | X |  |
|  |  | | | Do you plan how you're going to measure process improvement activities? | | | | Y | N | X |  |
|  |  | | | | Do you plan how to measure how well process improvement activities meet expectations? | | | Y | N | X |  |
|  |  | | | | | Do you plan how to measure how well process improvement activities apply policies? | | Y | N | X |  |
|  |  | | | | | Do you plan how to measure how well process improvement activities implement plans? | | Y | N | X |  |
|  |  | | | | | Do you plan how to measure how well process improvement activities follow procedures? | | Y | N | X |  |
|  |  | | | | | Do you plan how to measure how well process improvement activities achieve objectives? | | Y | N | X |  |
|  |  | | | | | Do you plan how to measure how well process improvement activities meet requirements? | | Y | N | X |  |
|  | Do you plan how you're going to measure customer satisfaction? | | | | | | | Y | N | X |  |
|  |  | Learn how your process customers feel about your process outputs? | | | | | | Y | N | X |  |
|  |  | | Do you figure out how to gather information about customer satisfaction? | | | | | Y | N | X |  |
|  |  | | | Do you figure out how to learn about customer satisfaction by doing customer surveys? | | | | Y | N | X |  |
|  |  | | | Do you figure out how to learn about customer satisfaction by using face-to-face meetings? | | | | Y | N | X |  |
|  |  | | | Do you figure out how to learn about customer satisfaction by studying customer feedback? | | | | Y | N | X |  |
|  |  | | Do you figure out how to use information to evaluate customer satisfaction? | | | | | Y | N | X |  |
|  |  | | | Do you figure out how to use output information to evaluate customer satisfaction? | | | | Y | N | X |  |
|  |  | | | Do you figure out how to use delivery information to evaluate customer satisfaction? | | | | Y | N | X |  |
|  |  | | | Do you figure out how to use post-delivery information to evaluate customer satisfaction? | | | | Y | N | X |  |
|  |  | | | Do you figure out how to use corrective action information to evaluate customer satisfaction? | | | | Y | N | X |  |
| 5.1.3 figure out who will perform measurement tasks | | | | | | | | | | | |
|  | Do you allocate responsibility and authority for measuring customer satisfaction? | | | | | | | Y | N | X |  |
|  |  | Do you allocate responsibility and authority for carrying out customer surveys? | | | | | | Y | N | X |  |
|  |  | Do you allocate responsibility and authority for meeting with process customers? | | | | | | Y | N | X |  |
|  |  | Do you allocate responsibility and authority for studying feedback from customers? | | | | | | Y | N | X |  |
|  | Do you allocate responsibility and authority for measuring process elements? | | | | | | | Y | N | X |  |
|  |  | Do you allocate responsibility and authority for measuring process outputs? | | | | | | Y | N | X |  |
|  |  | Do you allocate responsibility and authority for measuring process inputs? | | | | | | Y | N | X |  |
|  |  | Do you allocate responsibility and authority for measuring process activities? | | | | | | Y | N | X |  |
|  |  | | Do you allocate responsibility and authority for measuring process control activities? | | | | | Y | N | X |  |
|  |  | | Do you allocate responsibility and authority for measuring process operating activities? | | | | | Y | N | X |  |
|  |  | | Do you allocate responsibility and authority for measuring process maintenance activities? | | | | | Y | N | X |  |
|  |  | | Do you allocate responsibility and authority for measuring process measurement activities? | | | | | Y | N | X |  |
|  |  | | Do you allocate responsibility and authority for measuring process monitoring activities? | | | | | Y | N | X |  |
|  |  | | Do you allocate responsibility and authority for measuring process evaluation activities? | | | | | Y | N | X |  |
|  |  | | | Do you allocate responsibility and authority for measuring process audit activities? | | | | Y | N | X |  |
|  |  | | | Do you allocate responsibility and authority for measuring process review activities? | | | | Y | N | X |  |
|  |  | | Do you allocate responsibility and authority for measuring process modification activities? | | | | | Y | N | X |  |
|  |  | | | Do you allocate responsibility and authority for measuring process correction activities? | | | | Y | N | X |  |
|  |  | | | Do you allocate responsibility and authority for measuring process improvement activities? | | | | Y | N | X |  |
| 5.2 QUALIFY THE RESOURCES NEEDED TO MEASURE PROCESS | | | | | | | | | | | |
|  | Do you select measurement resources that are fit for purpose? | | | | | | | Y | N | X |  |
|  |  | Do you select measurement resources that will yield valid and reliable results? | | | | | | Y | N | X |  |
|  |  | | Do you select measurement resources that will ensure that outputs meet requirements? | | | | | Y | N | X |  |
|  | Do you validate measurement resources before you use them? | | | | | | | Y | N | X |  |
|  |  | Do you validate resources that are used to measure process? | | | | | | Y | N | X |  |
|  |  | | Do you validate software before it is used to measure process? | | | | | Y | N | X |  |
|  |  | | Do you validate tools before they are used to measure process? | | | | | Y | N | X |  |
|  |  | | Do you validate equipment before it is used to measure process? | | | | | Y | N | X |  |
| 5.3 PROVIDE THE RESOURCES NEEDED TO MEASURE PROCESS | | | | | | | | | | | |
| 5.3.1 provide the expertise needed to measure your process | | | | | | | | | | | |
|  | Do you provide the expertise needed to ensure that  measuring methods will yield valid and reliable results? | | | | | | | Y | N | X |  |
|  |  | Do you provide the managers needed to measure your process? | | | | | | Y | N | X |  |
|  |  | | Do you acquire the knowledge that process managers  need to support process measurement activities? | | | | | Y | N | X |  |
|  |  | | | Do you ensure that process managers get the knowledge  they need to support process measurement activities? | | | | Y | N | X |  |
|  |  | | | | Do you deliver suitable training and awareness programmes  for managers of process measurement activities? | | | Y | N | X |  |
|  |  | Do you provide the personnel needed to measure your process? | | | | | | Y | N | X |  |
|  |  | | Do you acquire the knowledge that personnel need to measure your process? | | | | | Y | N | X |  |
|  |  | | | Do you consider internal sources of knowledge about process measurement? | | | | Y | N | X |  |
|  |  | | | Do you consider external sources of knowledge about process measurement? | | | | Y | N | X |  |
|  |  | | Do you ensure that personnel get the knowledge they need to measure your process? | | | | | Y | N | X |  |
|  |  | | | Do you deliver suitable training and awareness programmes for measuring personnel? | | | | Y | N | X |  |
| 5.3.2 provide the technology needed to measure your process | | | | | | | | | | | |
|  | Do you provide the technology needed to ensure that  measurement methods yield valid and reliable results? | | | | | | | Y | N | X |  |
|  |  | Do you provide the software needed to measure your process? | | | | | | Y | N | X |  |
|  |  | | Do you provide the software needed to support process measurement activities? | | | | | Y | N | X |  |
|  |  | Do you provide the hardware needed to measure your process? | | | | | | Y | N | X |  |
|  |  | | Do you provide the hardware needed to support process measurement activities? | | | | | Y | N | X |  |
|  |  | | | Do you provide the tools and equipment needed to measure your process? | | | | Y | N | X |  |
| 5.3.3 provide the infrastructure needed to measure your process | | | | | | | | | | | |
|  | Do you provide the infrastructure needed to ensure that  measurement methods yield valid and reliable results? | | | | | | | Y | N | X |  |
|  |  | Do you provide the infrastructure needed to support  process measurement and achieve conformity of outputs? | | | | | | Y | N | X |  |
| 5.4 USE AUTHORIZED METHODS TO MEASURE YOUR PROCESS | | | | | | | | | | | |
| 5.4.1 use authorized methods to measure process elements | | | | | | | | | | | |
|  | Do you use authorized methods to measure process outputs? | | | | | | | Y | N | X |  |
|  |  | Do you measure your outputs against expectations? | | | | | | Y | N | X |  |
|  |  | | Do you measure how well outputs meet requirements? | | | | | Y | N | X |  |
|  |  | | Do you measure how well outputs achieve objectives? | | | | | Y | N | X |  |
|  |  | | Do you measure how well outputs implement plans? | | | | | Y | N | X |  |
|  | Do you use authorized methods to measure process inputs? | | | | | | | Y | N | X |  |
|  |  | Do you measure your inputs against expectations? | | | | | | Y | N | X |  |
|  |  | | Do you measure how well inputs meet requirements? | | | | | Y | N | X |  |
|  |  | | Do you measure how well inputs achieve objectives? | | | | | Y | N | X |  |
|  |  | | Do you measure how well inputs implement plans? | | | | | Y | N | X |  |
|  | Do you use authorized methods to measure process activities? | | | | | | | Y | N | X |  |
|  |  | Do you use authorized methods to measure process operating activities? | | | | | | Y | N | X |  |
|  |  | | Do you measure how well process operating activities meet expectations? | | | | | Y | N | X |  |
|  |  | | | Do you measure how well process operating activities apply policies? | | | | Y | N | X |  |
|  |  | | | Do you measure how well process operating activities implement plans? | | | | Y | N | X |  |
|  |  | | | Do you measure how well process operating activities follow procedures? | | | | Y | N | X |  |
|  |  | | | Do you measure how well process operating activities achieve objectives? | | | | Y | N | X |  |
|  |  | | | Do you measure how well process operating activities comply with requirements? | | | | Y | N | X |  |
|  |  | Do you use authorized methods to measure process maintenance activities? | | | | | | Y | N | X |  |
|  |  | | Do you measure how well process maintenance activities meet expectations? | | | | | Y | N | X |  |
|  |  | | | Do you measure how well process maintenance activities apply policies? | | | | Y | N | X |  |
|  |  | | | Do you measure how well process maintenance activities implement plans? | | | | Y | N | X |  |
|  |  | | | Do you measure how well process maintenance activities follow procedures? | | | | Y | N | X |  |
|  |  | | | Do you measure how well process maintenance activities achieve objectives? | | | | Y | N | X |  |
|  |  | | | Do you measure how well process maintenance activities comply with requirements? | | | | Y | N | X |  |
|  |  | Do you use authorized methods to measure process measurement activities? | | | | | | Y | N | X |  |
|  |  | | Do you measure how well process measurement activities meet expectations? | | | | | Y | N | X |  |
|  |  | | | Do you measure how well process measurement activities apply policies? | | | | Y | N | X |  |
|  |  | | | Do you measure how well process measurement activities implement plans? | | | | Y | N | X |  |
|  |  | | | Do you measure how well process measurement activities follow procedures? | | | | Y | N | X |  |
|  |  | | | Do you measure how well process measurement activities achieve objectives? | | | | Y | N | X |  |
|  |  | | | Do you measure how well process measurement activities comply with requirements? | | | | Y | N | X |  |
|  |  | Do you use authorized methods to measure process monitoring activities? | | | | | | Y | N | X |  |
|  |  | | Do you measure how well process monitoring activities meet expectations? | | | | | Y | N | X |  |
|  |  | | | Do you measure how well process monitoring activities apply policies? | | | | Y | N | X |  |
|  |  | | | Do you measure how well process monitoring activities implement plans? | | | | Y | N | X |  |
|  |  | | | Do you measure how well process monitoring activities follow procedures? | | | | Y | N | X |  |
|  |  | | | Do you measure how well process monitoring activities achieve objectives? | | | | Y | N | X |  |
|  |  | | | Do you measure how well process monitoring activities comply with requirements? | | | | Y | N | X |  |
|  |  | Do you use authorized methods to measure process control activities? | | | | | | Y | N | X |  |
|  |  | | Do you measure how well process control activities meet expectations? | | | | | Y | N | X |  |
|  |  | | | Do you measure how well process control activities apply policies? | | | | Y | N | X |  |
|  |  | | | Do you measure how well process control activities implement plans? | | | | Y | N | X |  |
|  |  | | | Do you measure how well process control activities follow procedures? | | | | Y | N | X |  |
|  |  | | | Do you measure how well process control activities achieve objectives? | | | | Y | N | X |  |
|  |  | | | Do you measure how well process control activities comply with requirements? | | | | Y | N | X |  |
|  |  | Do you use authorized methods to measure process evaluation activities? | | | | | | Y | N | X |  |
|  |  | | Do you use authorized methods to measure process audit activities? | | | | | Y | N | X |  |
|  |  | | | Do you measure how well process audit activities meet expectations? | | | | Y | N | X |  |
|  |  | | | | Do you measure how well process audit activities apply policies? | | | Y | N | X |  |
|  |  | | | | Do you measure how well process audit activities implement plans? | | | Y | N | X |  |
|  |  | | | | Do you measure how well process audit activities follow procedures? | | | Y | N | X |  |
|  |  | | | | Do you measure how well process audit activities achieve objectives? | | | Y | N | X |  |
|  |  | | | | Do you measure how well process audit activities comply with requirements? | | | Y | N | X |  |
|  |  | | Do you use authorized methods to measure process review activities? | | | | | Y | N | X |  |
|  |  | | | Do you measure how well process review activities meet expectations? | | | | Y | N | X |  |
|  |  | | | | Do you measure how well process review activities apply policies? | | | Y | N | X |  |
|  |  | | | | Do you measure how well process review activities implement plans? | | | Y | N | X |  |
|  |  | | | | Do you measure how well process review activities follow procedures? | | | Y | N | X |  |
|  |  | | | | Do you measure how well process review activities achieve objectives? | | | Y | N | X |  |
|  |  | | | | Do you measure how well process review activities comply with requirements? | | | Y | N | X |  |
|  |  | Do you use authorized methods to measure process modification activities? | | | | | | Y | N | X |  |
|  |  | | Do you use authorized methods to measure process correction activities? | | | | | Y | N | X |  |
|  |  | | | Do you measure how well process correction activities meet expectations? | | | | Y | N | X |  |
|  |  | | | | Do you measure how well process correction activities apply policies? | | | Y | N | X |  |
|  |  | | | | Do you measure how well process correction activities implement plans? | | | Y | N | X |  |
|  |  | | | | Do you measure how well process correction activities follow procedures? | | | Y | N | X |  |
|  |  | | | | Do you measure how well process correction activities achieve objectives? | | | Y | N | X |  |
|  |  | | | | Do you measure how well process correction activities comply with requirements? | | | Y | N | X |  |
|  |  | | Do you use authorized methods to measure process improvement activities? | | | | | Y | N | X |  |
|  |  | | | Do you measure how well process improvement activities meet expectations? | | | | Y | N | X |  |
|  |  | | | | Do you measure how well process improvement activities apply policies? | | | Y | N | X |  |
|  |  | | | | Do you measure how well process improvement activities implement plans? | | | Y | N | X |  |
|  |  | | | | Do you measure how well process improvement activities follow procedures? | | | Y | N | X |  |
|  |  | | | | Do you measure how well process improvement activities achieve objectives? | | | Y | N | X |  |
|  |  | | | | Do you measure how well process improvement activities comply with requirements? | | | Y | N | X |  |
| 5.4.2 use authorized methods to measure process performance | | | | | | | | | | | |
|  | Do you use authorized methods to measure the performance of process personnel? | | | | | | | Y | N | X |  |
|  |  | Do you measure the competence and effectiveness of your process personnel? | | | | | | Y | N | X |  |
|  |  | | Do you measure the process knowledge and skill that has been acquired? | | | | | Y | N | X |  |
|  |  | Do you measure how well process personnel meet process expectations? | | | | | | Y | N | X |  |
|  |  | | Do you measure how well process personnel apply process policies? | | | | | Y | N | X |  |
|  |  | | Do you measure how well process personnel implement process plans? | | | | | Y | N | X |  |
|  |  | | Do you measure how well process personnel follow process procedures? | | | | | Y | N | X |  |
|  |  | | Do you measure how well process personnel meet process requirements? | | | | | Y | N | X |  |
|  |  | | Do you measure how well process personnel achieve process objectives? | | | | | Y | N | X |  |
|  |  | | | Do you measure how well process personnel achieve safety objectives? | | | | Y | N | X |  |
|  |  | | | Do you measure how well process personnel achieve quality objectives? | | | | Y | N | X |  |
|  |  | | | Do you measure how well process personnel achieve security objectives? | | | | Y | N | X |  |
|  |  | | | Do you measure how well process personnel achieve business objectives? | | | | Y | N | X |  |
|  |  | | | Do you measure how well process personnel achieve technical objectives? | | | | Y | N | X |  |
|  |  | | | Do you measure how well process personnel achieve continuity objectives? | | | | Y | N | X |  |
|  |  | | | Do you measure how well process personnel achieve environmental objectives? | | | | Y | N | X |  |
|  | Do you use authorized methods to measure the performance of process management? | | | | | | | Y | N | X |  |
|  |  | Do you use authorized methods to measure process management activities? | | | | | | Y | N | X |  |
|  |  | | Do you measure how well process management activities meet expectations? | | | | | Y | N | X |  |
|  |  | | | Do you measure how well process management activities apply policies? | | | | Y | N | X |  |
|  |  | | | Do you measure how well process management activities implement plans? | | | | Y | N | X |  |
|  |  | | | Do you measure how well process management activities follow procedures? | | | | Y | N | X |  |
|  |  | | | Do you measure how well process management activities meet requirements? | | | | Y | N | X |  |
|  |  | | | Do you measure how well process management activities achieve objectives? | | | | Y | N | X |  |
|  |  | | | | Do you measure how well process managers achieve safety objectives? | | | Y | N | X |  |
|  |  | | | | Do you measure how well process managers achieve quality objectives? | | | Y | N | X |  |
|  |  | | | | Do you measure how well process managers achieve security objectives? | | | Y | N | X |  |
|  |  | | | | Do you measure how well process managers achieve business objectives? | | | Y | N | X |  |
|  |  | | | | Do you measure how well process managers achieve technical objectives? | | | Y | N | X |  |
|  |  | | | | Do you measure how well process managers achieve continuity objectives? | | | Y | N | X |  |
|  |  | | | | Do you measure how well process managers achieve environmental objectives? | | | Y | N | X |  |
|  |  | Do you use authorized methods to measure process management programmes? | | | | | | Y | N | X |  |
|  |  | | Do you use authorized methods to measure your risk management programme? | | | | | Y | N | X |  |
|  |  | | Do you use authorized methods to measure your safety management programme? | | | | | Y | N | X |  |
|  |  | | Do you use authorized methods to measure your quality management programme? | | | | | Y | N | X |  |
|  |  | | | Do you use authorized methods to measure configuration management programme? | | | | Y | N | X |  |
|  |  | | Do you use authorized methods to measure your security management programme? | | | | | Y | N | X |  |
|  |  | | | Do you use authorized methods to measure personnel security management programme? | | | | Y | N | X |  |
|  |  | | | Do you use authorized methods to measure information management programme? | | | | Y | N | X |  |
|  |  | | | Do you use authorized methods to measure component management programme? | | | | Y | N | X |  |
|  |  | | | | Do you use authorized methods to measure counterfeit parts management programme? | | | Y | N | X |  |
|  |  | | Do you use authorized methods to measure your supplier management programme? | | | | | Y | N | X |  |
|  |  | | Do you use authorized methods to measure your environmental management programme? | | | | | Y | N | X |  |
|  |  | | Do you use authorized methods to measure your business continuity management programme? | | | | | Y | N | X |  |
|  | Do you use authorized methods to measure external providers? | | | | | | | Y | N | X |  |
|  |  | Do you use authorized criteria to measure the performance of external providers? | | | | | | Y | N | X |  |
|  |  | | Do you measure the performance of external process, product, and service providers? | | | | | Y | N | X |  |
|  |  | | | Do you use data and criteria to measure the performance of your external providers? | | | | Y | N | X |  |
|  |  | | | | Do you document performance measuring activities and retain these documents? | | | Y | N | X |  |
|  |  | | | | | Do you control documents that describe your performance measuring activities? | | Y | N | X |  |
|  |  | | Do you measure external process, product, and service verification activities? | | | | | Y | N | X |  |
|  |  | | | Do you measure verifications whenever they are delegated to external providers? | | | | Y | N | X |  |
|  | Do you use authorized methods to measure internal providers? | | | | | | | Y | N | X |  |
|  |  | Do you use authorized criteria to measure the performance of internal providers? | | | | | | Y | N | X |  |
| 5.5 CONTROL THE RESOURCES NEEDED TO MEASURE PROCESS | | | | | | | | | | | |
| 5.5.1 control the documents needed to measure your process | | | | | | | | | | | |
|  | Do you control the procedures needed to measure your process and its outputs? | | | | | | | Y | N | X |  |
|  | Do you control the instructions needed to measure your process and its outputs? | | | | | | | Y | N | X |  |
|  | Do you control the manuals needed to measure your process and its outputs? | | | | | | | Y | N | X |  |
| 5.5.2 control the technology needed to measure your process | | | | | | | | | | | |
|  | Do you control the software needed to measure your process and its outputs? | | | | | | | Y | N | X |  |
|  | Do you control the hardware needed to measure your process and its outputs? | | | | | | | Y | N | X |  |
|  |  | Do you control the tools needed to measure your process and its outputs? | | | | | | Y | N | X |  |
|  |  | Do you control the equipment needed to measure your process and its outputs? | | | | | | Y | N | X |  |
| 5.5.3 control the records needed to measure your process | | | | | | | | | | | |
|  | Do you establish records for process measurement activities and resources? | | | | | | | Y | N | X |  |
|  |  | Do you use records to control your process measuring activities and resources? | | | | | | Y | N | X |  |
|  |  | | Do you establish a register of process measurement activities and resources? | | | | | Y | N | X |  |
|  |  | | | Do you use register to record the identity of measurement resources? | | | | Y | N | X |  |
|  |  | | | | Do you use your register to describe the type or kind of resources being used? | | | Y | N | X |  |
|  |  | | | | | Do you use your register to describe your test hardware and software? | | Y | N | X |  |
|  |  | | | | | Do you use your register to document automated test equipment (ATE)? | | Y | N | X |  |
|  |  | | | | | Do you use your register to identify plotters used to produce verification data? | | Y | N | X |  |
|  |  | | | | | Do you use your register to list equipment used to provide evidence of conformity? | | Y | N | X |  |
|  |  | | | | | | Do you use register to list personally owned equipment used to verify conformity? | Y | N | X |  |
|  |  | | | | | | Do you use register to list customer supplied equipment used to verify conformity? | Y | N | X |  |
|  |  | | | | Do you use your register to specify a unique identifier for each piece of equipment? | | | Y | N | X |  |
|  |  | | | Do you use register to specify the location of your measurement tools and equipment? | | | | Y | N | X |  |
|  |  | | | Do you use register to control the calibration of your measurement tools and equipment? | | | | Y | N | X |  |
|  |  | | | | Do you use your register to record calibration or verification methods and results? | | | Y | N | X |  |
|  |  | | | | | Do you use your register to record calibration or verification acceptance criteria? | | Y | N | X |  |
|  |  | | | | Do you use your register to specify equipment calibration or verification frequency? | | | Y | N | X |  |
|  |  | | Do you maintain a register of your process measurement activities and resources? | | | | | Y | N | X |  |
|  |  | | | Do you maintain records that show that measurement resources are still fit for purpose? | | | | Y | N | X |  |
|  |  | | | | Do you control records that show that measurement resources are still fit for purpose? | | | Y | N | X |  |
|  |  | Do you use records to keep track of measurement activities and resources? | | | | | | Y | N | X |  |
|  |  | | Do you establish suitable measurement traceability methods? | | | | | Y | N | X |  |
|  |  | | | Do you maintain suitable measurement traceability resources? | | | | Y | N | X |  |
|  |  | | Do you establish recall methods for your measurement equipment? | | | | | Y | N | X |  |
|  |  | | | Do you implement recall methods for your measurement equipment? | | | | Y | N | X |  |
|  |  | | | | Do you recall measurement equipment that must be verified or calibrated? | | | Y | N | X |  |
|  |  | | | Do you maintain recall records for your process measurement equipment? | | | | Y | N | X |  |
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| Answer each of the above questions. Three answers are possible: Y (yes), N (no), and X (eXclude). Y means you're in compliance,  N means you're not in compliance, while X means that this question can be excluded because it’s not applicable in your situation.  Y answers and X answers require no further action, while N answers point to things that need to be done to improve the  overall performance of your process. Also, please use the column on the right to record your notes, and in the spaces  below, 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 MONITOR YOUR PROCESS | | | | | | | | | | |
| 6.1.1 figure out what needs to be monitored | | | | | | | | | | |
|  | Do you figure out what kind of policies and plans need to be monitored? | | | | | | Y | N | X |  |
|  | Do you figure out what kind of practices and procedures need to be monitored? | | | | | | Y | N | X |  |
|  | Do you figure out what kind of issues, factors, and concerns need to be monitored? | | | | | | Y | N | X |  |
|  |  | Do you figure out what kind of internal issues and factors need to be monitored? | | | | | Y | N | X |  |
|  |  | Do you figure out what kind of external issues and factors need to be monitored? | | | | | Y | N | X |  |
|  | Do you figure out what kind of participants and providers need to be monitored? | | | | | | Y | N | X |  |
|  |  | Do you figure out what kind of process participants need to be monitored? | | | | | Y | N | X |  |
|  |  | | Do you figure out what kind of process managers need to be monitored? | | | | Y | N | X |  |
|  |  | | Do you figure out what kind of process personnel need to be monitored? | | | | Y | N | X |  |
|  |  | Do you figure out what kind of process providers need to be monitored? | | | | | Y | N | X |  |
|  |  | | Do you figure out what kind of internal process providers need to be monitored? | | | | Y | N | X |  |
|  |  | | Do you figure out what kind of external process providers need to be monitored? | | | | Y | N | X |  |
|  | Do you figure out what kind of process inputs and outputs need to be monitored? | | | | | | Y | N | X |  |
|  |  | Do you figure out what kind of output characteristics need to be monitored? | | | | | Y | N | X |  |
|  |  | Do you figure out what kind of input characteristics need to be monitored? | | | | | Y | N | X |  |
|  | Do you figure out what kind of internal process resources need to be monitored? | | | | | | Y | N | X |  |
|  |  | Do you figure out what kind of data and information needs to be monitored? | | | | | Y | N | X |  |
|  |  | Do you figure out what kind of documents and records need to be monitored? | | | | | Y | N | X |  |
|  |  | Do you figure out what kind of hardware and software needs to be monitored? | | | | | Y | N | X |  |
|  |  | Do you figure out what kind of parts and components need to be monitored? | | | | | Y | N | X |  |
|  |  | Do you figure out what kind of products and services need to be monitored? | | | | | Y | N | X |  |
|  |  | Do you figure out what kind of property and supplies need to be monitored? | | | | | Y | N | X |  |
| 6.1.2 figure out how monitoring will be done | | | | | | | | | | |
|  | Do you plan how you're going to monitor customer satisfaction? | | | | | | Y | N | X |  |
|  |  | Do you plan how to monitor customer feelings about process outputs? | | | | | Y | N | X |  |
|  |  | | Do you plan how to monitor information about customer satisfaction? | | | | Y | N | X |  |
|  | Do you plan how you're going to monitor process performance? | | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to monitor process outputs? | | | | | Y | N | X |  |
|  |  | | Do you plan how you're going to monitor output deliveries? | | | | Y | N | X |  |
|  |  | | | Do you plan how to monitor post-delivery performance? | | | Y | N | X |  |
|  |  | | Do you plan how you're going to monitor output characteristics? | | | | Y | N | X |  |
|  |  | Do you plan how you're going to monitor process activities? | | | | | Y | N | X |  |
|  |  | | Do you plan how you're going to monitor process management activities? | | | | Y | N | X |  |
|  |  | | | Do you plan how to monitor how well process management activities meet expectations? | | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process management activities apply policies? | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process management activities implement plans? | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process management activities follow procedures? | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process management activities achieve objectives? | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process management activities meet requirements? | | Y | N | X |  |
|  |  | | Do you plan how you're going to monitor process operating activities? | | | | Y | N | X |  |
|  |  | | | Do you plan how to monitor how well process operating activities meet expectations? | | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process operating activities apply policies? | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process operating activities implement plans? | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process operating activities follow procedures? | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process operating activities achieve objectives? | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process operating activities meet requirements? | | Y | N | X |  |
|  |  | | Do you plan how you're going to monitor process maintenance activities? | | | | Y | N | X |  |
|  |  | | | Do you plan how to monitor how well process maintenance activities meet expectations? | | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process maintenance activities apply policies? | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process maintenance activities implement plans? | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process maintenance activities follow procedures? | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process maintenance activities achieve objectives? | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process maintenance activities meet requirements? | | Y | N | X |  |
|  |  | | Do you plan how you're going to monitor process monitoring activities? | | | | Y | N | X |  |
|  |  | | | Do you plan how to monitor how well process monitoring activities meet expectations? | | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process monitoring activities apply policies? | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process monitoring activities implement plans? | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process monitoring activities follow procedures? | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process monitoring activities achieve objectives? | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process monitoring activities meet requirements? | | Y | N | X |  |
|  |  | | Do you plan how you're going to monitor process measurement activities? | | | | Y | N | X |  |
|  |  | | | Do you plan how to monitor how well process measurement activities meet expectations? | | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process measurement activities apply policies? | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process measurement activities implement plans? | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process measurement activities follow procedures? | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process measurement activities achieve objectives? | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process measurement activities meet requirements? | | Y | N | X |  |
|  |  | | Do you plan how you're going to monitor process control activities? | | | | Y | N | X |  |
|  |  | | | Do you plan how to monitor how well process control activities meet expectations? | | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process control activities apply policies? | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process control activities implement plans? | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process control activities follow procedures? | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process control activities achieve objectives? | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process control activities meet requirements? | | Y | N | X |  |
|  |  | | Do you plan how you're going to monitor process evaluation activities? | | | | Y | N | X |  |
|  |  | | | Do you plan how you're going to monitor process audit activities? | | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process audit activities meet expectations? | | Y | N | X |  |
|  |  | | | | | Do you plan how to monitor how well process audit activities apply policies? | Y | N | X |  |
|  |  | | | | | Do you plan how to monitor how well process audit activities implement plans? | Y | N | X |  |
|  |  | | | | | Do you plan how to monitor how well process audit activities follow procedures? | Y | N | X |  |
|  |  | | | | | Do you plan how to monitor how well process audit activities achieve objectives? | Y | N | X |  |
|  |  | | | | | Do you plan how to monitor how well process audit activities meet requirements? | Y | N | X |  |
|  |  | | | Do you plan how you're going to monitor process review activities? | | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process review activities meet expectations? | | Y | N | X |  |
|  |  | | | | | Do you plan how to monitor how well process review activities apply policies? | Y | N | X |  |
|  |  | | | | | Do you plan how to monitor how well process review activities implement plans? | Y | N | X |  |
|  |  | | | | | Do you plan how to monitor how well process review activities follow procedures? | Y | N | X |  |
|  |  | | | | | Do you plan how to monitor how well process review activities achieve objectives? | Y | N | X |  |
|  |  | | | | | Do you plan how to monitor how well process review activities meet requirements? | Y | N | X |  |
|  |  | | Do you plan how you're going to monitor process modification activities? | | | | Y | N | X |  |
|  |  | | | Do you plan how you're going to monitor process correction activities? | | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process correction activities meet expectations? | | Y | N | X |  |
|  |  | | | | | Do you plan how to monitor how well process correction activities apply policies? | Y | N | X |  |
|  |  | | | | | Do you plan how to monitor how well process correction activities implement plans? | Y | N | X |  |
|  |  | | | | | Do you plan how to monitor how well process correction activities follow procedures? | Y | N | X |  |
|  |  | | | | | Do you plan how to monitor how well process correction activities achieve objectives? | Y | N | X |  |
|  |  | | | | | Do you plan how to monitor how well process correction activities meet requirements? | Y | N | X |  |
|  |  | | | Do you plan how you're going to monitor process improvement activities? | | | Y | N | X |  |
|  |  | | | | Do you plan how to monitor how well process improvement activities meet expectations? | | Y | N | X |  |
|  |  | | | | | Do you plan how to monitor how well process improvement activities apply policies? | Y | N | X |  |
|  |  | | | | | Do you plan how to monitor how well process improvement activities implement plans? | Y | N | X |  |
|  |  | | | | | Do you plan how to monitor how well process improvement activities follow procedures? | Y | N | X |  |
|  |  | | | | | Do you plan how to monitor how well process improvement activities achieve objectives? | Y | N | X |  |
|  |  | | | | | Do you plan how to monitor how well process improvement activities meet requirements? | Y | N | X |  |
|  | Do you plan how you're going to monitor process resources? | | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to monitor process parts? | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to monitor process plans? | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to monitor process policies? | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to monitor process supplies? | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to monitor process hardware? | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to monitor process software? | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to monitor process services? | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to monitor process products? | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to monitor process property? | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to monitor process providers? | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to monitor process documents? | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to monitor process components? | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to monitor process infrastructure? | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to monitor process participants? | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to monitor process procedures? | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to monitor process practices? | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to monitor process records? | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to monitor process inputs? | | | | | Y | N | X |  |
|  |  | | Do you plan how you're going to monitor internal process inputs? | | | | Y | N | X |  |
|  |  | | Do you plan how you're going to monitor external process inputs? | | | | Y | N | X |  |
|  |  | | | Do you plan how you're going to monitor reports about counterfeit parts? | | | Y | N | X |  |
|  |  | Do you plan how you're going to monitor process technologies? | | | | | Y | N | X |  |
|  |  | | Do you plan how you're going to monitor process tools and equipment? | | | | Y | N | X |  |
|  |  | | | Do you plan how you're going to monitor process monitoring tools and equipment? | | | Y | N | X |  |
|  |  | | | | Do you plan how you're going to recall monitoring tools  and equipment that must be recalibrated or reverified? | | Y | N | X |  |
|  |  | | | Do you plan how you're going to monitor process measurement tools and equipment? | | | Y | N | X |  |
|  |  | | | | Do you plan how you're going to recall measurement tools  and equipment that must be recalibrated or reverified? | | Y | N | X |  |
|  | Do you plan how you're going to monitor process environment? | | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to monitor your process's external context? | | | | | Y | N | X |  |
|  |  | | Do you figure out how you're going to monitor the external  issues and factors that could affect your process? | | | | Y | N | X |  |
|  |  | | Do you figure out how you're going to monitor the external  interested parties that could affect your process? | | | | Y | N | X |  |
|  |  | Do you plan how you're going to monitor your process's internal context? | | | | | Y | N | X |  |
|  |  | | Do you figure out how you're going to monitor the internal  issues and factors that could affect your process? | | | | Y | N | X |  |
|  |  | | Do you figure out how you're going to monitor the internal  interested parties that could affect your process? | | | | Y | N | X |  |
| 6.1.3 figure out who will perform monitoring tasks | | | | | | | | | | |
|  | Do you allocate responsibility and authority for monitoring process plans? | | | | | | Y | N | X |  |
|  | Do you allocate responsibility and authority for monitoring process policies? | | | | | | Y | N | X |  |
|  | Do you allocate responsibility and authority for monitoring process outputs? | | | | | | Y | N | X |  |
|  | Do you allocate responsibility and authority for monitoring process supplies? | | | | | | Y | N | X |  |
|  | Do you allocate responsibility and authority for monitoring process materials? | | | | | | Y | N | X |  |
|  | Do you allocate responsibility and authority for monitoring process hardware? | | | | | | Y | N | X |  |
|  | Do you allocate responsibility and authority for monitoring process software? | | | | | | Y | N | X |  |
|  | Do you allocate responsibility and authority for monitoring process services? | | | | | | Y | N | X |  |
|  | Do you allocate responsibility and authority for monitoring process products? | | | | | | Y | N | X |  |
|  | Do you allocate responsibility and authority for monitoring process property? | | | | | | Y | N | X |  |
|  | Do you allocate responsibility and authority for monitoring process providers? | | | | | | Y | N | X |  |
|  | Do you allocate responsibility and authority for monitoring process objectives? | | | | | | Y | N | X |  |
|  | Do you allocate responsibility and authority for monitoring process documents? | | | | | | Y | N | X |  |
|  | Do you allocate responsibility and authority for monitoring process participants? | | | | | | Y | N | X |  |
|  | Do you allocate responsibility and authority for monitoring process components? | | | | | | Y | N | X |  |
|  | Do you allocate responsibility and authority for monitoring process technologies? | | | | | | Y | N | X |  |
|  | Do you allocate responsibility and authority for monitoring process characteristics? | | | | | | Y | N | X |  |
|  | Do you allocate responsibility and authority for monitoring process requirements? | | | | | | Y | N | X |  |
|  | Do you allocate responsibility and authority for monitoring process infrastructure? | | | | | | Y | N | X |  |
|  | Do you allocate responsibility and authority for monitoring process environment? | | | | | | Y | N | X |  |
|  | Do you allocate responsibility and authority for monitoring process procedures? | | | | | | Y | N | X |  |
|  | Do you allocate responsibility and authority for monitoring process practices? | | | | | | Y | N | X |  |
|  | Do you allocate responsibility and authority for monitoring process records? | | | | | | Y | N | X |  |
|  | Do you allocate responsibility and authority for monitoring process parties? | | | | | | Y | N | X |  |
|  | Do you allocate responsibility and authority for monitoring process inputs? | | | | | | Y | N | X |  |
| 6.2 QUALIFY THE RESOURCES NEEDED TO MONITOR PROCESS | | | | | | | | | | |
|  | Do you select monitoring resources that are fit for purpose? | | | | | | Y | N | X |  |
|  |  | Do you select monitoring resources that will yield valid and reliable results? | | | | | Y | N | X |  |
|  |  | | Do you select resources that will help ensure that outputs meet requirements? | | | | Y | N | X |  |
|  | Do you validate monitoring resources before you use them? | | | | | | Y | N | X |  |
|  |  | Do you validate tools before they are used to monitor process? | | | | | Y | N | X |  |
|  |  | Do you validate equipment before it is used to monitor process? | | | | | Y | N | X |  |
|  |  | Do you validate software before it is used to monitor process? | | | | | Y | N | X |  |
| 6.3 PROVIDE THE RESOURCES NEEDED TO MONITOR PROCESS | | | | | | | | | | |
| 6.3.1 provide the expertise needed to monitor your process | | | | | | | | | | |
|  | Do you provide the expertise needed to ensure that monitoring  methods will consistently yield valid and reliable results? | | | | | | Y | N | X |  |
|  |  | Do you provide the managers needed to monitor your process? | | | | | Y | N | X |  |
|  |  | | Do you acquire the knowledge that managers need to support  process monitoring and achieve conformity of outputs? | | | | Y | N | X |  |
|  |  | | Do you share the knowledge that managers need so that they can  support process monitoring and achieve conformity of outputs? | | | | Y | N | X |  |
|  |  | | | Do you deliver suitable training and awareness programmes  for managers of process monitoring activities? | | | Y | N | X |  |
|  |  | Do you provide the personnel needed to monitor your process? | | | | | Y | N | X |  |
|  |  | | Do you acquire the knowledge that personnel need to  monitor your process and achieve conformity of outputs? | | | | Y | N | X |  |
|  |  | | | Do you consider internal sources of knowledge about process monitoring? | | | Y | N | X |  |
|  |  | | | Do you consider external sources of knowledge about process monitoring? | | | Y | N | X |  |
|  |  | | Do you share the knowledge that personnel need to  monitor your process and achieve conformity of outputs? | | | | Y | N | X |  |
|  |  | | | Do you deliver suitable training and awareness  programmes for your process monitoring personnel? | | | Y | N | X |  |
| 6.3.2 provide the technology needed to monitor your process | | | | | | | | | | |
|  | Do you provide the technology needed to ensure that your monitoring methods will yield valid and reliable results? | | | | | | Y | N | X |  |
|  |  | Do you provide the software needed to monitor your process? | | | | | Y | N | X |  |
|  |  | | Do you provide the software needed to support process  monitoring and achieve conformity of outputs? | | | | Y | N | X |  |
|  |  | Do you provide the hardware needed to monitor your process? | | | | | Y | N | X |  |
|  |  | | Do you provide the hardware needed to support process  monitoring and achieve conformity of outputs? | | | | Y | N | X |  |
| 6.3.3 provide the infrastructure needed to monitor your process | | | | | | | | | | |
|  | Do you provide the infrastructure needed to ensure that your monitoring methods will yield valid and reliable results? | | | | | | Y | N | X |  |
|  |  | Do you provide the infrastructure needed to support your process monitoring and achieve conformity of outputs? | | | | | Y | N | X |  |
| 6.4 USE AUTHORIZED METHODS TO MONITOR YOUR PROCESS | | | | | | | | | | |
| 6.4.1 use authorized methods to monitor process activities | | | | | | | | | | |
|  | Do you use authorized methods to monitor process management activities? | | | | | | Y | N | X |  |
|  |  | Do you monitor how well process management activities meet expectations? | | | | | Y | N | X |  |
|  |  | | Do you monitor how well process management activities apply policies? | | | | Y | N | X |  |
|  |  | | Do you monitor how well process management activities implement plans? | | | | Y | N | X |  |
|  |  | | Do you monitor how well process management activities follow procedures? | | | | Y | N | X |  |
|  |  | | Do you monitor how well process management activities achieve objectives? | | | | Y | N | X |  |
|  |  | | Do you monitor how well process management activities comply with requirements? | | | | Y | N | X |  |
|  | Do you use authorized methods to monitor process operating activities? | | | | | | Y | N | X |  |
|  |  | Do you monitor how well process operating activities meet expectations? | | | | | Y | N | X |  |
|  |  | | Do you monitor how well process operating activities apply policies? | | | | Y | N | X |  |
|  |  | | Do you monitor how well process operating activities implement plans? | | | | Y | N | X |  |
|  |  | | Do you monitor how well process operating activities follow procedures? | | | | Y | N | X |  |
|  |  | | Do you monitor how well process operating activities achieve objectives? | | | | Y | N | X |  |
|  |  | | Do you monitor how well process operating activities comply with requirements? | | | | Y | N | X |  |
|  | Do you use authorized methods to monitor process maintenance activities? | | | | | | Y | N | X |  |
|  |  | Do you monitor how well process maintenance activities meet expectations? | | | | | Y | N | X |  |
|  |  | | Do you monitor how well process maintenance activities apply policies? | | | | Y | N | X |  |
|  |  | | Do you monitor how well process maintenance activities implement plans? | | | | Y | N | X |  |
|  |  | | Do you monitor how well process maintenance activities follow procedures? | | | | Y | N | X |  |
|  |  | | Do you monitor how well process maintenance activities achieve objectives? | | | | Y | N | X |  |
|  |  | | Do you monitor how well process maintenance activities comply with requirements? | | | | Y | N | X |  |
|  | Do you use authorized methods to monitor process measurement activities? | | | | | | Y | N | X |  |
|  |  | Do you monitor how well process measurement activities meet expectations? | | | | | Y | N | X |  |
|  |  | | Do you monitor how well process measurement activities apply policies? | | | | Y | N | X |  |
|  |  | | Do you monitor how well process measurement activities implement plans? | | | | Y | N | X |  |
|  |  | | Do you monitor how well process measurement activities follow procedures? | | | | Y | N | X |  |
|  |  | | Do you monitor how well process measurement activities achieve objectives? | | | | Y | N | X |  |
|  |  | | Do you monitor how well process measurement activities comply with requirements? | | | | Y | N | X |  |
|  | Do you use authorized methods to monitor process monitoring activities? | | | | | | Y | N | X |  |
|  |  | Do you monitor how well process monitoring activities meet expectations? | | | | | Y | N | X |  |
|  |  | | Do you monitor how well process monitoring activities apply policies? | | | | Y | N | X |  |
|  |  | | Do you monitor how well process monitoring activities implement plans? | | | | Y | N | X |  |
|  |  | | Do you monitor how well process monitoring activities follow procedures? | | | | Y | N | X |  |
|  |  | | Do you monitor how well process monitoring activities achieve objectives? | | | | Y | N | X |  |
|  |  | | Do you monitor how well process monitoring activities comply with requirements? | | | | Y | N | X |  |
|  | Do you use authorized methods to monitor process control activities? | | | | | | Y | N | X |  |
|  |  | Do you monitor how well process control activities meet expectations? | | | | | Y | N | X |  |
|  |  | | Do you monitor how well process control activities apply policies? | | | | Y | N | X |  |
|  |  | | Do you monitor how well process control activities implement plans? | | | | Y | N | X |  |
|  |  | | Do you monitor how well process control activities follow procedures? | | | | Y | N | X |  |
|  |  | | Do you monitor how well process control activities achieve objectives? | | | | Y | N | X |  |
|  |  | | Do you monitor how well process control activities comply with requirements? | | | | Y | N | X |  |
|  | Do you use authorized methods to monitor process evaluation activities? | | | | | | Y | N | X |  |
|  |  | Do you use authorized methods to monitor process audit activities? | | | | | Y | N | X |  |
|  |  | | Do you monitor how well process audit activities meet expectations? | | | | Y | N | X |  |
|  |  | | | Do you monitor how well process audit activities apply policies? | | | Y | N | X |  |
|  |  | | | Do you monitor how well process audit activities implement plans? | | | Y | N | X |  |
|  |  | | | Do you monitor how well process audit activities follow procedures? | | | Y | N | X |  |
|  |  | | | Do you monitor how well process audit activities achieve objectives? | | | Y | N | X |  |
|  |  | | | Do you monitor how well process audit activities comply with requirements? | | | Y | N | X |  |
|  |  | Do you use authorized methods to monitor process review activities? | | | | | Y | N | X |  |
|  |  | | Do you monitor how well process review activities meet expectations? | | | | Y | N | X |  |
|  |  | | | Do you monitor how well process review activities apply policies? | | | Y | N | X |  |
|  |  | | | Do you monitor how well process review activities implement plans? | | | Y | N | X |  |
|  |  | | | Do you monitor how well process review activities follow procedures? | | | Y | N | X |  |
|  |  | | | Do you monitor how well process review activities achieve objectives? | | | Y | N | X |  |
|  |  | | | Do you monitor how well process review activities comply with requirements? | | | Y | N | X |  |
|  | Do you use authorized methods to monitor process modification activities? | | | | | | Y | N | X |  |
|  |  | Do you use authorized methods to monitor process correction activities? | | | | | Y | N | X |  |
|  |  | | Do you monitor how well process correction activities meet expectations? | | | | Y | N | X |  |
|  |  | | | Do you monitor how well process correction activities apply policies? | | | Y | N | X |  |
|  |  | | | Do you monitor how well process correction activities implement plans? | | | Y | N | X |  |
|  |  | | | Do you monitor how well process correction activities follow procedures? | | | Y | N | X |  |
|  |  | | | Do you monitor how well process correction activities achieve objectives? | | | Y | N | X |  |
|  |  | | | Do you monitor how well process correction activities comply with requirements? | | | Y | N | X |  |
|  |  | Do you use authorized methods to monitor process improvement activities? | | | | | Y | N | X |  |
|  |  | | Do you monitor how well process improvement activities meet expectations? | | | | Y | N | X |  |
|  |  | | | Do you monitor how well process improvement activities apply policies? | | | Y | N | X |  |
|  |  | | | Do you monitor how well process improvement activities implement plans? | | | Y | N | X |  |
|  |  | | | Do you monitor how well process improvement activities follow procedures? | | | Y | N | X |  |
|  |  | | | Do you monitor how well process improvement activities achieve objectives? | | | Y | N | X |  |
|  |  | | | Do you monitor how well process improvement activities comply with requirements? | | | Y | N | X |  |
| 6.4.2 use authorized methods to monitor process outputs | | | | | | | | | | |
|  | Do you monitor how well process outputs meet expectations? | | | | | | Y | N | X |  |
|  |  | Do you monitor how well process outputs apply policies? | | | | | Y | N | X |  |
|  |  | Do you monitor how well process outputs implement plans? | | | | | Y | N | X |  |
|  |  | Do you monitor how well process outputs follow procedures? | | | | | Y | N | X |  |
|  |  | Do you monitor how well process outputs achieve objectives? | | | | | Y | N | X |  |
|  |  | Do you monitor how well process outputs comply with requirements? | | | | | Y | N | X |  |
|  |  | | Do you monitor how well process outputs meet customer requirements? | | | | Y | N | X |  |
|  |  | | Do you monitor how well process outputs meet regulatory requirements? | | | | Y | N | X |  |
|  |  | | Do you monitor how well process outputs meet corporate requirements? | | | | Y | N | X |  |
| 6.4.3 use authorized methods to monitor process inputs | | | | | | | | | | |
|  | Do you monitor supplies that have or could have a major impact on outputs? | | | | | | Y | N | X |  |
|  | Do you monitor services that have or could have a major impact on outputs? | | | | | | Y | N | X |  |
|  | Do you monitor materials that have or could have a major impact on outputs? | | | | | | Y | N | X |  |
|  | Do you monitor products that have or could have a major impact on outputs? | | | | | | Y | N | X |  |
|  | Do you monitor components that have or could have a major impact on outputs? | | | | | | Y | N | X |  |
|  |  | Do you monitor all of your “critical items” and “key characteristics”? | | | | | Y | N | X |  |
|  |  | Do you monitor all relevant counterfeit parts and components? | | | | | Y | N | X |  |
|  |  | | Do you monitor external reports about counterfeit parts? | | | | Y | N | X |  |
| 6.4.4 use authorized methods to monitor process documents | | | | | | | | | | |
|  | Do you monitor documents that specify how your process should be operated? | | | | | | Y | N | X |  |
|  | Do you monitor documents that specify how your process should be maintained? | | | | | | Y | N | X |  |
|  | Do you monitor documents that specify how your process should be monitored? | | | | | | Y | N | X |  |
|  | Do you monitor documents that specify how your process should be measured? | | | | | | Y | N | X |  |
|  | Do you monitor documents that specify how your process should be controlled? | | | | | | Y | N | X |  |
|  | Do you monitor documents that specify how your process should be audited? | | | | | | Y | N | X |  |
|  | Do you monitor documents that specify how your process should be reviewed? | | | | | | Y | N | X |  |
|  | Do you monitor documents that specify how your process should be corrected? | | | | | | Y | N | X |  |
|  | Do you monitor documents that specify how your process should be improved? | | | | | | Y | N | X |  |
| 6.4.5 use authorized methods to monitor process records | | | | | | | | | | |
|  | Do you monitor records of personnel performance and competence? | | | | | | Y | N | X |  |
|  |  | Do you retain records of personnel performance and competence? | | | | | Y | N | X |  |
|  |  | | Do you use records to show that personnel know how to perform process tasks? | | | | Y | N | X |  |
|  | Do you monitor records that track the performance of your process? | | | | | | Y | N | X |  |
|  |  | Do you monitor records that keep track of process operations? | | | | | Y | N | X |  |
|  |  | | Do you monitor records that keep track of process outputs? | | | | Y | N | X |  |
|  |  | | Do you monitor records that keep track of process activities? | | | | Y | N | X |  |
|  |  | | Do you monitor records that keep track of process inputs? | | | | Y | N | X |  |
|  |  | Do you monitor records that keep track of process maintenance? | | | | | Y | N | X |  |
|  |  | Do you monitor records that keep track of process measurement? | | | | | Y | N | X |  |
|  |  | Do you monitor records that keep track of process monitoring? | | | | | Y | N | X |  |
|  |  | Do you monitor records that keep track of process controls? | | | | | Y | N | X |  |
|  |  | Do you monitor records that keep track of process audits? | | | | | Y | N | X |  |
|  |  | Do you monitor records that keep track of process reviews? | | | | | Y | N | X |  |
|  |  | Do you monitor records that keep track of process corrections? | | | | | Y | N | X |  |
|  |  | Do you monitor records that keep track of process improvements? | | | | | Y | N | X |  |
| 6.4.6 use authorized methods to monitor process property | | | | | | | | | | |
|  | Do you monitor process property owned by customers and  suppliers that is needed to achieve conformity of outputs? | | | | | | Y | N | X |  |
|  |  | Do you report problematic property to your customers and external providers? | | | | | Y | N | X |  |
|  |  | | Do you report unsuitable property to customers and external providers? | | | | Y | N | X |  |
|  |  | | Do you report lost or damaged property to customers and external providers? | | | | Y | N | X |  |
|  | Do you monitor process property owned by your organization  that is needed to achieve conformity of outputs? | | | | | | Y | N | X |  |
| 6.4.7 use authorized methods to monitor process participants | | | | | | | | | | |
|  | Do you use authorized methods to monitor process personnel? | | | | | | Y | N | X |  |
|  |  | Do you monitor the process objectives that process personnel must achieve? | | | | | Y | N | X |  |
|  |  | | Do you monitor the safety objectives that process personnel must achieve? | | | | Y | N | X |  |
|  |  | | Do you monitor the quality objectives that process personnel must achieve? | | | | Y | N | X |  |
|  |  | | Do you monitor the security objectives that process personnel must achieve? | | | | Y | N | X |  |
|  |  | | Do you monitor the business objectives that process personnel must achieve? | | | | Y | N | X |  |
|  |  | | Do you monitor the technical objectives that process personnel must achieve? | | | | Y | N | X |  |
|  |  | | Do you monitor the continuity objectives that process personnel must achieve? | | | | Y | N | X |  |
|  |  | | Do you monitor the environmental objectives that process personnel must achieve? | | | | Y | N | X |  |
|  |  | Do you monitor the competence and performance of process personnel? | | | | | Y | N | X |  |
|  |  | | Do you monitor the process knowledge and skill that has been acquired? | | | | Y | N | X |  |
|  |  | | | Do you consider the need to protect and preserve process lessons learned? | | | Y | N | X |  |
|  |  | | | Do you consider the need to protect and preserve your intellectual property? | | | Y | N | X |  |
|  |  | | Do you monitor changes and trends in process knowledge and information? | | | | Y | N | X |  |
|  | Do you use authorized methods to monitor process management? | | | | | | Y | N | X |  |
|  |  | Do you use authorized methods to monitor process management personnel? | | | | | Y | N | X |  |
|  |  | Do you use authorized methods to monitor process management programmes? | | | | | Y | N | X |  |
|  |  | | Do you use authorized methods to monitor risk management programme? | | | | Y | N | X |  |
|  |  | | Do you use authorized methods to monitor safety management programme? | | | | Y | N | X |  |
|  |  | | Do you use authorized methods to monitor quality management programme? | | | | Y | N | X |  |
|  |  | | | Do you use authorized methods to monitor configuration management programme? | | | Y | N | X |  |
|  |  | | Do you use authorized methods to monitor security management programme? | | | | Y | N | X |  |
|  |  | | | Do you use authorized methods to monitor personnel security management programme? | | | Y | N | X |  |
|  |  | | | Do you use authorized methods to monitor information security management programme? | | | Y | N | X |  |
|  |  | | | Do you use authorized methods to monitor component security management programme? | | | Y | N | X |  |
|  |  | | | | Do you use authorized methods to monitor counterfeit parts management programme? | | Y | N | X |  |
|  |  | | Do you use authorized methods to monitor supplier management programme? | | | | Y | N | X |  |
|  |  | | Do you use authorized methods to monitor environmental management programme? | | | | Y | N | X |  |
|  |  | | Do you use authorized methods to monitor business continuity management programme? | | | | Y | N | X |  |
|  | Do you use authorized methods to monitor external providers? | | | | | | Y | N | X |  |
|  |  | Do you use authorized criteria to monitor the performance of external providers? | | | | | Y | N | X |  |
|  |  | | Do you used criteria to monitor verification activities delegated to external providers? | | | | Y | N | X |  |
|  | Do you use authorized methods to monitor interested parties? | | | | | | Y | N | X |  |
|  |  | Do you monitor the external parties that could influence your process? | | | | | Y | N | X |  |
|  |  | | Do you monitor performance of external process, product, and service providers? | | | | Y | N | X |  |
|  |  | | | Do you expect process managers to use data and criteria  to monitor the performance of their external providers? | | | Y | N | X |  |
|  |  | | | | Do you expect process managers to document performance  monitoring activities and retain these documents? | | Y | N | X |  |
|  |  | | | | | Do you expect process managers to control documents  that describe their performance monitoring activities? | Y | N | X |  |
|  |  | | Do you monitor external process, product, and service verification activities? | | | | Y | N | X |  |
|  |  | | | Do you monitor verifications whenever they are delegated to external providers? | | | Y | N | X |  |
|  |  | Do you monitor the internal parties that could influence your process? | | | | | Y | N | X |  |
| 6.4.8 use authorized methods to monitor process technologies | | | | | | | | | | |
|  | Do you monitor technology used to perform process operations? | | | | | | Y | N | X |  |
|  |  | Do you monitor software used to perform process operations? | | | | | Y | N | X |  |
|  |  | Do you monitor hardware used to perform process operations? | | | | | Y | N | X |  |
|  | Do you monitor technology used to automate process operations? | | | | | | Y | N | X |  |
|  |  | Do you monitor software used to automate process operations? | | | | | Y | N | X |  |
|  |  | Do you monitor hardware used to automate process operations? | | | | | Y | N | X |  |
|  | Do you monitor technology used to maintain process operations? | | | | | | Y | N | X |  |
|  |  | Do you monitor software used to maintain process operations? | | | | | Y | N | X |  |
|  |  | Do you monitor hardware used to maintain process operations? | | | | | Y | N | X |  |
|  | Do you monitor technology used to monitor process operations? | | | | | | Y | N | X |  |
|  |  | Do you monitor software used to monitor process operations? | | | | | Y | N | X |  |
|  |  | Do you monitor hardware used to monitor process operations? | | | | | Y | N | X |  |
|  |  | | Do you recall monitoring equipment that must be recalibrated or reverified? | | | | Y | N | X |  |
|  | Do you monitor technology used to measure process operations? | | | | | | Y | N | X |  |
|  |  | Do you monitor software used to measure process operations? | | | | | Y | N | X |  |
|  |  | Do you monitor hardware used to measure process operations? | | | | | Y | N | X |  |
|  |  | | Do you recall measuring equipment that must be recalibrated or reverified? | | | | Y | N | X |  |
|  | Do you monitor technology used to control process operations? | | | | | | Y | N | X |  |
|  |  | Do you monitor software used to control process operations? | | | | | Y | N | X |  |
|  |  | Do you monitor hardware used to control process operations? | | | | | Y | N | X |  |
| 6.4.9 use authorized methods to monitor process environment | | | | | | | | | | |
|  | Do you use authorized methods to monitor your process's external environment? | | | | | | Y | N | X |  |
|  |  | Do you use authorized methods to monitor external interested parties and their requirements? | | | | | Y | N | X |  |
|  | Do you use authorized methods to monitor your process's internal environment? | | | | | | Y | N | X |  |
|  |  | Do you use authorized methods to monitor internal interested parties and their requirements? | | | | | Y | N | X |  |
| 6.4.10 use authorized methods to monitor process infrastructure | | | | | | | | | | |
|  | Do you use authorized methods to monitor process networks and communications? | | | | | | Y | N | X |  |
|  |  | Do you use authorized methods to monitor internal process networks and communications? | | | | | Y | N | X |  |
|  |  | Do you use authorized methods to monitor external process networks and communications? | | | | | Y | N | X |  |
|  | Do you use authorized methods to monitor process utilities and support services? | | | | | | Y | N | X |  |
| 6.5 CONTROL THE RESOURCES NEEDED TO MONITOR PROCESS | | | | | | | | | | |
|  | Do you control the technology needed to monitor your process? | | | | | | Y | N | X |  |
|  |  | Do you control the tools needed to monitor your process? | | | | | Y | N | X |  |
|  |  | Do you control the software needed to monitor your process? | | | | | Y | N | X |  |
|  |  | Do you control the equipment needed to monitor your process? | | | | | Y | N | X |  |
|  | Do you control the records needed to monitor your process? | | | | | | Y | N | X |  |
|  |  | Did you establish a register of your process monitoring resources? | | | | | Y | N | X |  |
|  |  | | Do you ensure that your monitoring resources continue to be fit for purpose? | | | | Y | N | X |  |
|  |  | | | Do you ensure that register describes the type of monitoring tools and equipment in use? | | | Y | N | X |  |
|  |  | | | Do you ensure that register specifies the location of your monitoring tools and equipment? | | | Y | N | X |  |
|  |  | | | Do you ensure that register tracks the calibration of your monitoring tools and equipment? | | | Y | N | X |  |
|  |  | | | | Do you ensure that your register records equipment calibration or verification methods? | | Y | N | X |  |
|  |  | | | | | Do you ensure that your register records calibration or verification acceptance criteria? | Y | N | X |  |
|  |  | | | | Do you ensure that register specifies equipment calibration or verification frequency? | | Y | N | X |  |
|  |  | Do you maintain a register of your process monitoring resources? | | | | | Y | N | X |  |
|  |  | | Do you maintain records that show that monitoring resources are still fit for purpose? | | | | Y | N | X |  |
|  |  | | | Do you control records that show that monitoring resources are still fit for purpose? | | | Y | N | X |  |
|  | | | | | | | | | | |
|  | | | | | | | | | | |
| Answer each of the above questions. Three answers are possible: Y (yes), N (no), and X (eXclude). Y means you're in compliance,  N means you're not in compliance, while X means that this question can be excluded because it’s not applicable in your situation.  Y answers and X answers require no further action, while N answers point to things that need to be done to improve the  overall performance of your process. Also, please use the column on the right to record your notes, and in the spaces  below, enter the name and location of your organization, who completed this page, who reviewed it, and the dates. | | | | | | | | | | |

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

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 8.1 PLAN HOW YOU'RE GOING TO EVALAUTE PROCESS | | | | | | | | | | | |
| 8.1.1 plan how you're going to audit your process | | | | | | | | | | | |
|  | Have you developed an internal audit programme? | | | | | | | Y | N | X |  |
|  |  | Did you develop a programme that can find out if your process meets requirements? | | | | | | Y | N | X |  |
|  |  | | Do you make sure it can determine how well your process meets corporate expectations? | | | | | Y | N | X |  |
|  |  | | Do you make sure it can determine how well your process meets international standards? | | | | | Y | N | X |  |
|  |  | Did you develop a programme that can determine if your process is actually effective? | | | | | | Y | N | X |  |
|  |  | | Do you make sure that your programme is capable of producing valid results? | | | | | Y | N | X |  |
|  | Did you establish an internal audit programme? | | | | | | | Y | N | X |  |
|  |  | Do you assign internal audit responsibilities? | | | | | | Y | N | X |  |
|  |  | Do you develop your internal audit methods? | | | | | | Y | N | X |  |
|  |  | Do you clarify your internal audit standards? | | | | | | Y | N | X |  |
|  |  | | Do you expect auditors to be objective? | | | | | Y | N | X |  |
|  |  | | Do you expect auditors to be impartial? | | | | | Y | N | X |  |
|  |  | Do you specify internal audit planning requirements? | | | | | | Y | N | X |  |
|  |  | | Do you expect auditors to consider the results of previous audits? | | | | | Y | N | X |  |
|  |  | | Do you expect auditors to consider the impact proposed changes could have? | | | | | Y | N | X |  |
|  |  | | Do you expect auditors to consider the importance of the processes being audited? | | | | | Y | N | X |  |
|  |  | Do you define internal audit reporting requirements? | | | | | | Y | N | X |  |
|  |  | | Do you expect auditors to report results to management? | | | | | Y | N | X |  |
|  |  | Do you formulate internal audit schedules? | | | | | | Y | N | X |  |
|  |  | | Do you expect audits to be done at planned intervals? | | | | | Y | N | X |  |
| 8.1.2 plan how you're going to analyze your process | | | | | | | | | | | |
|  | Do you plan how you're going to analyze the opinions and satisfaction of process customers? | | | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to use your analytical results to evaluate satisfaction? | | | | | | Y | N | X |  |
|  |  | | Do you plan how you're going to analyze the degree of customer satisfaction? | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to use your analytical results to evaluate effectiveness? | | | | | | Y | N | X |  |
|  |  | | Do you plan how you're going to analyze the effectiveness of process operations? | | | | | Y | N | X |  |
|  |  | | | Do you plan how you're going to determine if you need to improve effectiveness? | | | | Y | N | X |  |
|  |  | | Do you plan how you're going to analyze the effectiveness of your process planning? | | | | | Y | N | X |  |
|  |  | | | Do you plan how you're going to determine if plans are effectively implemented? | | | | Y | N | X |  |
|  |  | | Do you plan how you're going to analyze the effectiveness of actions taken by managers? | | | | | Y | N | X |  |
|  |  | | | Do you plan how to analyze the effectiveness of actions taken to address risks? | | | | Y | N | X |  |
|  |  | | | Do you plan how to analyze the effectiveness of actions taken to exploit opportunities? | | | | Y | N | X |  |
|  | Do you plan how you're going to analyze the conformance and effectiveness of your process? | | | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to use analytical results to evaluate conformance? | | | | | | Y | N | X |  |
|  |  | | Do you plan how you're going to analyze the conformity of process outputs? | | | | | Y | N | X |  |
|  |  | | | Do you plan how you're going to analyze your process output problems? | | | | Y | N | X |  |
|  |  | | | | Do you plan how to analyze output problems reported by external sources? | | | Y | N | X |  |
|  |  | | | | | Do you plan how to analyze output problems reported using advisories? | | Y | N | X |  |
|  |  | | | | | Do you plan how to analyze output problems reported by means of alerts? | | Y | N | X |  |
|  |  | | | | | | Do you plan how to analyze problems reported by means of industry alerts? | Y | N | X |  |
|  |  | | | | | | Do you plan how to analyze problems reported by means of government alerts? | Y | N | X |  |
|  |  | | | | Do you plan how to analyze output problems revealed by internal sources? | | | Y | N | X |  |
|  |  | Do you plan how you're going to use analytical results to evaluate effectiveness? | | | | | | Y | N | X |  |
|  |  | | Do you plan how to analyze the effectiveness of your process operations? | | | | | Y | N | X |  |
|  |  | | | Do you plan how to determine if you need to improve its effectiveness? | | | | Y | N | X |  |
|  | Do you plan how you're going to analyze the competence and performance of process personnel? | | | | | | | Y | N | X |  |
|  |  | Do you plan how to analyze the effectiveness of actions taken to acquire competence? | | | | | | Y | N | X |  |
|  | Do you plan how you're going to analyze the conformance and performance of external providers? | | | | | | | Y | N | X |  |
|  |  | Do you plan how to analyze process, product, and service conformity of each external provider? | | | | | | Y | N | X |  |
|  |  | | Do you plan how to analyze the on-time delivery performance of each external provider? | | | | | Y | N | X |  |
|  |  | | | Do you plan how to analyze the approval status of each external provider? | | | | Y | N | X |  |
|  |  | Do you plan how to define actions to take when external providers fail to meet requirements? | | | | | | Y | N | X |  |
| 8.1.3 plan how you're going to review your process | | | | | | | | | | | |
|  | Do you consider how you're going to review your process? | | | | | | | Y | N | X |  |
|  |  | Do you consider how you're going to review the suitability of your process? | | | | | | Y | N | X |  |
|  |  | Do you consider how you're going to review the adequacy of your process? | | | | | | Y | N | X |  |
|  |  | Do you consider how you're going to review the effectiveness of your process? | | | | | | Y | N | X |  |
|  | Do you consider the issues that are relevant to your process? | | | | | | | Y | N | X |  |
|  |  | Do you consider changes in the external issues that influence your process? | | | | | | Y | N | X |  |
|  |  | Do you consider changes in the internal issues that influence your process? | | | | | | Y | N | X |  |
|  | Do you consider the status of your previous management reviews? | | | | | | | Y | N | X |  |
|  |  | Do you consider the status of the actions that were previously taken? | | | | | | Y | N | X |  |
| 8.2 PROVIDE RESOURCES NEEDED TO EVALUATE PROCESS | | | | | | | | | | | |
| 8.2.1 provide the people that you need to evalaute your process | | | | | | | | | | | |
|  | Do you provide the people that you need in order to audit your process? | | | | | | | Y | N | X |  |
|  | Do you provide the people that you need in order to analyze your process? | | | | | | | Y | N | X |  |
|  | Do you provide the people that you need in order to review your process? | | | | | | | Y | N | X |  |
| 8.2.2 provide the knowledge that YOU need to evaluate your process | | | | | | | | | | | |
|  | Do you provide the knowledge that you need in order to audit your process? | | | | | | | Y | N | X |  |
|  | Do you provide the knowledge that you need in order to analyze your process? | | | | | | | Y | N | X |  |
|  | Do you provide the knowledge that you need in order to review your process? | | | | | | | Y | N | X |  |
| 8.2.3 provide the technology that YOU need to evaluate your process | | | | | | | | | | | |
|  | Do you provide the technology that you need in order to audit your process? | | | | | | | Y | N | X |  |
|  | Do you provide the technology that you need in order to analyze your process? | | | | | | | Y | N | X |  |
|  | Do you provide the technology that you need in order to review your process? | | | | | | | Y | N | X |  |
| 8.2.4 provide the infrastructure that you need to evaluate your process | | | | | | | | | | | |
|  | Do you provide the infrastructure that you need in order to audit your process? | | | | | | | Y | N | X |  |
|  | Do you provide the infrastructure that you need in order to analyze your process? | | | | | | | Y | N | X |  |
|  | Do you provide the infrastructure that you need in order to review your process? | | | | | | | Y | N | X |  |
| 8.3 USE AUTHORIZED METHODS TO EVALUATE PROCESS | | | | | | | | | | | |
| 8.3.1 use authorized methods to audit your process | | | | | | | | | | | |
|  | Do you plan your internal process audit activities? | | | | | | | Y | N | X |  |
|  |  | Do you define the scope for each internal process audit? | | | | | | Y | N | X |  |
|  |  | Do you specify audit criteria for each internal process audit? | | | | | | Y | N | X |  |
|  |  | Do you clarify internal process audit methods and techniques? | | | | | | Y | N | X |  |
|  |  | Do you select impartial and objective internal process auditors? | | | | | | Y | N | X |  |
|  |  | Do you schedule internal process audits at planned intervals? | | | | | | Y | N | X |  |
|  | Do you carry out internal process audits at planned intervals? | | | | | | | Y | N | X |  |
|  |  | Do you conduct internal conformance audits of your process? | | | | | | Y | N | X |  |
|  |  | | Do you determine if your process meets relevant requirements? | | | | | Y | N | X |  |
|  |  | | | Do you determine if your process meets internal requirements? | | | | Y | N | X |  |
|  |  | | | Do you determine if your process meets external requirements? | | | | Y | N | X |  |
|  |  | | | | Do you determine if your process meets external customer requirements? | | | Y | N | X |  |
|  |  | | | | Do you determine if your process meets external statutory requirements? | | | Y | N | X |  |
|  |  | | | | Do you determine if your process meets external regulatory requirements? | | | Y | N | X |  |
|  |  | | | | | Do you determine if your process complies with government regulations? | | Y | N | X |  |
|  |  | | | | | Do you determine if your process complies with international standards? | | Y | N | X |  |
|  |  | | | | | | Do you determine how well process meets safety management requirements? | Y | N | X |  |
|  |  | | | | | | Do you determine how well process meets security management requirements? | Y | N | X |  |
|  |  | | | | | | Do you determine how well process meets quality management requirements? | Y | N | X |  |
|  |  | | | | | | Do you determine how well process meets environmental management requirements? | Y | N | X |  |
|  |  | | | | | | Do you determine how well process meets continuity management requirements? | Y | N | X |  |
|  |  | Do you conduct internal effectiveness audits of your process? | | | | | | Y | N | X |  |
|  |  | | Do you determine how effective process implementation was? | | | | | Y | N | X |  |
|  |  | | | Do you use performance indicators to see if process is effectively implemented? | | | | Y | N | X |  |
|  |  | | Do you determine how effective process operations are? | | | | | Y | N | X |  |
|  |  | | | Do you use performance indicators to see if process is effectively operated? | | | | Y | N | X |  |
|  |  | | Do you determine how effective process control is? | | | | | Y | N | X |  |
|  |  | | | Do you use performance indicators to see if process is effectively controlled? | | | | Y | N | X |  |
|  |  | | Do you determine how effective process maintenance is? | | | | | Y | N | X |  |
|  |  | | | Do you use performance indicators to see if process is effectively maintained? | | | | Y | N | X |  |
|  |  | | Do you determine how effective process monitoring is? | | | | | Y | N | X |  |
|  |  | | | Do you use performance indicators to see if process is effectively monitored? | | | | Y | N | X |  |
|  |  | | Do you determine how effective process measurement is? | | | | | Y | N | X |  |
|  |  | | | Do you use performance indicators to see if process is effectively measured? | | | | Y | N | X |  |
|  |  | | Do you determine how effective process evaluations are? | | | | | Y | N | X |  |
|  |  | | | Do you use performance indicators to see if process is effectively evaluated? | | | | Y | N | X |  |
|  |  | | | | Do you use performance indicators to see if process is effectively audited? | | | Y | N | X |  |
|  |  | | | | Do you use performance indicators to see if process is effectively reviewed? | | | Y | N | X |  |
|  |  | | Do you determine how effective process modifications are? | | | | | Y | N | X |  |
|  |  | | | Do you use performance indicators to see if process is effectively modified? | | | | Y | N | X |  |
|  |  | | | | Do you use performance indicators to see if process corrections are effective? | | | Y | N | X |  |
|  |  | | | | Do you use performance indicators to see if process improvements are effective? | | | Y | N | X |  |
|  | Do you report process audit results to management? | | | | | | | Y | N | X |  |
|  | Do you maintain your internal process audit programme? | | | | | | | Y | N | X |  |
|  |  | Do you retain documented information about your process audit programme? | | | | | | Y | N | X |  |
|  |  | | Do you retain your internal process audit results and control these results? | | | | | Y | N | X |  |
| 8.3.2 use authorized methods to analyze your process | | | | | | | | | | | |
|  | Do you analyze the opinions of process customers? | | | | | | | Y | N | X |  |
|  |  | Do you use your analytical results to evaluate satisfaction? | | | | | | Y | N | X |  |
|  |  | | Do you evaluate the degree of customer satisfaction? | | | | | Y | N | X |  |
|  | Do you analyze the performance of your process? | | | | | | | Y | N | X |  |
|  |  | Do you use your results to analyze conformance? | | | | | | Y | N | X |  |
|  |  | | Do you analyze the conformity of process outputs? | | | | | Y | N | X |  |
|  |  | | | Do you analyze your process output problems? | | | | Y | N | X |  |
|  |  | | | | Do you analyze output problems reported by external sources? | | | Y | N | X |  |
|  |  | | | | | Do you analyze output problems reported using advisories? | | Y | N | X |  |
|  |  | | | | | Do you analyze output problems reported by means of alerts? | | Y | N | X |  |
|  |  | | | | | | Do you analyze problems reported by means of industry alerts? | Y | N | X |  |
|  |  | | | | | | Do you analyze problems reported by means of government alerts? | Y | N | X |  |
|  |  | | | | Do you analyze output problems revealed by internal sources? | | | Y | N | X |  |
|  |  | Do you use your results to analyze effectiveness? | | | | | | Y | N | X |  |
|  |  | | Do you analyze the effectiveness of your process operations? | | | | | Y | N | X |  |
|  |  | | | Do you determine if you need to improve its effectiveness? | | | | Y | N | X |  |
|  | Do you analyze the effectiveness of your process? | | | | | | | Y | N | X |  |
|  |  | Do you use your results to analyze process effectiveness? | | | | | | Y | N | X |  |
|  |  | | Do you analyze the effectiveness of process operations? | | | | | Y | N | X |  |
|  |  | | | Do you determine if you need to improve process operations? | | | | Y | N | X |  |
|  |  | | Do you analyze the effectiveness of process maintenance? | | | | | Y | N | X |  |
|  |  | | | Do you determine if you need to improve process maintenance? | | | | Y | N | X |  |
|  |  | | Do you analyze the effectiveness of process monitoring? | | | | | Y | N | X |  |
|  |  | | | Do you determine if you need to improve process monitoring? | | | | Y | N | X |  |
|  |  | | Do you analyze the effectiveness of process measurement? | | | | | Y | N | X |  |
|  |  | | | Do you determine if you need to improve process measurement? | | | | Y | N | X |  |
|  |  | | Do you analyze the effectiveness of process evaluations? | | | | | Y | N | X |  |
|  |  | | | Do you analyze the effectiveness of process audits? | | | | Y | N | X |  |
|  |  | | | | Do you determine if you need to improve process audits? | | | Y | N | X |  |
|  |  | | | Do you analyze the effectiveness of process reviews? | | | | Y | N | X |  |
|  |  | | | | Do you determine if you need to improve process reviews? | | | Y | N | X |  |
|  |  | | Do you analyze the effectiveness of process modifications? | | | | | Y | N | X |  |
|  |  | | | Do you analyze the effectiveness of process corrections? | | | | Y | N | X |  |
|  |  | | | | Do you determine if you need to improve process correction activities? | | | Y | N | X |  |
|  |  | | | Do you analyze the effectiveness of process improvements? | | | | Y | N | X |  |
|  |  | | | | Do you determine if you need to improve process improvement activities? | | | Y | N | X |  |
|  |  | Do you use your results to analyze process management? | | | | | | Y | N | X |  |
|  |  | | Do you analyze the effectiveness of actions taken by managers? | | | | | Y | N | X |  |
|  |  | | | Do you analyze the effectiveness of actions taken to address process risks? | | | | Y | N | X |  |
|  |  | | | Do you analyze the effectiveness of actions taken to address process opportunities? | | | | Y | N | X |  |
|  |  | | | Do you analyze the effectiveness of actions taken to address process nonconformities? | | | | Y | N | X |  |
|  |  | | | Do you analyze the effectiveness of actions taken to address process performance problems? | | | | Y | N | X |  |
|  | Do you analyze the competence of process participants? | | | | | | | Y | N | X |  |
|  |  | Do you analyze the competence and performance of process personnel? | | | | | | Y | N | X |  |
|  |  | | Do you analyze the effectiveness of actions taken to acquire competence? | | | | | Y | N | X |  |
|  |  | Do you analyze the competence and performance of external providers? | | | | | | Y | N | X |  |
|  |  | | Do you analyze the process, product, and service conformity of each external provider? | | | | | Y | N | X |  |
|  |  | | | Do you analyze the on-time delivery performance of each external provider? | | | | Y | N | X |  |
|  |  | | | | Do you analyze the approval status of each external provider? | | | Y | N | X |  |
|  |  | | Do you define the actions to take when external providers fail to meet requirements? | | | | | Y | N | X |  |
| 8.3.3 use authorized methods to review your process | | | | | | | | | | | |
|  | Do you review the performance of your process? | | | | | | | Y | N | X |  |
|  |  | Do you review your process nonconformities? | | | | | | Y | N | X |  |
|  |  | Do you review process output nonconformities? | | | | | | Y | N | X |  |
|  |  | | Do you review customer perceptions and satisfaction? | | | | | Y | N | X |  |
|  |  | | | Do you use output conformity information to review customer satisfaction? | | | | Y | N | X |  |
|  |  | | | Do you use on-time delivery performance to review customer satisfaction? | | | | Y | N | X |  |
|  |  | | | Do you use corrective action requests to review customer satisfaction? | | | | Y | N | X |  |
|  |  | | | Do you use customer complaints to review customer satisfaction? | | | | Y | N | X |  |
|  |  | Do you review the performance of process personnel? | | | | | | Y | N | X |  |
|  |  | | Do you review how well objectives are being met? | | | | | Y | N | X |  |
|  |  | | Do you review the competence of process personnel? | | | | | Y | N | X |  |
|  |  | Do you review process management activities and results? | | | | | | Y | N | X |  |
|  |  | | Do you review process control methods and results? | | | | | Y | N | X |  |
|  |  | | Do you review process operations methods and results? | | | | | Y | N | X |  |
|  |  | | Do you review process monitoring methods and results? | | | | | Y | N | X |  |
|  |  | | Do you review process measurement methods and results? | | | | | Y | N | X |  |
|  |  | | Do you review process maintenance methods and results? | | | | | Y | N | X |  |
|  |  | | Do you review process evaluation methods and results? | | | | | Y | N | X |  |
|  |  | | | Do you review process audit activities and results? | | | | Y | N | X |  |
|  |  | | | Do you review process analysis activities and results? | | | | Y | N | X |  |
|  |  | | Do you review process modification methods and results? | | | | | Y | N | X |  |
|  |  | | | Do you review actual process modifications? | | | | Y | N | X |  |
|  |  | | | | Do you review actions taken to modify your process? | | | Y | N | X |  |
|  |  | | | | | Do you review the effectiveness of actions taken to improve process? | | Y | N | X |  |
|  |  | | | | | Do you review the effectiveness of corrective and preventive actions? | | Y | N | X |  |
|  |  | | | | | | Do you review corrective actions taken to address process nonconformities? | Y | N | X |  |
|  |  | | | | | | Do you review preventive actions taken to address process nonconformities? | Y | N | X |  |
|  |  | | | Do you review potential process modifications? | | | | Y | N | X |  |
|  |  | | | | Do you review potential improvement opportunities? | | | Y | N | X |  |
|  |  | | | | Do you review potential corrective and preventive actions? | | | Y | N | X |  |
|  |  | Do you review process risks and opportunities? | | | | | | Y | N | X |  |
|  |  | | Do you review actions taken to address risks and opportunities? | | | | | Y | N | X |  |
|  |  | | | Do you review the effectiveness of the actions that were taken? | | | | Y | N | X |  |
|  |  | Do you review suitability of process environment? | | | | | | Y | N | X |  |
|  |  | | Do you review external process, product, and service providers? | | | | | Y | N | X |  |
|  |  | | | Do you review your external process, product, and service verification activities? | | | | Y | N | X |  |
|  |  | | | | Do you review verifications whenever they are delegated to external providers? | | | Y | N | X |  |
|  |  | | Do you review the issues that could influence process performance? | | | | | Y | N | X |  |
|  |  | | | Do you review and evaluate the issues and concerns of interested parties? | | | | Y | N | X |  |
|  |  | | | | Do you review and evaluate their changing needs and expectations? | | | Y | N | X |  |
|  |  | Do you review the adequacy of process resources? | | | | | | Y | N | X |  |
|  | Do you generate suitable management review outputs? | | | | | | | Y | N | X |  |
| 8.4 RECORD THE RESULTS OF PROCESS EVALUATIONS | | | | | | | | | | | |
|  | Do you record your process audit activities and results? | | | | | | | Y | N | X |  |
|  |  | Do you maintain and control your process audit records? | | | | | | Y | N | X |  |
|  | Do you record your process analysis activities and results? | | | | | | | Y | N | X |  |
|  |  | Do you maintain and control your process analysis records? | | | | | | Y | N | X |  |
|  | Do you record your process review activities and results? | | | | | | | Y | N | X |  |
|  |  | Do you maintain and control your process review records? | | | | | | Y | N | X |  |
|  | | | | | | | | | | | |
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| Answer each of the above questions. Three answers are possible: Y (yes), N (no), and X (eXclude). Y means you're in compliance,  N means you're not in compliance, while X means that this question can be excluded because it’s not applicable in your situation.  Y answers and X answers require no further action, while N answers point to things that need to be done to improve the  overall performance of your process. Also, please use the column on the right to record your notes, and in the spaces  below, enter the name and location of your organization, who completed this page, who reviewed it, and the dates. | | | | | | | | | | | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 9.1 ESTABLISH YOUR PROCESS MODIFICATION METHODS | | | | | | | | | | |
| 9.1.1 establish methods for correcting process and outputs | | | | | | | | | | |
|  | Do you establish appropriate corrective action methods and procedures? | | | | | | Y | N | X |  |
|  |  | Do you document your corrective action methods and procedures? | | | | | Y | N | X |  |
|  |  | | Do you maintain documents that describe corrective action methods and procedures? | | | | Y | N | X |  |
|  | Do you establish appropriate corrective action record keeping methods? | | | | | | Y | N | X |  |
|  |  | Do you figure out how to record the actions taken to correct process and outputs? | | | | | Y | N | X |  |
|  |  | Do you figure out how to record the process and output corrections that are made? | | | | | Y | N | X |  |
| 9.1.2 establish methods for improving process and outputs | | | | | | | | | | |
|  | Do you establish appropriate process and output improvement methods and procedures? | | | | | | Y | N | X |  |
|  |  | Do you document your process and output improvement methods and procedures? | | | | | Y | N | X |  |
|  |  | | Do you keep documents describing process and output improvement methods and procedures? | | | | Y | N | X |  |
|  | Do you establish appropriate process and output improvement record keeping methods? | | | | | | Y | N | X |  |
|  |  | Do you figure out how to record the actions taken to improve process and outputs? | | | | | Y | N | X |  |
|  |  | Do you figure out how to record the process and output improvements that are made? | | | | | Y | N | X |  |
| 9.2 IDENTIFY OPPORTUNITIES TO MODIFY YOUR PROCESS | | | | | | | | | | |
| 9.2.1 Discover opportunities to modify process and outputs | | | | | | | | | | |
|  | Do you discover opportunities to correct your process and its outputs? | | | | | | Y | N | X |  |
|  |  | Do you discover opportunities to make corrections by examining audit reports? | | | | | Y | N | X |  |
|  |  | Do you discover opportunities to make corrections by examining review results? | | | | | Y | N | X |  |
|  |  | Do you discover opportunities to make corrections by examining best practices? | | | | | Y | N | X |  |
|  |  | Do you discover opportunities to make corrections by examining lessons learned? | | | | | Y | N | X |  |
|  |  | Do you discover opportunities to make corrections by examining nonconformities? | | | | | Y | N | X |  |
|  |  | Do you discover opportunities to make corrections by examining customer feedback? | | | | | Y | N | X |  |
|  | Do you discover opportunities to improve your process and its outputs? | | | | | | Y | N | X |  |
|  |  | Do you discover improvement opportunities by examining audit reports? | | | | | Y | N | X |  |
|  |  | Do you discover improvement opportunities by examining review results? | | | | | Y | N | X |  |
|  |  | Do you discover improvement opportunities by examining best practices? | | | | | Y | N | X |  |
|  |  | Do you discover improvement opportunities by examining lessons learned? | | | | | Y | N | X |  |
|  |  | Do you discover improvement opportunities by examining nonconformities? | | | | | Y | N | X |  |
|  |  | Do you discover improvement opportunities by examining customer feedback? | | | | | Y | N | X |  |
| 9.2.2 define opportunities to modify your process and outputs | | | | | | | | | | |
|  | Do you define opportunities to correct and improve process outputs? | | | | | | Y | N | X |  |
|  |  | Do you define opportunities to correct and improve the quality of your outputs? | | | | | Y | N | X |  |
|  |  | Do you define opportunities to correct and improve the safety of your outputs? | | | | | Y | N | X |  |
|  |  | Do you define opportunities to correct and improve the security of your outputs? | | | | | Y | N | X |  |
|  | Do you define opportunities to correct and improve process performance? | | | | | | Y | N | X |  |
|  |  | Do you define opportunities to correct and improve process operations? | | | | | Y | N | X |  |
|  |  | Do you define opportunities to correct and improve process maintenance? | | | | | Y | N | X |  |
|  |  | Do you define opportunities to correct and improve process monitoring? | | | | | Y | N | X |  |
|  |  | Do you define opportunities to correct and improve process measurement? | | | | | Y | N | X |  |
|  |  | Do you define opportunities to correct and improve process controls? | | | | | Y | N | X |  |
|  |  | Do you define opportunities to correct and improve process evaluations? | | | | | Y | N | X |  |
|  |  | | Do you define opportunities to correct and improve process audits? | | | | Y | N | X |  |
|  |  | | Do you define opportunities to correct and improve process reviews? | | | | Y | N | X |  |
| 9.2.3 confirm that process and output modifications are needed | | | | | | | | | | |
|  | Do you confirm that proposed process modifications are necessary? | | | | | | Y | N | X |  |
|  |  | Do you confirm that proposed process modifications would be feasible? | | | | | Y | N | X |  |
|  |  | Do you confirm that proposed process modifications would be appropriate? | | | | | Y | N | X |  |
|  |  | Do you confirm that proposed process modifications would be effective? | | | | | Y | N | X |  |
|  |  | | Do you confirm that proposed process modifications would be cost-effective? | | | | Y | N | X |  |
|  | Do you confirm that proposed output modifications would be necessary? | | | | | | Y | N | X |  |
|  |  | Do you confirm that proposed output modifications would be feasible? | | | | | Y | N | X |  |
|  |  | Do you confirm that proposed output modifications would be appropriate? | | | | | Y | N | X |  |
|  |  | Do you confirm that proposed output modifications would be effective? | | | | | Y | N | X |  |
|  |  | | Do you confirm that proposed output modifications would be cost-effective? | | | | Y | N | X |  |
| 9.2.4 approve opportunities to modify your process and outputs | | | | | | | | | | |
|  | Do you authorize proposed process corrections and improvements? | | | | | | Y | N | X |  |
|  | Do you authorize proposed output corrections and improvements? | | | | | | Y | N | X |  |
| 9.3 PLAN HOW YOU'RE GOING TO MODIFY YOUR PROCESS | | | | | | | | | | |
| 9.3.1 plan how you're going to correct process and its outputs | | | | | | | | | | |
|  | Do you plan how you're going to apply your corrective action methods and procedures? | | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to react to your process and output nonconformities? | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to control and correct process and output nonconformities? | | | | | Y | N | X |  |
|  |  | | Do you plan how you're going to deal with all relevant effects and consequences? | | | | Y | N | X |  |
|  | Do you plan how you're going to document your corrective action activities and results? | | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to document the actions taken and the results achieved? | | | | | Y | N | X |  |
|  |  | | Do you plan how you're going to retain and control your record of actions and results? | | | | Y | N | X |  |
|  | Do you plan how you're going to evaluate the need to eliminate causes? | | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to review and analyze the nonconformity? | | | | | Y | N | X |  |
|  |  | | Do you plan how you're going to determine the causes of the nonconformity? | | | | Y | N | X |  |
|  |  | | | Do you plan how to determine if human factors are responsible for the nonconformity? | | | Y | N | X |  |
|  |  | | | Do you plan how to determine if external providers are responsible for nonconformity? | | | Y | N | X |  |
|  |  | | | | Do you plan how to flow down corrective action requirements to external providers? | | Y | N | X |  |
|  |  | Do you plan how you're going to decide if corrective action should be taken? | | | | | Y | N | X |  |
|  | Do you plan how you're going to develop corrective actions to address causes? | | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to make sure that your actions are feasible? | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to make sure that your actions are appropriate? | | | | | Y | N | X |  |
|  |  | | Do you plan how you're going to make sure that actions also consider consequences? | | | | Y | N | X |  |
|  |  | Do you plan how you're going to make sure that your actions are effective? | | | | | Y | N | X |  |
|  |  | | Do you plan how you're going to make sure that your actions are cost-effective? | | | | Y | N | X |  |
|  | Do you plan how you're going to get managers to authorize corrective action? | | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to submit corrective action requests? | | | | | Y | N | X |  |
|  | Do you plan how you're going to take corrective actions to deal with causes? | | | | | | Y | N | X |  |
|  |  | Do you plan how you're going to correct your process and its outputs? | | | | | Y | N | X |  |
|  | Do you plan how you're going to review the effectiveness of corrective actions? | | | | | | Y | N | X |  |
|  | Do you plan how you're going to respond when correction actions aren't taken? | | | | | | Y | N | X |  |
|  | Do you plan how you're going to update your list of process and output risks? | | | | | | Y | N | X |  |
| 9.3.2 plan how you're going to improve process and its outputs | | | | | | | | | | |
|  | Do you plan improvements and other changes to your process? | | | | | | Y | N | X |  |
|  |  | Have you identified people authorized to approve changes in your process? | | | | | Y | N | X |  |
|  |  | Do you use your process purpose and scope to guide process improvements? | | | | | Y | N | X |  |
|  |  | | Do you use process policy statements to guide process improvements? | | | | Y | N | X |  |
|  |  | | | Do you use your quality policy to guide your process improvements? | | | Y | N | X |  |
|  |  | | | | Do you use your quality objectives to guide process improvements? | | Y | N | X |  |
|  |  | | | Do you use your safety policy to guide your process improvements? | | | Y | N | X |  |
|  |  | | | | Do you use your safety objectives to guide process improvements? | | Y | N | X |  |
|  |  | | | Do you use your security policy to guide your process improvements? | | | Y | N | X |  |
|  |  | | | | Do you use your security objectives to guide process improvements? | | Y | N | X |  |
|  |  | | | Do you use your environmental policy to guide your process improvements? | | | Y | N | X |  |
|  |  | | | | Do you use your environmental objectives to guide process improvements? | | Y | N | X |  |
|  |  | | | Do you use your business continuity policy to guide your process improvements? | | | Y | N | X |  |
|  |  | | | | Do you use your business continuity objectives to guide process improvements? | | Y | N | X |  |
|  |  | Do you consider improvements and other changes to your process? | | | | | Y | N | X |  |
|  |  | | Do you consider the purpose and effects of the changes you intend to make? | | | | Y | N | X |  |
|  |  | | Do you consider responsibilities and authorities whenever you make changes? | | | | Y | N | X |  |
|  |  | | | Do you consider allocating or reallocating responsibilities and authorities? | | | Y | N | X |  |
|  |  | | Do you consider the consequences that changes could potentially produce? | | | | Y | N | X |  |
|  |  | | Do you consider the availability of resources whenever you make changes? | | | | Y | N | X |  |
|  |  | | Do you consider the integrity of your process whenever you make changes? | | | | Y | N | X |  |
|  |  | Do you figure out how you're going to control changes in your process? | | | | | Y | N | X |  |
|  |  | | Do you ensure that process continues to work properly even though changes are being made? | | | | Y | N | X |  |
|  | Do you plan improvements and other changes to process outputs? | | | | | | Y | N | X |  |
|  |  | Have you identified people authorized to approve changes in process outputs? | | | | | Y | N | X |  |
|  |  | Do you use your process purpose and scope to guide output improvements? | | | | | Y | N | X |  |
|  |  | | Do you use process policy statements to guide process improvements? | | | | Y | N | X |  |
|  |  | | | Do you use your quality policy to guide your output improvements? | | | Y | N | X |  |
|  |  | | | | Do you use your quality objectives to guide output improvements? | | Y | N | X |  |
|  |  | | | Do you use your safety policy to guide your output improvements? | | | Y | N | X |  |
|  |  | | | | Do you use your safety objectives to guide output improvements? | | Y | N | X |  |
|  |  | | | Do you use your security policy to guide your output improvements? | | | Y | N | X |  |
|  |  | | | | Do you use your security objectives to guide output improvements? | | Y | N | X |  |
|  |  | | | Do you use your environmental policy to guide your output improvements? | | | Y | N | X |  |
|  |  | | | | Do you use your environmental objectives to guide output improvements? | | Y | N | X |  |
|  |  | Do you consider improvements and other changes to your outputs? | | | | | Y | N | X |  |
|  |  | | Do you consider the purpose and effects of the output changes you intend to make? | | | | Y | N | X |  |
|  |  | | Do you consider responsibilities and authorities whenever you make output changes? | | | | Y | N | X |  |
|  |  | | Do you consider the consequences that output changes could potentially produce? | | | | Y | N | X |  |
|  |  | | Do you consider the availability of resources whenever you make output changes? | | | | Y | N | X |  |
|  |  | | Do you consider the integrity of your outputs whenever you make changes? | | | | Y | N | X |  |
|  |  | Do you figure out how you're going to control changes in your process outputs? | | | | | Y | N | X |  |
|  |  | | Do you ensure that outputs still meet requirements even though changes are being made? | | | | Y | N | X |  |
| 9.4 USE AUTHORIZED METHODS TO MODIFY YOUR PROCESS | | | | | | | | | | |
| 9.4.1 use authorized methods to correct process and outputs | | | | | | | | | | |
|  | Do you apply your corrective action methods and procedures? | | | | | | Y | N | X |  |
|  |  | Do you evaluate the need to eliminate causes of nonconformity? | | | | | Y | N | X |  |
|  |  | | Do you review and analyze your process and output nonconformities? | | | | Y | N | X |  |
|  |  | | | Do you determine the causes of process and output nonconformities? | | | Y | N | X |  |
|  |  | | | | Do you determine if human factors are responsible for nonconformity? | | Y | N | X |  |
|  |  | | | | Do you determine if external providers are responsible for nonconformity? | | Y | N | X |  |
|  |  | | | | | Do you flow down corrective action requirements to your external providers? | Y | N | X |  |
|  |  | | Do you decide if the causes of process or output nonconformity must be addressed? | | | | Y | N | X |  |
|  |  | Do you develop corrective actions to address causes of nonconformity? | | | | | Y | N | X |  |
|  |  | | Do you make sure that your corrective actions are feasible? | | | | Y | N | X |  |
|  |  | | Do you make sure that your corrective actions are appropriate? | | | | Y | N | X |  |
|  |  | | | Do you make sure that actions also consider effects and consequences? | | | Y | N | X |  |
|  |  | | Do you make sure that your corrective actions are effective? | | | | Y | N | X |  |
|  |  | | | Do you make sure that your corrective actions are cost-effective? | | | Y | N | X |  |
|  |  | Do you take corrective action to address the causes of nonconformity? | | | | | Y | N | X |  |
|  | Do you provide the resources needed to correct process and outputs? | | | | | | Y | N | X |  |
|  |  | Do you provide suitable resources needed to correct process outputs? | | | | | Y | N | X |  |
|  |  | Do you provide suitable resources needed to correct process activities? | | | | | Y | N | X |  |
|  | Do you control your corrective action activities and results? | | | | | | Y | N | X |  |
|  | Do you monitor your corrective action activities and results? | | | | | | Y | N | X |  |
|  | Do you record your corrective action activities and results? | | | | | | Y | N | X |  |
|  |  | Do you document the actions taken and the results achieved? | | | | | Y | N | X |  |
|  |  | | Do you retain and control your record of corrective actions taken? | | | | Y | N | X |  |
| 9.4.2 use authorized methods to improve process and outputs | | | | | | | | | | |
|  | Do you apply process and output improvement methods and procedures? | | | | | | Y | N | X |  |
|  |  | Do you evaluate the need to make process and output improvements? | | | | | Y | N | X |  |
|  | Do you provide the resources needed to make process and output improvements? | | | | | | Y | N | X |  |
|  |  | Do you provide suitable resources needed to improve your process outputs? | | | | | Y | N | X |  |
|  |  | Do you provide suitable resources needed to improve your process activities? | | | | | Y | N | X |  |
|  | Do you develop improvements to your process and process outputs? | | | | | | Y | N | X |  |
|  |  | Do you make sure that your process and output improvements are feasible? | | | | | Y | N | X |  |
|  |  | Do you make sure that your process and output improvements are appropriate? | | | | | Y | N | X |  |
|  |  | | Do you make sure that process and output improvements also consider effects? | | | | Y | N | X |  |
|  |  | Do you make sure that your process and output improvements are effective? | | | | | Y | N | X |  |
|  |  | | Do you make sure that your process and output improvements are cost-effective? | | | | Y | N | X |  |
|  | Do you implement improvements to your process and process outputs? | | | | | | Y | N | X |  |
|  |  | Do you improve the suitability, adequacy, and effectiveness of your process? | | | | | Y | N | X |  |
|  |  | Do you improve the quality, safety, and security of your process outputs? | | | | | Y | N | X |  |
|  | Do you control improvements to your process and process outputs? | | | | | | Y | N | X |  |
|  |  | Do you control improvements and other changes affecting process software? | | | | | Y | N | X |  |
|  |  | Do you control improvements and other changes affecting process operations? | | | | | Y | N | X |  |
|  |  | Do you control improvements and other changes affecting process equipment? | | | | | Y | N | X |  |
|  |  | Do you control improvements and other changes affecting process tools? | | | | | Y | N | X |  |
|  | Do you monitor improvements to your process and process outputs? | | | | | | Y | N | X |  |
|  |  | Do you monitor the implementation of process and output improvement activities? | | | | | Y | N | X |  |
|  | Do you record improvements to your process and process outputs? | | | | | | Y | N | X |  |
| 9.5 REVIEW AND EVALUATE PROCESS MODIFICATIONS | | | | | | | | | | |
| 9.5.1 review and evaluate process and output corrections | | | | | | | | | | |
|  | Do you review and evaluate actions taken to correct your process? | | | | | | Y | N | X |  |
|  |  | Do you document your process correction reviews and the actions that are taken? | | | | | Y | N | X |  |
|  |  | Do you establish and maintain records of process correction reviews and actions taken? | | | | | Y | N | X |  |
|  | Do you review and evaluate actions taken to correct outputs? | | | | | | Y | N | X |  |
|  |  | Do you document your output correction reviews and the actions that are taken? | | | | | Y | N | X |  |
|  |  | Do you establish and maintain records of output correction reviews and actions taken? | | | | | Y | N | X |  |
| 9.5.2 review and evaluate process and output improvements | | | | | | | | | | |
|  | Do you review and evaluate improvements and changes to your process? | | | | | | Y | N | X |  |
|  |  | Do you document your process improvement reviews and the actions that are taken? | | | | | Y | N | X |  |
|  |  | Do you establish a record of process improvement reviews and the actions taken? | | | | | Y | N | X |  |
|  | Do you review and evaluate improvements and changes to process outputs? | | | | | | Y | N | X |  |
|  |  | Do you document your output improvement reviews and the actions that are taken? | | | | | Y | N | X |  |
|  |  | Do you establish a record of output improvement reviews and the actions taken? | | | | | Y | N | X |  |
|  | | | | | | | | | | |
| Answer each of the above questions. Three answers are possible: Y (yes), N (no), and X (eXclude). Y means you're in compliance,  N means you're not in compliance, while X means that this question can be excluded because it’s not applicable in your situation.  Y answers and X answers require no further action, while N answers point to things that need to be done to improve the  overall performance of your process. Also, please use the column on the right to record your notes, and in the spaces  below, enter the name and location of your organization, who completed this page, who reviewed it, and the dates. | | | | | | | | | | |

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| --- | --- |
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| **Publisher** | Praxiom Research Group Limited |
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| **Contact** | Praxiom Research Group Limited <http://www.praxiom.com>/ [support@praxiom.com](mailto:support@praxiom.com) 780-461-4514 First Edmonton Place, 14th Floor, 10665 Jasper Avenue, Edmonton, Alberta, Canada |

