

PROCESS AUDIT TOOL

**PRAXIOM
RESEARCH GROUP LIMITED**

PLAIN ENGLISH PROCESS MANAGEMENT AUDIT TOOL

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License agreement and contact information

PLAIN ENGLISH PROCESS MANAGEMENT AUDIT TOOL

A. INTRODUCTION TO PROCESS MANAGEMENT AUDIT

ISO'S PROCESS BASED STANDARDS	<p>Almost all ISO management standards now expect organizations to use a process approach. These include:</p> <ul style="list-style-type: none">• 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. <p>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.</p> <p>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).</p>
OUR PROCESS AUDIT METHODOLOGY	<p>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.</p> <p>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.</p>

PLAIN ENGLISH PROCESS MANAGEMENT AUDIT TOOL

A. INTRODUCTION TO PROCESS MANAGEMENT AUDIT

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>

PLAIN ENGLISH PROCESS MANAGEMENT AUDIT TOOL

B. PROFILE OF PROCESS MANAGEMENT AUDIT PROJECT

PROCESS AUDIT SCOPE

NAME OF ORGANIZATION BEING AUDITED	ADDRESS OF ORGANIZATION BEING AUDITED

PROCESS AUDIT SCOPE

AUDITORS

AUDIT MANAGER	AUDIT STAFF

AUDIT SCHEDULE

AUDIT START DATE	AUDIT FINISH DATE

AUDIT REVIEWER

AUDIT REVIEWED BY	DATE AUDIT REVIEWED

REVIEW COMMENTS

PROCESS BEING AUDITED:**C. MINI PROCESS MANAGEMENT AUDIT QUESTIONNAIRE****1. ASSESS PROCESS DEVELOPMENT ACTIVITIES**

1.1	Did you study the context of your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
1.1.1	Did you consider process participants?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
1.1.2	Did you consider process environment?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
1.1.3	Did you consider process risks and threats?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
1.1.4	Did you consider process opportunities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
1.2	Did you clarify the purpose of your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
1.2.1	Did you define process scope and boundaries?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
1.2.2	Did you establish your process objectives?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
1.3	Did you consider your process requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
1.3.1	Did you clarify process output requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
1.3.2	Did you clarify process knowledge requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
1.3.3	Did you clarify process competence requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
1.3.4	Did you clarify process management requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
1.3.5	Did you clarify process communication requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
1.3.6	Did you clarify process infrastructure requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
1.3.7	Did you clarify process environment requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
1.3.8	Did you clarify process resource requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
1.4	Did you plan process design and development?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
1.4.1	Did you carry out output planning?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
1.4.2	Did you carry out process planning?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
1.4.3	Did you carry out input planning?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
1.5	Did you design process support programmes?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

ORGANIZATION:

COMPLETED BY:

REVIEWED BY:

YOUR LOCATION:

DATE COMPLETED:

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JULY 2021

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PART C

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PROCESS BEING AUDITED:**C. MINI PROCESS MANAGEMENT AUDIT QUESTIONNAIRE**

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	

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PROCESS BEING AUDITED:**C. MINI PROCESS MANAGEMENT AUDIT QUESTIONNAIRE****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	

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4.1	Do you provide the resources needed to maintain process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
4.1.1	Do you provide the expertise needed to maintain your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
4.1.2	Do you provide the technology needed to maintain your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
4.1.3	Do you provide the infrastructure needed to maintain your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
4.2	Do you use authorized methods to maintain your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
4.2.1	Do you use authorized methods to maintain process documents?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
4.2.2	Do you use authorized methods to maintain process records?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
4.2.3	Do you use authorized methods to maintain process property?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
4.2.4	Do you use authorized methods to maintain process procedures?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
4.2.5	Do you use authorized methods to maintain process programmes?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
4.2.6	Do you use authorized methods to maintain process competence?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
4.2.7	Do you use authorized methods to maintain process technologies?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
4.2.8	Do you use authorized methods to maintain process infrastructure?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
4.2.9	Do you use authorized methods to maintain process communications?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

5. ASSESS PROCESS MEASUREMENT ACTIVITIES

5.1	Do you plan how you're going to measure your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
5.1.1	Do you figure out what needs to be measured?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
5.1.2	Do you figure out how measurements will be done?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
5.1.3	Do you figure out who will perform measurement tasks?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
5.2	Do you qualify the resources needed to measure process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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PROCESS BEING AUDITED:**C. MINI PROCESS MANAGEMENT AUDIT QUESTIONNAIRE**

5.3	Do you provide the resources needed to measure process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
5.3.1	Do you provide the expertise needed to measure your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
5.3.2	Do you provide the technology needed to measure your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
5.3.3	Do you provide the infrastructure needed to measure your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
5.4	Do you use authorized methods to measure your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
5.4.1	Do you use authorized methods to measure process elements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
5.4.2	Do you use authorized methods to measure process performance?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
5.5	Do you control the resources needed to measure process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
5.5.1	Do you control the documents needed to measure your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
5.5.2	Do you control the technology needed to measure your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
5.5.3	Do you control the records needed to measure your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

6. ASSESS PROCESS MONITORING ACTIVITIES

6.1	Do you plan how you're going to monitor your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
6.1.1	Do you figure out what needs to be monitored?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
6.1.2	Do you figure out how monitoring will be done?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
6.1.3	Do you figure out who will perform monitoring tasks?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
6.2	Do you qualify the resources needed to monitor process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
6.3	Do you provide the resources needed to monitor process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
6.3.1	Do you provide the expertise needed to monitor your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
6.3.2	Do you provide the technology needed to monitor your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
6.3.3	Do you provide the infrastructure needed to monitor your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
6.4	Do you use authorized methods to monitor your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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PROCESS BEING AUDITED:**C. MINI PROCESS MANAGEMENT AUDIT QUESTIONNAIRE**

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	

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PROCESS BEING AUDITED:**C. MINI PROCESS MANAGEMENT AUDIT QUESTIONNAIRE**

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	

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PROCESS BEING AUDITED:**C. MINI PROCESS MANAGEMENT AUDIT QUESTIONNAIRE****9. ASSESS PROCESS MODIFICATION ACTIVITIES**

9.1	Do you establish process modification methods?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
9.1.1	Do you establish methods for correcting process and outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
9.1.2	Do you establish methods for improving process and outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
9.2	Do you identify opportunities to modify your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
9.2.1	Do you discover opportunities to modify process and outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
9.2.2	Do you define opportunities to modify your process and outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
9.2.3	Do you confirm that process and output modifications are needed?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
9.2.4	Do you approve opportunities to modify your process and outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
9.3	Do you plan how you're going to modify your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
9.3.1	Do you plan how you're going to correct process and its outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
9.3.2	Do you plan how you're going to improve process and its outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
9.4	Do you use authorized methods to modify your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
9.4.1	Do you use authorized methods to correct process and outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
9.4.2	Do you use authorized methods to improve process and outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
9.5	Do you review and evaluate process modifications?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
9.5.1	Do you review and evaluate process and output corrections?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
9.5.2	Do you review and evaluate process and output improvements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> 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.

ORGANIZATION:

COMPLETED BY:

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PROCESS BEING AUDITED:

1. ASSESS PROCESS DEVELOPMENT ACTIVITIES

1.1 STUDY THE CONTEXT OF YOUR PROCESS

1.1.1 CONSIDER PROCESS PARTICIPANTS

1	Have you identified the parties that have an interest in your process?	Y	N	X	
2	Have you identified the internal parties that have an interest in your process?	Y	N	X	
3	Have you identified the internal parties that could influence your process?	Y	N	X	
4	Do you clarify the needs and expectations of interested internal parties?	Y	N	X	
5	Do you clarify the issues and concerns that interested internal parties have?	Y	N	X	
6	Have you identified the external parties that have an interest in your process?	Y	N	X	
7	Have you identified the external parties that could influence your process?	Y	N	X	
8	Do you clarify the needs and expectations of interested external parties?	Y	N	X	
9	Do you clarify the issues and concerns that interested external parties have?	Y	N	X	

1.1.2 CONSIDER PROCESS ENVIRONMENT

10	Do you consider your internal process environment?	Y	N	X	
11	Do you consider the impact it could have on process performance?	Y	N	X	
12	Do you consider the impact your organization's culture could have?	Y	N	X	
13	Do you consider the impact your organization's expertise could have?	Y	N	X	
14	Do you consider the impact your organization's technology could have?	Y	N	X	
15	Do you consider the impact your organization's infrastructure could have?	Y	N	X	
16	Do you consider your external process environment?	Y	N	X	
17	Do you consider the impact it could have on process performance?	Y	N	X	
18	Do you consider the impact your legal environment could have?	Y	N	X	
19	Have you identified statutory process output requirements?	Y	N	X	

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20	Have you identified regulatory process output requirements?	Y	N	X	
21	Do you consider the impact your social environment could have?	Y	N	X	
22	Do you consider the impact your market environment could have?	Y	N	X	
23	Have you identified your customers' process output requirements?	Y	N	X	
24	Do you consider the impact your economic environment could have?	Y	N	X	
25	Do you consider the impact your competitive environment could have?	Y	N	X	
26	Do you consider the impact your technological environment could have?	Y	N	X	

1.1.3 CONSIDER PROCESS RISKS AND THREATS

27	Do you consider how your context could weaken process performance?	Y	N	X	
28	Do you consider how interested parties could threaten process performance or disrupt process operations?	Y	N	X	
29	Do you consider how interested parties could weaken your ability to provide outputs that meet customer requirements?	Y	N	X	
30	Do you consider how interested parties could weaken your ability to provide outputs that meet legal requirements?	Y	N	X	
31	Do you consider how problems could threaten process performance or disrupt operations?	Y	N	X	
32	Do you consider how internal problems could affect your ability to achieve process objectives?	Y	N	X	
33	Do you consider how your values could weaken your ability to achieve objectives?	Y	N	X	
34	Do you consider how your culture could weaken your ability to achieve objectives?	Y	N	X	
35	Do you consider how your knowledge could weaken your ability to achieve objectives?	Y	N	X	
36	Do you consider how your infrastructure could weaken your ability to achieve objectives?	Y	N	X	
37	Do you consider how your performance could weaken your ability to achieve objectives?	Y	N	X	
38	Do you consider how external problems could affect your ability to achieve process objectives?	Y	N	X	

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39	Do you consider how legal problems could weaken your ability to achieve objectives?	Y	N	X	
40	Do you consider how social problems could weaken your ability to achieve objectives?	Y	N	X	
41	Do you consider how cultural problems could weaken your ability to achieve objectives?	Y	N	X	
42	Do you consider how market problems could weaken your ability to achieve objectives?	Y	N	X	
43	Do you consider how economic problems could weaken your ability to achieve objectives?	Y	N	X	
44	Do you consider how competitive problems could weaken your ability to achieve objectives?	Y	N	X	
45	Do you consider how technological problems could weaken your ability to achieve objectives?	Y	N	X	
46	Do you consider how to address the risks that could weaken process performance?	Y	N	X	
47	Do you figure out what needs to be done to ensure that process achieves process objectives?	Y	N	X	
48	Do you figure out how to prevent or reduce undesired affects that process could cause?	Y	N	X	

1.1.4 CONSIDER PROCESS OPPORTUNITIES

49	Do you consider opportunities to enhance process operations?	Y	N	X	
50	Do you consider how your organization's context could reveal opportunities to enhance process operations?	Y	N	X	
51	Do you consider how interested parties could represent opportunities to enhance process performance?	Y	N	X	
52	Do you consider how interested parties could represent opportunities to enhance your ability to provide outputs that meet customer requirements?	Y	N	X	
53	Do you consider how interested parties could represent opportunities to enhance your ability to provide outputs that meet legal requirements?	Y	N	X	
54	Do you consider how potential challenges could represent opportunities to enhance process performance?	Y	N	X	
55	Do you consider how internal challenges could create opportunities to improve your ability to achieve process objectives?	Y	N	X	

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56	Do you consider how your values could generate opportunities to enhance your ability to achieve process objectives?	Y	N	X	
57	Do you consider how your culture could generate opportunities to enhance your ability to achieve process objectives?	Y	N	X	
58	Do you consider how your knowledge could generate opportunities to enhance your ability to achieve process objectives?	Y	N	X	
59	Do you consider how your infrastructure could generate opportunities to enhance your ability to achieve process objectives?	Y	N	X	
60	Do you consider how your performance could generate opportunities to enhance your ability to achieve process objectives?	Y	N	X	
61	Do you consider how external challenges could create opportunities to improve your ability to achieve process objectives?	Y	N	X	
62	Do you consider how your legal environment could create opportunities to enhance your ability to achieve process objectives?	Y	N	X	
63	Do you consider how your social environment could create opportunities to enhance your ability to achieve process objectives?	Y	N	X	
64	Do you consider how your cultural environment could create opportunities to enhance your ability to achieve process objectives?	Y	N	X	
65	Do you consider how your market environment could create opportunities to enhance your ability to achieve process objectives?	Y	N	X	
66	Do you consider how your economic environment could create opportunities to enhance your ability to achieve process objectives?	Y	N	X	
67	Do you consider how your competitive environment could create opportunities to enhance your ability to achieve process objectives?	Y	N	X	
68	Do you consider how your technological environment could create opportunities to enhance your ability to achieve process objectives?	Y	N	X	
69	Do you figure out what you could do to exploit process opportunities?	Y	N	X	
70	Do you figure out what you could do to improve process performance?	Y	N	X	

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1. ASSESS PROCESS DEVELOPMENT ACTIVITIES

1.2 CLARIFY THE PURPOSE OF YOUR PROCESS

1.2.1 DEFINE PROCESS SCOPE AND BOUNDARIES

71	Do you clarify the scope and boundaries of your process?	Y	N	X	
72	Do you consider how your context could influence your process?	Y	N	X	
73	Do you consider how internal issues could influence your process?	Y	N	X	
74	Do you consider the impact your organization's values could have?	Y	N	X	
75	Do you consider the impact your organization's culture could have?	Y	N	X	
76	Do you consider the impact your organization's services could have?	Y	N	X	
77	Do you consider the impact your organization's products could have?	Y	N	X	
78	Do you consider the impact your organization's knowledge could have?	Y	N	X	
79	Do you consider the impact your organization's infrastructure could have?	Y	N	X	
80	Do you consider the impact your organization's performance could have?	Y	N	X	
81	Do you consider how external issues could influence your process?	Y	N	X	
82	Do you consider the impact legal issues and factors could have?	Y	N	X	
83	Do you consider the impact social issues and factors could have?	Y	N	X	
84	Do you consider the impact cultural issues and factors could have?	Y	N	X	
85	Do you consider the impact market issues and factors could have?	Y	N	X	
86	Do you consider the impact economic issues and factors could have?	Y	N	X	
87	Do you consider the impact competitive issues and factors could have?	Y	N	X	
88	Do you consider the impact technological issues and factors could have?	Y	N	X	
89	Have you documented the scope and boundaries of your process?	Y	N	X	

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1. ASSESS PROCESS DEVELOPMENT ACTIVITIES

90	Do you retain the documents that describe the scope and boundaries of your process?	Y	N	X	
91	Do you control the documents that describe the scope and boundaries of your process?	Y	N	X	

1.2.2 ESTABLISH YOUR PROCESS OBJECTIVES

92	Do you establish business objectives for your process?	Y	N	X	
93	Do you establish technical objectives for your process?	Y	N	X	
94	Do you establish safety objectives for your process?	Y	N	X	
95	Do you establish quality objectives for your process?	Y	N	X	
96	Do you establish security objectives for your process?	Y	N	X	
97	Do you establish continuity objectives for your process?	Y	N	X	
98	Do you establish environmental objectives for your process?	Y	N	X	

1.3 CONSIDER YOUR PROCESS REQUIREMENTS

1.3.1 CLARIFY PROCESS OUTPUT REQUIREMENTS

99	Do you consider output quality requirements?	Y	N	X	
100	Do you consider output reliability requirements?	Y	N	X	
101	Do you consider output consistency requirements?	Y	N	X	
102	Do you consider output availability requirements?	Y	N	X	
103	Do you consider output suitability requirements?	Y	N	X	
104	Do you consider suitability requirements for parts and materials to be used in outputs?	Y	N	X	
105	Do you consider suitability requirements for software to be embedded in outputs?	Y	N	X	
106	Do you consider suitability requirements for software that you plan to purchase?	Y	N	X	
107	Do you consider suitability requirements for software that you plan to develop?	Y	N	X	

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108	Do you consider output purity requirements?	Y	N	X	
109	Do you consider the need to control foreign objects?	Y	N	X	
110	Do you consider the need to detect foreign objects?	Y	N	X	
111	Do you consider the need to remove foreign objects?	Y	N	X	
112	Do you consider the need to prevent foreign objects?	Y	N	X	
113	Do you consider output verification requirements?	Y	N	X	
114	Do you consider how to verify that output requirements are being met?	Y	N	X	
115	Do you consider how verifications will be done at all appropriate stages?	Y	N	X	
116	Do you consider output validation requirements?	Y	N	X	
117	Do you consider how to confirm that intended use requirements are being met?	Y	N	X	
118	Do you consider how validations will be done at all appropriate stages?	Y	N	X	
119	Do you consider output control requirements?	Y	N	X	
120	Do you consider how nonconforming outputs will be controlled?	Y	N	X	
121	Do you consider output safety requirements?	Y	N	X	
122	Do you consider personal safety requirements?	Y	N	X	
123	Do you consider output security requirements?	Y	N	X	
124	Do you consider personnel security requirements?	Y	N	X	
125	Do you consider information security requirements?	Y	N	X	
126	Do you consider output production requirements?	Y	N	X	
127	Do you consider output producibility requirements?	Y	N	X	
128	Do you consider output inspectability requirements?	Y	N	X	

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1. ASSESS PROCESS DEVELOPMENT ACTIVITIES

129	Do you consider output maintenance requirements?	Y	N	X	
130	Do you consider output maintainability requirements?	Y	N	X	
131	Do you consider output handling requirements?	Y	N	X	
132	Do you consider output packaging requirements?	Y	N	X	
133	Do you consider output preservation requirements?	Y	N	X	
134	Do you consider output obsolescence requirements?	Y	N	X	
135	Do you consider output recycling requirements?	Y	N	X	
136	Do you consider output disposal requirements?	Y	N	X	
137	Do you consider final disposal requirements?	Y	N	X	

1.3.2 CLARIFY PROCESS KNOWLEDGE REQUIREMENTS

138	Do you determine the knowledge that process personnel need to have?	Y	N	X	
139	Do you determine the knowledge that process personnel need in order to support process operations and achieve conformity of outputs?	Y	N	X	
140	Do you consider internal sources of process knowledge?	Y	N	X	
141	Do you consider the need to learn from failures and successes?	Y	N	X	
142	Do you consider the need to gather knowledge about processes?	Y	N	X	
143	Do you consider the need to gather knowledge about process outputs?	Y	N	X	
144	Do you consider the need to capture undocumented knowledge?	Y	N	X	
145	Do you consider the need to capture the knowledge, expertise, and experience that your own people have accumulated?	Y	N	X	
146	Do you consider external sources of process knowledge?	Y	N	X	
147	Do you consider the knowledge that suppliers can provide?	Y	N	X	
148	Do you consider the knowledge that customers can share with you?	Y	N	X	

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1. ASSESS PROCESS DEVELOPMENT ACTIVITIES

149	Do you consider the knowledge that can be gathered at conferences?	Y	N	X	
150	Do you consider the knowledge that can be acquired from academia?	Y	N	X	

1.3.3 CLARIFY PROCESS COMPETENCE REQUIREMENTS

151	Have you identified the people under your control who have an impact on the performance and effectiveness of your process?	Y	N	X	
152	Do you establish competence requirements for your process?	Y	N	X	
153	Do you make sure that process personnel have the appropriate training?	Y	N	X	
154	Do you make sure that process personnel have the appropriate education?	Y	N	X	
155	Do you make sure that process personnel have the appropriate experience?	Y	N	X	
156	Do you make sure that process personnel have the appropriate knowledge?	Y	N	X	
157	Do you implement competence requirements for your process?	Y	N	X	
158	Do you define the knowledge and skill required to implement this process?	Y	N	X	
159	Do you define the knowledge and skill required to operate this process?	Y	N	X	
160	Do you define the knowledge and skill required to maintain this process?	Y	N	X	
161	Do you define the knowledge and skill required to monitor this process?	Y	N	X	
162	Do you define the knowledge and skill required to measure this process?	Y	N	X	
163	Do you define the knowledge and skill required to control this process?	Y	N	X	
164	Do you define the knowledge and skill required to evaluate this process?	Y	N	X	
165	Do you define the knowledge and skill required to audit this process?	Y	N	X	
166	Do you define the knowledge and skill required to review this process?	Y	N	X	
167	Do you define the knowledge and skill required to modify this process?	Y	N	X	
168	Do you define the knowledge and skill required to correct this process?	Y	N	X	

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169	Do you define the knowledge and skill required to improve this process?	Y	N	X	
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1.3.4 CLARIFY PROCESS MANAGEMENT REQUIREMENTS

170	Do you specify risk management requirements for your process?	Y	N	X	
171	Do you specify legal management requirements for your process?	Y	N	X	
172	Do you specify legal management requirements for process outputs?	Y	N	X	
173	Do you specify statutory management requirements for process outputs?	Y	N	X	
174	Do you specify regulatory management requirements for process outputs?	Y	N	X	
175	Do you specify business management requirements for your process?	Y	N	X	
176	Do you specify technical management requirements for your process?	Y	N	X	
177	Do you specify quality management requirements for your process?	Y	N	X	
178	Do you derive quality requirements from your quality policy?	Y	N	X	
179	Do you derive quality requirements from customer expectations?	Y	N	X	
180	Do you specify safety management requirements for your process?	Y	N	X	
181	Do you specify safety management requirements for process personnel?	Y	N	X	
182	Do you specify security management requirements for your process?	Y	N	X	
183	Do you specify personnel security management requirements?	Y	N	X	
184	Do you specify information security management requirements?	Y	N	X	
185	Do you specify component security management requirements?	Y	N	X	
186	Do you specify counterfeit parts management requirements?	Y	N	X	
187	Do you specify supplier management requirements for your process?	Y	N	X	
188	Do you specify configuration management requirements for your process?	Y	N	X	

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189	Do you specify environmental management requirements for your process?	Y	N	X	
190	Do you specify business continuity management requirements for your process?	Y	N	X	

1.3.5 CLARIFY PROCESS COMMUNICATION REQUIREMENTS

191	Do you figure out how internal process communications will be handled?	Y	N	X	
192	Do you figure out what internal process communications need to say?	Y	N	X	
193	Do you figure out when internal process communications should be done?	Y	N	X	
194	Do you figure out who should carry out internal process communications?	Y	N	X	
195	Do you figure out who should receive internal process communications?	Y	N	X	
196	Do you figure out how external process communications will be handled?	Y	N	X	
197	Do you figure out what external process communications need to say?	Y	N	X	
198	Do you figure out when external process communications should be done?	Y	N	X	
199	Do you figure out who should carry out external process communications?	Y	N	X	

1.3.6 CLARIFY PROCESS INFRASTRUCTURE REQUIREMENTS

200	Have you identified the infrastructure that your process needs in order to support operations and achieve conformity of outputs?	Y	N	X	
201	Do you consider the buildings that your process needs?	Y	N	X	
202	Do you consider the utilities that your process needs?	Y	N	X	
203	Do you consider the equipment that your process needs?	Y	N	X	
204	Do you consider the hardware that your process needs?	Y	N	X	
205	Do you consider the software that your process needs?	Y	N	X	
206	Do you consider the technology that your process need?	Y	N	X	
207	Do you consider your information technology needs?	Y	N	X	

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208	Do you consider your communication technology needs?	Y	N	X	
209	Do you consider your transportation technology needs?	Y	N	X	

1.3.7 CLARIFY PROCESS ENVIRONMENT REQUIREMENTS

210	Have you identified the environment that your process needs in order to achieve conformity of outputs?	Y	N	X	
211	Do you consider the social factors that could affect your process?	Y	N	X	
212	Do you consider the cultural factors that could affect your process?	Y	N	X	
213	Do you consider the psychological factors that could affect your process?	Y	N	X	
214	Do you consider the ergonomic factors that could affect your process?	Y	N	X	
215	Do you consider the climatic factors that could affect your process?	Y	N	X	
216	Do you consider whether humidity could affect process?	Y	N	X	
217	Do you consider whether temperature could affect process?	Y	N	X	
218	Do you consider whether pollution could affect your process?	Y	N	X	
219	Do you consider the physical factors that could affect your process?	Y	N	X	
220	Do you consider the sanitation factors that could affect your process?	Y	N	X	
221	Do you consider whether cleanliness is an important factor?	Y	N	X	

1.3.8 CLARIFY PROCESS RESOURCE REQUIREMENTS

222	Do you consider internal capabilities and external sources?	Y	N	X	
223	Do you consider your organization's internal capabilities and constraints?	Y	N	X	
224	Do you consider what needs to be obtained from external resource providers?	Y	N	X	
225	Do you determine the resources that your process needs?	Y	N	X	
226	Have you identified the resources needed to implement your process?	Y	N	X	

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227	Have you identified the resources needed to operate your process?	Y	N	X	
228	Have you identified the resources needed to monitor your process?	Y	N	X	
229	Have you identified the resources needed to measure your process?	Y	N	X	
230	Have you identified the resources needed to control your process?	Y	N	X	
231	Have you identified the resources needed to maintain your process?	Y	N	X	
232	Have you identified the resources needed to evaluate your process?	Y	N	X	
233	Have you identified the resources needed to audit your process?	Y	N	X	
234	Have you identified the resources needed to review your process?	Y	N	X	
235	Have you identified the resources needed to modify your process?	Y	N	X	
236	Have you identified the resources needed to correct your process?	Y	N	X	
237	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**

238	Do you determine criteria for your outputs?	Y	N	X	
239	Do you establish acceptance criteria for outputs?	Y	N	X	
240	Do you use statistical techniques to support outputs?	Y	N	X	
241	Do you use statistical techniques to verify output designs?	Y	N	X	
242	Do you use statistical techniques to verify output safety?	Y	N	X	
243	Do you use statistical techniques to verify output quality?	Y	N	X	
244	Do you determine the outputs that are needed?	Y	N	X	
245	Do you plan output design and development activities?	Y	N	X	

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246	Do you consider your output needs and complexities?	Y	N	X	
247	Do you consider your ability to meet output requirements?	Y	N	X	
248	Do you consider how you're going to meet output safety requirements?	Y	N	X	
249	Do you consider how you're going to meet output quality requirements?	Y	N	X	
250	Do you consider how you're going to meet output control requirements?	Y	N	X	
251	Do you consider how you're going to meet output testing requirements?	Y	N	X	
252	Do you consider how you're going to meet output suitability requirements?	Y	N	X	
253	Do you consider how you're going to meet output availability requirements?	Y	N	X	
254	Do you consider how you're going to meet output reliability requirements?	Y	N	X	
255	Do you consider how you're going to meet output monitoring requirements?	Y	N	X	
256	Do you consider how you're going to meet output measurement requirements?	Y	N	X	
257	Do you consider how you're going to meet output production requirements?	Y	N	X	
258	Do you consider how you're going to meet output preservation requirements?	Y	N	X	
259	Do you consider how you're going to meet output maintenance requirements?	Y	N	X	
260	Do you consider how you're going to meet output obsolescence requirements?	Y	N	X	
261	Do you consider how you're going to meet output delivery requirements?	Y	N	X	
262	Do you consider output design and development complexities?	Y	N	X	
263	Do you consider your output design and development activities?	Y	N	X	
264	Do you consider dividing output design and development into distinct activities?	Y	N	X	
265	Do you define content for each set of output design and development activities?	Y	N	X	
266	Do you define tasks for each set of output design and development activities?	Y	N	X	

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PROCESS BEING AUDITED:**1. ASSESS PROCESS DEVELOPMENT ACTIVITIES**

267	Do you define inputs for each set of output design and development activities?	Y	N	X	
268	Do you define outputs for each set of output design and development activities?	Y	N	X	
269	Do you define resources for each set of output design and development activities?	Y	N	X	
270	Do you define responsibilities for each set of output design and development activities?	Y	N	X	
271	Do you consider output design and development requirements?	Y	N	X	
272	Do you consider your output evaluation requirements?	Y	N	X	
273	Do you consider output review requirements?	Y	N	X	
274	Do you consider output verification requirements?	Y	N	X	
275	Do you consider output validation requirements?	Y	N	X	
276	Do you consider design and development output requirements?	Y	N	X	
277	Do you consider output design and development expectations?	Y	N	X	
278	Do you consider output control expectations?	Y	N	X	
279	Do you consider the level of control expected by your customers?	Y	N	X	
280	Do you consider the level of control expected by interested parties?	Y	N	X	
281	Do you consider output design and development relationships?	Y	N	X	
282	Do you consider the need to control interactions between people?	Y	N	X	
283	Do you consider the need to control interactions between groups?	Y	N	X	
284	Do you consider output design and development responsibilities?	Y	N	X	
285	Do you consider design and development authorities?	Y	N	X	
286	Do you consider output design and development documentation?	Y	N	X	
287	Do you consider the need to control and maintain documentation?	Y	N	X	

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288	Do you consider the need to confirm that requirements are being met?	Y	N	X	
289	Do you consider output design and development resources?	Y	N	X	
290	Do you consider internal design and development resource needs?	Y	N	X	
291	Do you consider external design and development resource needs?	Y	N	X	
292	Do you consider output verification and validation activities?	Y	N	X	
293	Do you plan your design verification and validation testing activities?	Y	N	X	
294	Do you make sure that test plans and specifications specify test items?	Y	N	X	
295	Do you make sure that test plans and specifications specify test requirements?	Y	N	X	
296	Do you make sure that plans and specifications specify testing objectives?	Y	N	X	
297	Do you make sure that plans and specifications specify testing conditions?	Y	N	X	
298	Do you make sure that plans and specifications specify testing parameters?	Y	N	X	
299	Do you make sure that plans and specifications specify testing resources?	Y	N	X	
300	Do you make sure that plans and specifications specify acceptance criteria?	Y	N	X	
301	Do you control your design verification and validation testing activities?	Y	N	X	
302	Do you make sure that test procedures describe how testing is performed?	Y	N	X	
303	Do you make sure that test procedures describe testing methods and techniques?	Y	N	X	
304	Do you make sure that test procedures describe how testing results are recorded?	Y	N	X	
305	Do you review your design verification and validation testing activities?	Y	N	X	
306	Do you make sure that the correct items were used for testing?	Y	N	X	
307	Do you make sure that the right configuration was submitted?	Y	N	X	
308	Do you make sure that your testing procedures were followed?	Y	N	X	

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309	Do you make sure that all testing objectives were achieved?	Y	N	X	
310	Do you make sure that test plan requirements were met?	Y	N	X	
311	Do you make sure that acceptance criteria were met?	Y	N	X	
312	Do you document your design verification and validation testing activities?	Y	N	X	
313	Do you make sure that records show that test items were identified?	Y	N	X	
314	Do you make sure that records show that test requirements were met?	Y	N	X	
315	Do you make sure that records show that testing objectives were set?	Y	N	X	
316	Do you make sure that records show that testing resources were allocated?	Y	N	X	
317	Do you make sure that records show that testing conditions were specified?	Y	N	X	
318	Do you make sure that records show that testing procedures were followed?	Y	N	X	
319	Do you make sure that records show that testing parameters were recorded?	Y	N	X	
320	Do you make sure that records show that testing reviews were carried out?	Y	N	X	
321	Do you make sure that records show that acceptance criteria were used?	Y	N	X	
322	Do you make sure that records show that operational conditions were examined?	Y	N	X	
323	Do you make sure that reports show that the design for output meets specification requirements for all identified operational conditions?	Y	N	X	
324	Do you make sure that calculations show that the design for output meets specification requirements for all identified operational conditions?	Y	N	X	
325	Do you make sure that test results show that the design for output meets specification requirements for all identified operational conditions?	Y	N	X	
326	Do you determine how outputs will be controlled?	Y	N	X	
327	Do you define your configuration management requirements?	Y	N	X	
328	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	

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329	Do you make sure that your configuration management methods are appropriate for your organization and the outputs it produces?	Y	N	X	
330	Do you define how you intend to control nonconforming outputs?	Y	N	X	
331	Do you document your output nonconformity control methods?	Y	N	X	
332	Do you define responsibility and authority for handling nonconforming outputs?	Y	N	X	
333	Do you define responsibility and authority for review of nonconforming outputs?	Y	N	X	
334	Do you define the process that will be used to approve personnel who will make all output nonconformity review decisions?	Y	N	X	
335	Do you define responsibility and authority for disposition of nonconforming outputs?	Y	N	X	
336	Do you define the process that will be used to approve personnel who will make output nonconformity disposition decisions?	Y	N	X	
337	Do you define how you plan to manage and control your nonconforming outputs?	Y	N	X	
338	Do you define how you're going to contain the impact of nonconformities?	Y	N	X	
339	Do you define how you intend to contain the effect on other processes?	Y	N	X	
340	Do you define how you intend to contain the effect on other outputs?	Y	N	X	
341	Do you define how you intend to contain the effect on other parties?	Y	N	X	
342	Do you define how you intend to contain the effect on customers?	Y	N	X	
343	Do you define how you intend to report your nonconforming outputs?	Y	N	X	
344	Do you define how nonconformities affecting products and services are reported?	Y	N	X	
345	Do you define how you intend to notify interested parties about nonconformities?	Y	N	X	
346	Do you define how internal parties will be notified about nonconformities?	Y	N	X	
347	Do you define how you plan to notify internal organizations about nonconformities?	Y	N	X	
348	Do you define how external parties will be notified about nonconformities?	Y	N	X	

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349	Do you define how you plan to notify customers about nonconformities?	Y	N	X	
350	Do you define how you plan to notify distributors about nonconformities?	Y	N	X	
351	Do you define how you plan to notify regulators about nonconformities?	Y	N	X	
352	Do you define how you plan to notify suppliers about nonconformities?	Y	N	X	
353	Do you define how appropriate corrective actions will be implemented?	Y	N	X	
354	Do you define how corrective action will be developed and taken whenever nonconforming outputs are detected after delivery?	Y	N	X	
355	Do you define how you intend to ensure that actions will deal with impacts?	Y	N	X	

1.4.2 CARRY OUT PROCESS PLANNING

356	Do you select the people that should be involved in process planning?	Y	N	X	
357	Do you ask people from affected organizational functions to participate?	Y	N	X	
358	Do you establish performance criteria that your process should meet?	Y	N	X	
359	Do you establish performance criteria that process outputs should meet?	Y	N	X	
360	Do you determine the activities that should make up your process?	Y	N	X	
361	Do you determine the activities needed to generate your outputs?	Y	N	X	
362	Do you determine the activities needed to control your “critical items”?	Y	N	X	
363	Do you determine the activities needed to prevent unintended deliveries?	Y	N	X	
364	Do you develop suitable process verification methods?	Y	N	X	
365	Do you consider using risk assessments to help ensure that your process is able to produce outputs that meet requirements?	Y	N	X	
366	Do you consider using capacity studies to help ensure that your process is able to produce outputs that meet requirements?	Y	N	X	
367	Do you consider using capability studies to help ensure that your process is able to produce outputs that meet requirements?	Y	N	X	

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1. ASSESS PROCESS DEVELOPMENT ACTIVITIES

368	Do you consider using control plans to help ensure that your process is able to produce outputs that meet requirements?	Y	N	X	
369	Do you clarify process interactions and interconnections?	Y	N	X	
370	Have you identified downstream processes?	Y	N	X	
371	Have you identified upstream processes?	Y	N	X	
372	Do you allocate the resources needed to support process?	Y	N	X	
373	Do you allocate the resources needed to manage process?	Y	N	X	
374	Do you allocate the resources needed to manage projects?	Y	N	X	
375	Do you allocate the resources needed to manage "critical items"?	Y	N	X	

1.4.3 CARRY OUT INPUT PLANNING

376	Have you identified your process input requirements?	Y	N	X	
377	Have you identified the products that your process will need to have?	Y	N	X	
378	Have you identified the product providers that will be needed?	Y	N	X	
379	Have you identified the services that your process will need to have?	Y	N	X	
380	Have you identified the service providers that will be needed?	Y	N	X	
381	Have you identified the technologies that your process will need to have?	Y	N	X	
382	Have you identified the hardware that your process will need to have?	Y	N	X	
383	Have you identified the software that your process will need to have?	Y	N	X	
384	Have you identified the information that your process will need to have?	Y	N	X	
385	Have you identified the materials that your process will need to have?	Y	N	X	
386	Have you identified the supplies that your process will need to have?	Y	N	X	
387	Have you identified the parts that your process will need to have?	Y	N	X	

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1. ASSESS PROCESS DEVELOPMENT ACTIVITIES

388	Do you document your process input requirements?	Y	N	X	
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1.5 DESIGN PROCESS SUPPORT PROGRAMMES

1.5.1 DESIGN RISK MANAGEMENT PROGRAMME

389	Do you make sure that your risk management methods are appropriate for your process and the outputs it generates?	Y	N	X	
390	Do you plan the assignment of risk management responsibilities?	Y	N	X	
391	Do you clarify and define your operational risk assessment criteria?	Y	N	X	
392	Do you figure out how you're going to determine the likelihood of an occurrence?	Y	N	X	
393	Do you figure out how you're going to evaluate potentially negative consequences?	Y	N	X	
394	Do you figure out how you're going to make operational risk acceptance decisions?	Y	N	X	
395	Do you describe how you intend to manage operational risks?	Y	N	X	
396	Do you figure out how operational risks will be identified?	Y	N	X	
397	Do you figure out how operational risks will be assessed?	Y	N	X	
398	Do you figure out how operational risks will be communicated?	Y	N	X	
399	Do you specify how risk management initiatives will be taken?	Y	N	X	
400	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	
401	Do you figure out how you're going to formulate the actions that must be taken to mitigate operational risks?	Y	N	X	
402	Do you figure out how you're going to implement the actions that must be taken to mitigate operational risks?	Y	N	X	
403	Do you define how residual operational risks will be controlled?	Y	N	X	
404	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	

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1. ASSESS PROCESS DEVELOPMENT ACTIVITIES

1.5.2 DESIGN SAFETY MANAGEMENT PROGRAMME

405	Did you plan your safety management programme?	Y	N	X	
406	Do you make sure that your safety programme is appropriate for your process?	Y	N	X	
407	Do you make sure that safety programme is appropriate for your outputs?	Y	N	X	
408	Do you ensure that your programme applies to the entire output life cycle?	Y	N	X	
409	Did you develop a safety management programme?	Y	N	X	
410	Did you develop a way of managing safety hazards and threats?	Y	N	X	
411	Did you develop a safety hazard and threat assessment process?	Y	N	X	
412	Did you develop a suitable safety risk management process?	Y	N	X	
413	Did you develop a way of managing activities that affect safety?	Y	N	X	
414	Did you develop a way of analyzing activities that affect safety?	Y	N	X	
415	Did you develop a way of reporting activities that affect safety?	Y	N	X	
416	Did you develop a way of managing safety training services?	Y	N	X	
417	Did you develop a way of managing safety communications?	Y	N	X	

1.5.3 DESIGN QUALITY MANAGEMENT PROGRAMME

418	Do you establish quality expectations for your process?	Y	N	X	
419	Do you define quality requirements for your process?	Y	N	X	
420	Do you formulate quality policies for your process?	Y	N	X	
421	Do you write quality procedures for your process?	Y	N	X	
422	Do you prepare quality criteria for your process?	Y	N	X	
423	Do you develop quality plans for your process?	Y	N	X	
424	Do you set quality objectives for your process?	Y	N	X	

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425	Do you clarify criteria for setting quality objectives?	Y	N	X	
426	Do you make sure that quality objectives are measurable?	Y	N	X	
427	Do you make sure that quality objectives consider requirements?	Y	N	X	
428	Do you make sure that quality objectives support your strategic direction?	Y	N	X	
429	Do you make sure that quality objectives are compatible with your context?	Y	N	X	
430	Do you make sure that quality objectives are consistent with your policies?	Y	N	X	
431	Do you define quality objectives for your process?	Y	N	X	
432	Do you set quality objectives in all relevant areas of your process?	Y	N	X	
433	Do you set quality objectives for all relevant process functions?	Y	N	X	
434	Do you set objectives that address the need to provide compliant outputs?	Y	N	X	
435	Do you set objectives that address the need to enhance customer satisfaction?	Y	N	X	
436	Do you create quality controls for your process?	Y	N	X	
437	Did you establish a configuration management system?	Y	N	X	
438	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	
439	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

440	Did you develop a personnel security management programme?	Y	N	X	
441	Do you define personnel security requirements for your process?	Y	N	X	
442	Do you formulate personnel security policies for your process?	Y	N	X	
443	Do you write personnel security procedures for your process?	Y	N	X	
444	Do you prepare personnel security criteria for your process?	Y	N	X	

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445	Do you develop personnel security plans for your process?	Y	N	X	
446	Do you set personnel security objectives for your process?	Y	N	X	
447	Did you develop an information security management programme?	Y	N	X	
448	Do you define information security requirements for your process?	Y	N	X	
449	Do you formulate information security policies for your process?	Y	N	X	
450	Do you write information security procedures for your process?	Y	N	X	
451	Do you prepare information security criteria for your process?	Y	N	X	
452	Do you develop information security plans for your process?	Y	N	X	
453	Do you set information security objectives for your process?	Y	N	X	
454	Did you develop a component security management programme?	Y	N	X	
455	Did you develop a counterfeit parts management programme?	Y	N	X	
456	Did you plan your counterfeit part management programme?	Y	N	X	
457	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	
458	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	
459	Did you develop your counterfeit part management programme?	Y	N	X	
460	Did you develop a process to teach people about counterfeit parts?	Y	N	X	
461	Did you develop a process to monitor counterfeit parts and components?	Y	N	X	
462	Did you develop a process to monitor obsolete parts and components?	Y	N	X	
463	Did you develop a process to control the acquisition of parts and components?	Y	N	X	
464	Did you develop a process to detect suspicious and counterfeit parts and components?	Y	N	X	
465	Do you develop methodologies to test and to verify your parts and components?	Y	N	X	

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466	Do you develop methodologies to detect counterfeit parts and components?	Y	N	X	
467	Did you develop a process to quarantine suspicious or counterfeit parts and components?	Y	N	X	
468	Did you develop a process to report suspicious or counterfeit parts and components?	Y	N	X	
469	Did you develop a process to trace parts and components back to suppliers?	Y	N	X	
470	Do you ensure that you can trace them back to original or authorized manufacturers?	Y	N	X	

1.5.5 DESIGN SUPPLIER MANAGEMENT PROGRAMME

471	Did you develop a programme to manage, monitor, and control the use of external providers?	Y	N	X	
472	Do you clarify what you expect from external process, product, and service providers?	Y	N	X	
473	Do you specify your external document and record keeping requirements?	Y	N	X	
474	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

475	Did you plan your environmental management programme?	Y	N	X	
476	Do you make sure that your environmental programme is appropriate for your process?	Y	N	X	
477	Do you make sure that your environmental programme is appropriate for your outputs?	Y	N	X	
478	Do you ensure that your programme applies to the entire output life cycle?	Y	N	X	
479	Did you develop an environmental management programme?	Y	N	X	
480	Did you develop ways of analyzing environmental aspects and impacts?	Y	N	X	
481	Did you develop a way of managing environmental aspects and impacts?	Y	N	X	

1.5.7 DESIGN BUSINESS CONTINUITY MANAGEMENT PROGRAMME

482	Did you plan your business continuity management programme?	Y	N	X	
483	Do you make sure that your continuity programme is appropriate for your process?	Y	N	X	
484	Do you make sure that business continuity programme is appropriate for your outputs?	Y	N	X	

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485	Do you ensure that your continuity programme applies to the entire output life cycle?	Y	N	X	
486	Did you develop a business continuity management programme?	Y	N	X	
487	Do you ensure that operations continue at specified levels?	Y	N	X	
488	Did you develop ways of identifying potential threats?	Y	N	X	
489	Did you develop ways of analyzing all possible impacts?	Y	N	X	
490	Did you develop ways of responding to disruptive incidents?	Y	N	X	
491	Did you develop ways of resuming prioritized process activities?	Y	N	X	
492	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

493	Do you figure out how extensive documented process information should be?	Y	N	X	
494	Do you consider process activities when you establish documents and records?	Y	N	X	
495	Do you consider your process outputs when you establish documents and records?	Y	N	X	
496	Do you consider process personnel when you establish documents and records?	Y	N	X	
497	Do you consider the competence and expertise of your process personnel?	Y	N	X	
498	Do you consider your process obligations when you establish documents and records?	Y	N	X	
499	Do you consider process property and information provided by your customers?	Y	N	X	
500	Do you consider process property and information provided by external providers?	Y	N	X	

1.6.2 SELECT PROCESS DOCUMENTS AND RECORDS

501	Do you select all the documents and records that your process needs?	Y	N	X	
502	Do you select all the internal documents and records that your process needs?	Y	N	X	
503	Do you include documented information that your process needs to be effective?	Y	N	X	

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504	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	
505	Do you include documented information required by external standards?	Y	N	X	
506	Do you include information that documents the scope of your process?	Y	N	X	
507	Do you include information that documents your process goals and objectives?	Y	N	X	
508	Do you include information that documents your process policies and procedures?	Y	N	X	
509	Do you include information that documents your monitoring and measuring resources?	Y	N	X	
510	Do you include documented information that can prove that your monitoring and measuring resources are fit for purpose?	Y	N	X	
511	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	
512	Do you include information that documents your process monitoring and measuring activities and results?	Y	N	X	
513	Do you include information that documents the competence of process personnel?	Y	N	X	
514	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	
515	Do you include information that documents process activities and results?	Y	N	X	
516	Do you include documented information that can prove that your process is being carried out as planned?	Y	N	X	
517	Do you include documented information that facilitates the traceability of process outputs whenever traceability is a requirement?	Y	N	X	
518	Do you include information that documents your output characteristics?	Y	N	X	
519	Do you include information that documents your output requirements?	Y	N	X	
520	Do you include information that documents changes in requirements?	Y	N	X	
521	Do you include information that documents your output compliance?	Y	N	X	

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1. ASSESS PROCESS DEVELOPMENT ACTIVITIES

522	Do you include information that documents your output reviews?	Y	N	X	
523	Do you include information that documents results whenever you review output requirements?	Y	N	X	
524	Do you include information that documents process development activities?	Y	N	X	
525	Do you include information that documents process development inputs?	Y	N	X	
526	Do you include documented information that describes changes in inputs?	Y	N	X	
527	Do you include information that documents process development outputs?	Y	N	X	
528	Do you include documented information that describes changes in outputs?	Y	N	X	
529	Do you include information that documents process development changes?	Y	N	X	
530	Do you include documents that authorize changes in process development?	Y	N	X	
531	Do you include documents that record reviews of all relevant changes?	Y	N	X	
532	Do you include information that records actions taken to prevent adverse impacts?	Y	N	X	
533	Do you include information that records process development requirements?	Y	N	X	
534	Do you include documents that confirm that requirements were met?	Y	N	X	
535	Do you include information that documents external provider performance?	Y	N	X	
536	Do you include documented information that describes the results of your evaluation of external providers?	Y	N	X	
537	Do you include information that describes your re-evaluation results?	Y	N	X	
538	Do you include information that describes your monitoring results?	Y	N	X	
539	Do you include information that documents other people's property and information?	Y	N	X	
540	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	
541	Do you include information that documents your process operations and outputs?	Y	N	X	

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PROCESS BEING AUDITED:

1. ASSESS PROCESS DEVELOPMENT ACTIVITIES

542	Do you include documented information that describes the process activities to be performed and the results to be achieved?	Y	N	X	
543	Do you include information that documents unplanned changes in process activities?	Y	N	X	
544	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	
545	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	
546	Do you include information that documents the release of process outputs?	Y	N	X	
547	Do you include information that documents your process nonconformities?	Y	N	X	
548	Do you include documented information that describes the corrective actions taken and the results achieved?	Y	N	X	
549	Do you include documented information that describes the actions that are taken whenever nonconforming process outputs are produced?	Y	N	X	
550	Do you include information that documents your internal process audit results?	Y	N	X	
551	Do you include documented information that can demonstrate that you have implemented an internal process audit programme?	Y	N	X	
552	Do you include information that documents your management review outputs?	Y	N	X	
553	Do you select all the external documents and records that your process needs?	Y	N	X	
554	Do you include all documented information of external origin that you need in order to plan your process?	Y	N	X	
555	Do you include all documented information of external origin that you need in order to operate your process?	Y	N	X	
556	Do you include all documented information of external origin that you need in order to maintain your process?	Y	N	X	
557	Do you include all documented information of external origin that you need in order to monitor your process?	Y	N	X	
558	Do you include all documented information of external origin that you need in order to measure your process?	Y	N	X	

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559	Do you include all documented information of external origin that you need in order to control your process?	Y	N	X	
560	Do you include all documented information of external origin that you need in order to evaluate your process?	Y	N	X	
561	Do you include all documented information of external origin that you need in order to audit your process?	Y	N	X	
562	Do you include all documented information of external origin that you need in order to review your process?	Y	N	X	
563	Do you include all documented information of external origin that you need in order to modify your process?	Y	N	X	
564	Do you include all documented information of external origin that you need in order to correct your process?	Y	N	X	
565	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

566	Do you document your process participants?	Y	N	X	
567	Do you document the parties that have an interest in your process?	Y	N	X	
568	Do you document the scope of your process?	Y	N	X	
569	Do you consider interested party requirements when you document the scope of your process?	Y	N	X	
570	Do you consider your process environment when you document the scope of your process?	Y	N	X	
571	Do you consider your process outputs when you document the scope of your process?	Y	N	X	
572	Do you document your process outputs?	Y	N	X	
573	Do you develop documents defining expected output results?	Y	N	X	
574	Do you document characteristics of outputs you plan to produce?	Y	N	X	
575	Do you develop and document your output definition data?	Y	N	X	

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576	Do you document your process activities?	Y	N	X	
577	Do you document characteristics of process activities to be performed?	Y	N	X	
578	Do you document performance criteria that your process should meet?	Y	N	X	
579	Do you document performance criteria that process outputs should meet?	Y	N	X	
580	Do you document the activities that should make up your process?	Y	N	X	
581	Do you document the activities needed to generate your outputs?	Y	N	X	
582	Do you document the activities needed to control your “critical items”?	Y	N	X	
583	Do you document the activities needed to prevent unintended deliveries?	Y	N	X	
584	Do you document suitable process verification methods?	Y	N	X	
585	Do you document process interactions and interconnections?	Y	N	X	
586	Do you document your downstream processes?	Y	N	X	
587	Do you document your upstream processes?	Y	N	X	
588	Do you document the resources needed to support your process?	Y	N	X	
589	Do you document the resources needed to manage your process?	Y	N	X	
590	Do you document the resources needed to manage your projects?	Y	N	X	
591	Do you document the resources needed to manage your “critical items”?	Y	N	X	
592	Do you document your process inputs?	Y	N	X	
593	Do you document the products that your process will need to have?	Y	N	X	
594	Do you document the product providers that will be needed?	Y	N	X	
595	Do you document the services that your process will need to have?	Y	N	X	
596	Do you document the service providers that will be needed?	Y	N	X	
597	Do you document the technologies that your process will need to have?	Y	N	X	

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1. ASSESS PROCESS DEVELOPMENT ACTIVITIES

598	Do you document the hardware that your process will need to have?	Y	N	X	
599	Do you document the software that your process will need to have?	Y	N	X	
600	Do you document the information that your process will need to have?	Y	N	X	
601	Do you document the materials that your process will need to have?	Y	N	X	
602	Do you document the supplies that your process will need to have?	Y	N	X	
603	Do you document the parts that your process will need to have?	Y	N	X	
604	Do you document process assignments?	Y	N	X	
605	Do you document process authorities?	Y	N	X	
606	Do you document process responsibilities?	Y	N	X	
607	Do you document the objectives that your process must achieve?	Y	N	X	
608	Do you control documents that specify process objectives?	Y	N	X	
609	Do you retain documents that specify process objectives?	Y	N	X	
610	Do you document process policies, procedures, and work instructions?	Y	N	X	
611	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

612	Do you assign responsibility and authority for managing this process?	Y	N	X	
613	Do you assign responsibility and authority for applying your quality policy and procedures?	Y	N	X	
614	Do you assign responsibility and authority for complying with regulations and standards?	Y	N	X	
615	Do you assign responsibility and authority for maintaining a focus on process customers?	Y	N	X	
616	Do you assign responsibility and authority for meeting customer requirements?	Y	N	X	
617	Do you assign responsibility and authority for enhancing customer satisfaction?	Y	N	X	

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618	Do you assign responsibility and authority for interacting with external parties?	Y	N	X	
619	Do you assign responsibility and authority for interacting with external parties that have an interest in this process?	Y	N	X	
620	Do you assign responsibility and authority for interacting with external providers that support this process?	Y	N	X	
621	Do you assign responsibility and authority for deciding when external providers are used?	Y	N	X	
622	Do you assign responsibility and authority for granting an approval status to providers?	Y	N	X	
623	Do you allocate responsibility and authority for changing providers' approval status?	Y	N	X	
624	Do you assign responsibility and authority for operating this process?	Y	N	X	
625	Do you assign responsibility and authority for ensuring that process is efficient and effective?	Y	N	X	
626	Do you make managers accountable for ensuring that process produces intended outputs?	Y	N	X	
627	Do you assign responsibility and authority for maintaining this process?	Y	N	X	
628	Do you assign responsibility and authority for monitoring this process?	Y	N	X	
629	Do you assign responsibility and authority for measuring this process?	Y	N	X	
630	Do you assign responsibility and authority for controlling this process?	Y	N	X	
631	Do you assign responsibility and authority for controlling process modifications?	Y	N	X	
632	Do you make managers accountable for protecting process integrity when changes occur?	Y	N	X	
633	Do you assign responsibility and authority for evaluating this process?	Y	N	X	
634	Do you assign responsibility and authority for auditing process?	Y	N	X	
635	Do you assign responsibility and authority for preparing audit reports?	Y	N	X	
636	Do you assign responsibility and authority for reviewing process?	Y	N	X	
637	Do you assign responsibility and authority for preparing review reports?	Y	N	X	
638	Do you assign responsibility and authority for submitting process performance reports?	Y	N	X	

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PROCESS BEING AUDITED:

1. ASSESS PROCESS DEVELOPMENT ACTIVITIES

639	Do you assign responsibility and authority for reporting process improvement opportunities?	Y	N	X	
640	Do you assign responsibility and authority for modifying this process?	Y	N	X	
641	Do you assign responsibility and authority for correcting this process?	Y	N	X	
642	Do you assign responsibility and authority for improving this process?	Y	N	X	

1.7.2 DOCUMENT PROCESS RESPONSIBILITIES AND AUTHORITIES

643	Do you document responsibility and authority for managing this process?	Y	N	X	
644	Do you document responsibility and authority for operating this process?	Y	N	X	
645	Do you document responsibility and authority for maintaining this process?	Y	N	X	
646	Do you document responsibility and authority for monitoring this process?	Y	N	X	
647	Do you document responsibility and authority for measuring this process?	Y	N	X	
648	Do you document responsibility and authority for controlling this process?	Y	N	X	
649	Do you document responsibility and authority for evaluating this process?	Y	N	X	
650	Do you document responsibility and authority for auditing this process?	Y	N	X	
651	Do you document responsibility and authority for reviewing this process?	Y	N	X	
652	Do you document responsibility and authority for modifying this process?	Y	N	X	
653	Do you document responsibility and authority for correcting this process?	Y	N	X	
654	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.

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PROCESS BEING AUDITED:**2. ASSESS PROCESS IMPLEMENTATION ACTIVITIES****2.1 PROVIDE RESOURCES NEEDED TO IMPLEMENT PROCESS**

1	Did you provide the expertise needed to implement your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
2	Did you acquire the knowledge needed to implement your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
3	Did you consider internal sources of knowledge about process implementation?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
4	Did you consider external sources of knowledge about process implementation?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
5	Did you consider the implementation knowledge that suppliers can provide?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
6	Did you consider the implementation knowledge that customers can share with you?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
7	Did you consider the implementation knowledge that can be gathered at conferences?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
8	Did you consider the implementation knowledge that can be gained from training courses?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
9	Did you consider the implementation knowledge that can be gained from published materials?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
10	Did you share the knowledge needed to implement your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
11	Did you share implementation knowledge with managers?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
12	Did you teach managers how to implement your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
13	Did you share implementation knowledge with personnel?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
14	Did you teach personnel how to implement your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
15	Did you provide the technology needed to implement your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
16	Did you provide the software needed to implement your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
17	Did you provide the hardware needed to implement your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
18	Did you provide the tools needed to implement your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
19	Did you provide the equipment needed to implement your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
20	Did you provide the infrastructure needed to implement your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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2. ASSESS PROCESS IMPLEMENTATION ACTIVITIES

2.2 CREATE THE ENVIRONMENT THAT YOUR PROCESS NEEDS

21	Did you establish the environment that process needs in order to achieve conformity of outputs?	Y	N	X	
22	Do you create the culture that your process needs to achieve conformity of outputs?	Y	N	X	
23	Did you get the technology that your process needs in order to achieve conformity of outputs?	Y	N	X	
24	Do you acquire the knowledge that your process needs in order to achieve conformity of outputs?	Y	N	X	
25	Do you acquire the knowledge that process managers need to achieve conformity of outputs?	Y	N	X	
26	Do you acquire the knowledge that process personnel need to achieve conformity of outputs?	Y	N	X	
27	Do you develop the expertise that your process needs in order to achieve conformity of outputs?	Y	N	X	
28	Do you develop the management expertise that your process needs?	Y	N	X	
29	Do you deliver training and awareness programmes to managers?	Y	N	X	
30	Do you teach process managers how to operate your process?	Y	N	X	
31	Do you teach process managers how to maintain your process?	Y	N	X	
32	Do you teach process managers how to monitor your process?	Y	N	X	
33	Do you teach process managers how to measure your process?	Y	N	X	
34	Do you teach process managers how to control your process?	Y	N	X	
35	Do you develop the process expertise that process personnel needs?	Y	N	X	
36	Do you deliver training and awareness programmes to personnel?	Y	N	X	
37	Do you teach process personnel how to operate your process?	Y	N	X	
38	Do you teach process personnel how to maintain your process?	Y	N	X	
39	Do you teach process personnel how to monitor your process?	Y	N	X	
40	Do you teach process personnel how to measure your process?	Y	N	X	
41	Do you teach process personnel how to control your process?	Y	N	X	

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PROCESS BEING AUDITED:**2. ASSESS PROCESS IMPLEMENTATION ACTIVITIES****2.3 VERIFY THAT PROCESS CAN PRODUCE REQUIRED OUTPUTS**

42	Do you verify that process can produce outputs that meet requirements?	Y	N	X	
43	Do you verify that process documentation can produce the required results?	Y	N	X	
44	Do you verify that your process resources can produce the required results?	Y	N	X	
45	Do you validate resources that will be used to perform process?	Y	N	X	
46	Do you validate tools before they are used to perform process?	Y	N	X	
47	Do you validate equipment before it is used to perform process?	Y	N	X	
48	Do you validate software before it is used to perform process?	Y	N	X	
49	Do you validate resources that will be used to automate process?	Y	N	X	
50	Do you validate tools before they are used to automate process?	Y	N	X	
51	Do you validate equipment before it is used to automate process?	Y	N	X	
52	Do you validate software before it is used to automate process?	Y	N	X	
53	Do you validate resources that will be used to monitor process?	Y	N	X	
54	Do you validate tools before they are used to monitor process?	Y	N	X	
55	Do you validate equipment before it is used to monitor process?	Y	N	X	
56	Do you validate software before it is used to monitor process?	Y	N	X	
57	Do you validate resources that will be used to measure process?	Y	N	X	
58	Do you validate tools before they are used to measure process?	Y	N	X	
59	Do you validate equipment before it is used to measure process?	Y	N	X	
60	Do you validate software before it is used to measure process?	Y	N	X	
61	Do you validate resources that will be used to control process?	Y	N	X	
62	Do you validate tools before they are used to control process?	Y	N	X	

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PROCESS BEING AUDITED:**2. ASSESS PROCESS IMPLEMENTATION ACTIVITIES**

63	Do you validate equipment before it is used to control process?	Y	N	X	
64	Do you validate software before it is used to control process?	Y	N	X	

2.4 ESTABLISH PLANS TO ACHIEVE YOUR PROCESS OBJECTIVES

65	Do you figure out what must be done to achieve process objectives?	Y	N	X	
66	Do you figure out what must be done to achieve business objectives?	Y	N	X	
67	Do you figure out what must be done to achieve technical objectives?	Y	N	X	
68	Do you figure out what must be done to achieve quality objectives?	Y	N	X	
69	Do you figure out what must be done to achieve safety objectives?	Y	N	X	
70	Do you figure out what must be done to achieve security objectives?	Y	N	X	
71	Do you figure out what must be done to achieve continuity objectives?	Y	N	X	
72	Do you figure out what must be done to achieve environmental objectives?	Y	N	X	
73	Do you figure out who will be responsible for achieving process objectives?	Y	N	X	
74	Do you figure out who will be responsible for achieving business objectives?	Y	N	X	
75	Do you figure out who will be responsible for achieving technical objectives?	Y	N	X	
76	Do you figure out who will be responsible for achieving quality objectives?	Y	N	X	
77	Do you figure out who will be responsible for achieving safety objectives?	Y	N	X	
78	Do you figure out who will be responsible for achieving security objectives?	Y	N	X	
79	Do you figure out who will be responsible for achieving continuity objectives?	Y	N	X	
80	Do you figure out who will be responsible for achieving environmental objectives?	Y	N	X	
81	Do you figure out what resources will be needed to achieve process objectives?	Y	N	X	
82	Do you figure out what resources will be needed to achieve business objectives?	Y	N	X	

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83	Do you figure out what resources will be needed to achieve technical objectives?	Y	N	X	
84	Do you figure out what resources will be needed to achieve quality objectives?	Y	N	X	
85	Do you figure out what resources will be needed to achieve safety objectives?	Y	N	X	
86	Do you figure out what resources will be needed to achieve security objectives?	Y	N	X	
87	Do you figure out what resources will be needed to achieve continuity objectives?	Y	N	X	
88	Do you figure out what resources will be needed to achieve environmental objectives?	Y	N	X	

2.5 EXPLAIN PROCESS POLICIES, PROCEDURES, AND OBJECTIVES

89	Do you ensure that managers understand policies, procedures, and objectives?	Y	N	X	
90	Do you make sure that process managers understand your process policies?	Y	N	X	
91	Do you make sure that process managers know how to apply process policies?	Y	N	X	
92	Do you make sure that process managers understand your process procedures?	Y	N	X	
93	Do you make sure that process managers know how to follow process procedures?	Y	N	X	
94	Do you make sure that process managers understand their process objectives?	Y	N	X	
95	Do you make sure that process managers know how to achieve process objectives?	Y	N	X	
96	Do you make sure that managers know who is responsible for achieving objectives?	Y	N	X	
97	Do you ensure that personnel understand policies, procedures, and objectives?	Y	N	X	
98	Do you make sure that process personnel understand your process policies?	Y	N	X	
99	Do you make sure that process personnel know how to apply process policies?	Y	N	X	
100	Do you make sure that process personnel understand your process procedures?	Y	N	X	
101	Do you make sure that process personnel know how to follow process procedures?	Y	N	X	
102	Do you make sure that process personnel understand their process objectives?	Y	N	X	

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103	Do you make sure that process personnel know how to achieve process objectives?	Y	N	X	
104	Do you make sure that personnel know who is responsible for achieving objectives?	Y	N	X	

2.6 COMMUNICATE PROCESS MANAGEMENT EXPECTATIONS

105	Do you explain why process policies must be applied?	Y	N	X	
106	Do you explain why process procedures must be used?	Y	N	X	
107	Do you explain why process objectives must be achieved?	Y	N	X	
108	Do you explain why process requirements must be met?	Y	N	X	
109	Do you explain why output requirements must be met?	Y	N	X	
110	Do you explain why process methods must be followed?	Y	N	X	
111	Do you explain why the process approach is important?	Y	N	X	
112	Do you explain why management programmes are important?	Y	N	X	
113	Do you explain why risk management is important?	Y	N	X	
114	Do you explain why safety management is important?	Y	N	X	
115	Do you explain why safety policies must be implemented?	Y	N	X	
116	Do you explain why safety objectives must be achieved?	Y	N	X	
117	Do you explain why safety requirements must be met?	Y	N	X	
118	Do you explain why quality management is important?	Y	N	X	
119	Do you explain why quality policies must be implemented?	Y	N	X	
120	Do you explain why quality objectives must be achieved?	Y	N	X	
121	Do you explain why quality requirements must be met?	Y	N	X	
122	Do you explain why environmental management is important?	Y	N	X	

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PROCESS BEING AUDITED:**2. ASSESS PROCESS IMPLEMENTATION ACTIVITIES**

123	Do you explain why environmental policies must be implemented?	Y	N	X	
124	Do you explain why environmental objectives must be achieved?	Y	N	X	
125	Do you explain why environmental requirements must be met?	Y	N	X	
126	Do you explain why business continuity management is important?	Y	N	X	
127	Do you explain why business continuity policies must be implemented?	Y	N	X	
128	Do you explain why business continuity objectives must be achieved?	Y	N	X	
129	Do you explain why business continuity requirements must be met?	Y	N	X	
130	Do you explain why security management is important?	Y	N	X	
131	Do you explain why personnel security is important?	Y	N	X	
132	Do you explain why personnel security policies must be implemented?	Y	N	X	
133	Do you explain why personnel security objectives must be achieved?	Y	N	X	
134	Do you explain why personnel security requirements must be met?	Y	N	X	
135	Do you explain why information security is important?	Y	N	X	
136	Do you explain why information security policies must be implemented?	Y	N	X	
137	Do you explain why information security objectives must be achieved?	Y	N	X	
138	Do you explain why information security requirements must be met?	Y	N	X	
139	Do you explain why component security is important?	Y	N	X	
140	Do you explain why counterfeit parts management is important?	Y	N	X	
141	Do you explain why counterfeit parts policies must be implemented?	Y	N	X	
142	Do you explain why counterfeit parts objectives must be achieved?	Y	N	X	
143	Do you explain why counterfeit parts requirements must be met?	Y	N	X	

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2. ASSESS PROCESS IMPLEMENTATION ACTIVITIES

2.7 EXPECT ALL PROCESS MANAGERS TO BE ACCOUNTABLE

144	Do you ask managers to accept responsibility for their process?	Y	N	X	
145	Do you ask managers to be accountable for ensuring that process is effective?	Y	N	X	
146	Do you ask them to be accountable for ensuring that process produces intended outputs?	Y	N	X	
147	Do you ask managers to be accountable for ensuring that process meets requirements?	Y	N	X	
148	Do you ask them to be accountable for ensuring that process meets customer requirements?	Y	N	X	
149	Do you ask them to be accountable for ensuring that process meets technical requirements?	Y	N	X	
150	Do you ask them to be accountable for ensuring that process meets business requirements?	Y	N	X	
151	Do you ask them to be accountable for ensuring that process meets security requirements?	Y	N	X	
152	Do you ask them to be accountable for ensuring that process meets quality requirements?	Y	N	X	
153	Do you ask them to be accountable for ensuring that process meets safety requirements?	Y	N	X	
154	Do you ask them to be accountable for ensuring that process meets legal requirements?	Y	N	X	
155	Do you ask them to be accountable for ensuring that process meets environmental requirements?	Y	N	X	
156	Do you ask managers to be accountable for ensuring that process complies with standards?	Y	N	X	
157	Do you ask them to be accountable for ensuring that process complies with audit standards?	Y	N	X	
158	Do you ask them to be accountable for ensuring that process complies with safety standards?	Y	N	X	
159	Do you ask them to be accountable for ensuring that process complies with quality standards?	Y	N	X	
160	Do you ask them to be accountable for ensuring that process complies with service standards?	Y	N	X	
161	Do you ask them to be accountable for ensuring that process complies with product standards?	Y	N	X	
162	Do you ask them to be accountable for ensuring that process complies with security standards?	Y	N	X	
163	Do you ask them to be accountable for ensuring that process complies with environmental standards?	Y	N	X	

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PROCESS BEING AUDITED:**2. ASSESS PROCESS IMPLEMENTATION ACTIVITIES**

164	Do you ask managers to be accountable for ensuring that process implements policies?	Y	N	X	
165	Do you ask them to be accountable for ensuring that process implements audit policies?	Y	N	X	
166	Do you ask them to be accountable for ensuring that process implements safety policies?	Y	N	X	
167	Do you ask them to be accountable for ensuring that process implements quality policies?	Y	N	X	
168	Do you ask them to be accountable for ensuring that process implements service policies?	Y	N	X	
169	Do you ask them to be accountable for ensuring that process implements product policies?	Y	N	X	
170	Do you ask them to be accountable for ensuring that process implements security policies?	Y	N	X	
171	Do you ask them to be accountable for ensuring that process implements environmental policies?	Y	N	X	
172	Do you ask managers to be accountable for ensuring that process follows procedures?	Y	N	X	
173	Do you ask them to be accountable for ensuring that process follows safety procedures?	Y	N	X	
174	Do you ask them to be accountable for ensuring that process follows quality procedures?	Y	N	X	
175	Do you ask them to be accountable for ensuring that process follows service procedures?	Y	N	X	
176	Do you ask them to be accountable for ensuring that process follows product procedures?	Y	N	X	
177	Do you ask them to be accountable for ensuring that process follows security procedures?	Y	N	X	
178	Do you ask them to be accountable for ensuring that process follows environmental procedures?	Y	N	X	

2.8 ESTABLISH PROCESS MANAGEMENT PROGRAMMES

179	Did you establish a suitable quality management programme?	Y	N	X	
180	Do you formulate quality management requirements?	Y	N	X	
181	Do you allocate quality management goals and objectives?	Y	N	X	
182	Do you assign quality management responsibilities and authorities?	Y	N	X	
183	Do you implement quality management plans, policies, and procedures?	Y	N	X	

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PROCESS BEING AUDITED:**2. ASSESS PROCESS IMPLEMENTATION ACTIVITIES**

184	Have you identified suitable quality control points and do you apply quality controls?	Y	N	X	
185	Did you establish a suitable configuration management programme?	Y	N	X	
186	Did you establish a programme to identify and control the attributes of process outputs?	Y	N	X	
187	Did you establish a programme to identify and control output identities and characteristics?	Y	N	X	
188	Did you establish a programme to identify and control output traceability to requirements?	Y	N	X	
189	Did you establish a programme to identify and control output changes and modifications?	Y	N	X	
190	Did you establish a programme to identify and control output documents and records?	Y	N	X	
191	Do you make sure that your output documents and records are consistent with the actual attributes of your outputs?	Y	N	X	
192	Do you ensure that requirements documentation is consistent with actual attributes?	Y	N	X	
193	Do you ensure that your design documentation is consistent with actual attributes?	Y	N	X	
194	Do you ensure that your validation documentation is consistent with actual attributes?	Y	N	X	
195	Do you ensure that your verification documentation is consistent with actual attributes?	Y	N	X	
196	Do you ensure that your acceptance documentation is consistent with actual attributes?	Y	N	X	
197	Do you assign responsibility for identifying and controlling the attributes of process outputs?	Y	N	X	
198	Did you establish a suitable supplier management programme?	Y	N	X	
199	Did you establish a programme to manage and control external providers?	Y	N	X	
200	Do you allocate supplier management goals and objectives?	Y	N	X	
201	Do you assign supplier management responsibilities and authorities?	Y	N	X	
202	Do you implement supplier management plans, policies, and procedures?	Y	N	X	
203	Have you identified supplier control points and do you apply supplier controls?	Y	N	X	
204	Did you establish a register of external provider performance and status?	Y	N	X	

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PROCESS BEING AUDITED:**2. ASSESS PROCESS IMPLEMENTATION ACTIVITIES**

205	Did you establish a suitable risk management programme?	Y	N	X	
206	Do you assign risk management responsibilities?	Y	N	X	
207	Do you assign operational risk management tasks?	Y	N	X	
208	Do you manage risks related to process outputs?	Y	N	X	
209	Have you identified risks related to process outputs?	Y	N	X	
210	Do you assess risks related to process outputs?	Y	N	X	
211	Do you determine the likelihood that events will occur?	Y	N	X	
212	Do you determine the likelihood or probability that an undesirable occurrence or outcome will actually occur in the future?	Y	N	X	
213	Do you evaluate potentially severe consequences?	Y	N	X	
214	Do you make operational risk acceptance decisions?	Y	N	X	
215	Do you communicate risks related to process outputs?	Y	N	X	
216	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	
217	Have you identified the actions that must be taken to mitigate operational risks?	Y	N	X	
218	Do you implement actions that must be taken to mitigate operational risks?	Y	N	X	
219	Do you control the risks that remain after you've implemented actions to mitigate unacceptable operational risks?	Y	N	X	
220	Did you establish a suitable security management programme?	Y	N	X	
221	Did you establish a component security management programme?	Y	N	X	
222	Did you set up a counterfeit parts management programme?	Y	N	X	
223	Do you assign responsibility and authority for counterfeit parts?	Y	N	X	
224	Do you implement policies and procedures for counterfeit parts?	Y	N	X	

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225	Have you identified counterfeit control points and do you apply controls?	Y	N	X	
226	Do you teach people about counterfeit parts and components?	Y	N	X	
227	Do you explain how counterfeit parts can be prevented?	Y	N	X	
228	Do you explain how suspicious parts can be detected?	Y	N	X	
229	Do you monitor counterfeit parts reported by external sources?	Y	N	X	
230	Do you monitor suspicious and obsolete parts and components?	Y	N	X	
231	Do you control the acquisition and use of parts and components?	Y	N	X	
232	Do you acquire parts and components from original or authorized manufacturers?	Y	N	X	
233	Do you acquire items from authorized distributors or other approved sources?	Y	N	X	
234	Do you test and verify parts and components and detect all counterfeit items?	Y	N	X	
235	Do you quarantine and report suspicious or counterfeit parts and components?	Y	N	X	
236	Do you maintain a parts and components traceability programme?	Y	N	X	
237	Did you establish an information security management programme?	Y	N	X	
238	Do you allocate goals and objectives for information security?	Y	N	X	
239	Do you assign responsibility and authority for information security?	Y	N	X	
240	Do you implement plans, policies, and procedures for information security?	Y	N	X	
241	Have you identified suitable infosec control points and do you apply infosec controls?	Y	N	X	
242	Did you establish a personnel security management programme?	Y	N	X	
243	Do you allocate goals and objectives for personnel security?	Y	N	X	
244	Do you assign responsibility and authority for personnel security?	Y	N	X	
245	Do you implement plans, policies, and procedures for personnel security?	Y	N	X	
246	Have you identified suitable personnel control points and do you apply personnel controls?	Y	N	X	

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2. ASSESS PROCESS IMPLEMENTATION ACTIVITIES

247	Did you establish a suitable safety management programme?	Y	N	X	
248	Do you formulate safety management requirements?	Y	N	X	
249	Do you allocate safety management goals and objectives?	Y	N	X	
250	Do you assign safety management responsibilities and authorities?	Y	N	X	
251	Do you implement safety management plans, policies, and procedures?	Y	N	X	
252	Have you identified suitable safety control points and do you apply safety controls?	Y	N	X	
253	Did you establish a suitable environmental management programme?	Y	N	X	
254	Do you formulate environmental management requirements?	Y	N	X	
255	Do you allocate environmental management goals and objectives?	Y	N	X	
256	Do you assign environmental management responsibilities and authorities?	Y	N	X	
257	Do you implement environmental management plans, policies, and procedures?	Y	N	X	
258	Did you establish a suitable business continuity management programme?	Y	N	X	
259	Do you formulate business continuity management requirements?	Y	N	X	
260	Do you allocate business continuity management goals and objectives?	Y	N	X	
261	Do you assign business continuity management responsibilities and authorities?	Y	N	X	
262	Do you implement business continuity management plans, policies, and procedures?	Y	N	X	

2.9 RETAIN IMPLEMENTATION DOCUMENTATION

263	Do you retain a record of implementation responsibilities?	Y	N	X	
264	Do you retain a record of implementation plans and procedures?	Y	N	X	
265	Do you retain a record of implementation results and achievements?	Y	N	X	
266	Do you retain a record of process verification and validation activities?	Y	N	X	
267	Do you retain a record of process verification and validation results?	Y	N	X	

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3. ASSESS PROCESS OPERATION ACTIVITIES

3.1 PROVIDE RESOURCES TO FACILITATE PROCESS OPERATIONS

3.1.1 PROVIDE THE EXPERTISE NEEDED TO OPERATE YOUR PROCESS

1	Do you provide the managers needed to manage process operations?	Y	N	X	
2	Do you acquire the knowledge that managers need to manage process operations and achieve conformity of outputs?	Y	N	X	
3	Do you consider internal sources of knowledge about managing processes?	Y	N	X	
4	Do you consider external sources of knowledge about managing processes?	Y	N	X	
5	Do you share the knowledge that managers need in order to manage process operations and achieve conformity of outputs?	Y	N	X	
6	Do you deliver suitable process management training and awareness programmes to process managers?	Y	N	X	
7	Do you provide the personnel needed to operate your process?	Y	N	X	
8	Do you acquire the knowledge that personnel need in order to operate your process and achieve conformity of outputs?	Y	N	X	
9	Do you consider internal sources of knowledge about process operations?	Y	N	X	
10	Do you consider external sources of knowledge about process operations?	Y	N	X	
11	Do you share the knowledge that personnel need in order to operate your process and achieve conformity of outputs?	Y	N	X	
12	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

13	Do you provide the software needed to operate your process?	Y	N	X	
14	Do you provide software needed to support operations and achieve conformity of outputs?	Y	N	X	
15	Do you provide the hardware needed to operate your process?	Y	N	X	
16	Do you provide hardware needed to support operations and achieve conformity of outputs?	Y	N	X	

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3. ASSESS PROCESS OPERATION ACTIVITIES

3.1.3 PROVIDE THE INFRASTRUCTURE NEEDED TO OPERATE YOUR PROCESS

17	Do you provide the infrastructure needed to support process operations and achieve conformity of outputs?	Y	N	X	
18	Do you provide the physical infrastructure needed to support process operations and achieve conformity of outputs?	Y	N	X	
19	Do you provide the electrical infrastructure needed to support process operations and achieve conformity of outputs?	Y	N	X	
20	Do you provide the transportation infrastructure needed to support process operations and achieve conformity of outputs?	Y	N	X	
21	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

22	Do you expect process managers to identify the operational risks that could affect their ability to meet requirements?	Y	N	X	
23	Do you expect process managers to identify risks and opportunities?	Y	N	X	
24	Do you expect them to consider whether they have the capacity or are capable of meeting requirements?	Y	N	X	
25	Do you expect them to consider whether output delivery time frames can be accommodated?	Y	N	X	
26	Do you expect them to consider whether the use of new technologies could influence performance?	Y	N	X	
27	Do you expect process managers to identify the opportunities that could improve their ability to meet requirements?	Y	N	X	
28	Do you expect process managers to cope with process risks and opportunities?	Y	N	X	
29	Do you expect process managers to manage and control process risks?	Y	N	X	
30	Do you expect them to consider all of their risk treatment options?	Y	N	X	

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3. ASSESS PROCESS OPERATION ACTIVITIES

31	Do you expect them to consider avoiding or reducing their risk?	Y	N	X	
32	Do you expect them to consider eliminating the source of their risk?	Y	N	X	
33	Do you expect them to consider retaining the risk or sharing it with others?	Y	N	X	
34	Do you expect them to consider modifying the probabilities or consequences?	Y	N	X	
35	Do you expect process managers to define actions to address risks and opportunities?	Y	N	X	
36	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	
37	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	
38	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	
39	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	
40	Do you expect process managers to exploit process improvement opportunities?	Y	N	X	
41	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

42	Do you expect process managers to implement process policies?	Y	N	X	
43	Do you expect managers to implement business policies?	Y	N	X	
44	Do you expect managers to implement quality policies?	Y	N	X	
45	Do you expect managers to implement safety policies?	Y	N	X	
46	Do you expect managers to implement security policies?	Y	N	X	
47	Do you expect managers to implement continuity policies?	Y	N	X	
48	Do you expect managers to implement environmental policies?	Y	N	X	
49	Do you expect process managers to implement process procedures?	Y	N	X	

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50	Do you expect managers to implement business procedures?	Y	N	X	
51	Do you expect managers to implement quality procedures?	Y	N	X	
52	Do you expect managers to implement safety procedures?	Y	N	X	
53	Do you expect managers to implement security procedures?	Y	N	X	
54	Do you expect managers to implement continuity procedures?	Y	N	X	
55	Do you expect managers to implement environmental procedures?	Y	N	X	

3.2.3 EXPECT PROCESS MANAGERS TO SPECIFY OUTPUT REQUIREMENTS AND CAPABILITIES

56	Do you expect process managers to determine requirements for outputs offered to customers?	Y	N	X	
57	Do you expect managers to determine statutory and regulatory requirements for outputs?	Y	N	X	
58	Do you expect managers to determine your organization's own requirements for outputs?	Y	N	X	
59	Do you expect managers to determine any additional "special requirements" for outputs?	Y	N	X	
60	Do you expect managers to identify requirements that may be especially difficult to meet?	Y	N	X	
61	Do you expect them to identify requirements that force them to operate at the limit of their technical capability?	Y	N	X	
62	Do you expect them to identify requirements that force them to operate at the limit of their process capability?	Y	N	X	
63	Do you expect process managers to review output requirements before accepting orders?	Y	N	X	
64	Do you expect managers to review output requirements before making a commitment to supply outputs to customers?	Y	N	X	
65	Do you expect managers to coordinate reviews with applicable functions within your organization?	Y	N	X	
66	Do you expect them to review all documented requirements before accepting orders?	Y	N	X	
67	Do you expect them to review output requirements specified by customers?	Y	N	X	
68	Do you expect them to review delivery and post-delivery requirements before proceeding?	Y	N	X	

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69	Do you expect them to review output requirements specified by regulatory bodies?	Y	N	X	
70	Do you expect them to review applicable statutory and regulatory requirements?	Y	N	X	
71	Do you expect them to review output requirements specified by interested parties?	Y	N	X	
72	Do you expect them to review output requirements specified by your organization?	Y	N	X	
73	Do you expect them to review all undocumented requirements before accepting orders?	Y	N	X	
74	Do you expect them to review unstated requirements needed for specified or intended use?	Y	N	X	
75	Do you expect process managers to clarify all differences between the original proposal and the final order?	Y	N	X	
76	Do you expect process managers to review all orders and contractual requirements that have been modified?	Y	N	X	
77	Do you expect process managers to coordinate the review of contracts and orders that have been modified?	Y	N	X	
78	Do you expect them to resolve all differences between the original proposal and the final order?	Y	N	X	
79	Do you expect them to negotiate mutually acceptable requirements with customers whenever some customer requirements cannot be met?	Y	N	X	
80	Do you expect them to amend all relevant documented information to reflect changes in customers' output requirements?	Y	N	X	
81	Do you expect them to distribute amended information to all relevant people?	Y	N	X	
82	Do you expect process managers to confirm that they can meet output requirements?	Y	N	X	
83	Do you expect process managers to confirm that they can meet undocumented customer requirements before making a commitment to supply outputs?	Y	N	X	
84	Do you expect process managers to document the review of output requirements?	Y	N	X	
85	Do you expect process managers to document the results of output requirement reviews?	Y	N	X	
86	Do you expect process managers to retain documents that record results of their reviews?	Y	N	X	

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3. ASSESS PROCESS OPERATION ACTIVITIES

87	Do you expect process managers to control documents that record results of their reviews?	Y	N	X	
88	Do you expect process managers to document any new or changed output requirements?	Y	N	X	
89	Do you expect managers to retain documents that record new or changed requirements?	Y	N	X	
90	Do you expect managers to control documents that record new or changed requirements?	Y	N	X	
91	Do you expect process managers to amend documents when output requirements change?	Y	N	X	
92	Do you expect managers to control documents that record changes in output requirements?	Y	N	X	
93	Do you expect process managers to amend all relevant documented information to reflect changes in customers' output requirements?	Y	N	X	
94	Do you expect them to retain documents and records that describe new or modified output requirements?	Y	N	X	
95	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

96	Do you expect process managers to provide information to customers?	Y	N	X	
97	Do you expect process managers to share information about process outputs?	Y	N	X	
98	Do you expect process managers to discuss contingency plans (when relevant)?	Y	N	X	
99	Do you expect process managers to clarify specific requirements for action?	Y	N	X	
100	Do you expect process managers to obtain information from customers?	Y	N	X	
101	Do you expect process managers to obtain information about orders and contracts?	Y	N	X	
102	Do you expect managers to receive information about changes to orders and contracts?	Y	N	X	
103	Do you expect process managers to obtain information about process outputs?	Y	N	X	
104	Do you expect managers to gather customer feedback about process outputs?	Y	N	X	
105	Do you expect managers to gather complaints about their process outputs?	Y	N	X	

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106	Do you expect process managers to obtain information about property supplied by customers?	Y	N	X	
107	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

108	Do you expect process managers to accept responsibility for externally provided processes, products, and services?	Y	N	X	
109	Do you expect process managers to accept responsibility for conformity of external processes, products, and services?	Y	N	X	
110	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	
111	Do you expect process managers to identify risks related to the external provision of processes, products, and services?	Y	N	X	
112	Do you expect them to identify risks related to the selection and use of external providers and external sources?	Y	N	X	
113	Do you expect process managers to define data and criteria needed to manage external process, product, and service providers?	Y	N	X	
114	Do you expect them to use data and criteria to evaluate external process, product, and service providers?	Y	N	X	
115	Do you expect them to use data from external sources to evaluate external providers?	Y	N	X	
116	Do you expect them to use data from customer organizations to evaluate external providers?	Y	N	X	
117	Do you expect them to use data from government authorities to evaluate external providers?	Y	N	X	
118	Do you expect them to use data from certification bodies to evaluate external providers?	Y	N	X	
119	Do you expect them to use criteria to evaluate external process, product, and service providers?	Y	N	X	
120	Do you expect them to evaluate and re-evaluate their ability to meet specified requirements?	Y	N	X	
121	Do you expect them to document their external evaluation and re-evaluation activities?	Y	N	X	
122	Do you expect them to retain and control records of evaluation and re-evaluation activities?	Y	N	X	

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123	Do you expect them to use data and criteria to select external process, product, and service providers?	Y	N	X	
124	Do you expect them to use data from external sources to select external providers?	Y	N	X	
125	Do you expect them to use data from customer organizations to select external providers?	Y	N	X	
126	Do you expect them to use data from government authorities to select external providers?	Y	N	X	
127	Do you expect them to use data from certification bodies to select external providers?	Y	N	X	
128	Do you expect them to use criteria to select providers that can meet specified requirements?	Y	N	X	
129	Do you expect them to document provider selection activities and retain these documents?	Y	N	X	
130	Do you expect them to control documents that describe provider selection activities?	Y	N	X	
131	Do you expect them to record approval status of each provider and to retain these records?	Y	N	X	
132	Do you expect them to record scope of approvals and the work that has been authorized?	Y	N	X	
133	Do you expect them to specify what types of products and services have been approved?	Y	N	X	
134	Do you expect process managers to specify what they expect from external process, product, and service providers?	Y	N	X	
135	Do you expect process managers to identify process requirements?	Y	N	X	
136	Do you expect them to identify external process approval requirements?	Y	N	X	
137	Do you expect process managers to identify product requirements?	Y	N	X	
138	Do you expect them to identify external product acceptance requirements?	Y	N	X	
139	Do you expect them to identify statistical techniques that must be used?	Y	N	X	
140	Do you expect them to identify acceptance instructions that must be followed?	Y	N	X	
141	Do you expect them to identify external product approval requirements?	Y	N	X	
142	Do you expect them to identify external product release requirements?	Y	N	X	

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143	Do you expect process managers to identify service requirements?	Y	N	X	
144	Do you expect them to identify external service acceptance requirements?	Y	N	X	
145	Do you expect them to identify external service approval requirements?	Y	N	X	
146	Do you expect them to identify external service release requirements?	Y	N	X	
147	Do you expect process managers to identify equipment requirements?	Y	N	X	
148	Do you expect them to identify external equipment approval requirements?	Y	N	X	
149	Do you expect process managers to identify "special requirements"?	Y	N	X	
150	Do you expect them to identify "critical items" and "key characteristics"?	Y	N	X	
151	Do you expect process managers to identify information requirements?	Y	N	X	
152	Do you expect them to identify technical data and information requirements?	Y	N	X	
153	Do you expect them to identify requirements for specifications and drawings?	Y	N	X	
154	Do you expect process managers to identify procedural requirements?	Y	N	X	
155	Do you expect them to identify any work practices that providers need to follow?	Y	N	X	
156	Do you expect them to identify any work instructions that providers need to follow?	Y	N	X	
157	Do you expect process managers to identify methodological requirements?	Y	N	X	
158	Do you expect them to identify how external methods are approved?	Y	N	X	
159	Do you expect process managers to identify interaction requirements?	Y	N	X	
160	Do you expect them to identify how external providers interact with your process?	Y	N	X	
161	Do you expect process managers to identify notification requirements?	Y	N	X	
162	Do you expect them to specify supply chain notification requirements?	Y	N	X	
163	Do you expect them to ask external providers to notify them when changes are planned?	Y	N	X	

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164	Do you expect them to get approval whenever important changes are being considered?	Y	N	X	
165	Do you ask process managers to get approval when process changes are being planned?	Y	N	X	
166	Do you ask process managers to get approval when product changes are being planned?	Y	N	X	
167	Do you ask process managers to get approval when service changes are being planned?	Y	N	X	
168	Do you ask process managers to get approval when provider changes are being planned?	Y	N	X	
169	Do you ask process managers to get approval when location changes are being planned?	Y	N	X	
170	Do you ask them to get approval before changing manufacturing or assembly locations?	Y	N	X	
171	Do you expect them to specify nonconformance notification requirements?	Y	N	X	
172	Do you expect them to specify nonconformance approval and disposition requirements?	Y	N	X	
173	Do you expect process managers to identify design and development requirements?	Y	N	X	
174	Do you expect them to specify design and development control requirements?	Y	N	X	
175	Do you expect process managers to identify verification and validation requirements?	Y	N	X	
176	Do you expect them to identify verification and validation activities to be done at external premises?	Y	N	X	
177	Do you expect them to identify verifications and validations that customers plan to perform?	Y	N	X	
178	Do you expect them to identify verifications and validations that they intend to carry out?	Y	N	X	
179	Do you expect process managers to identify production requirements?	Y	N	X	
180	Do you expect them to specify production process verification requirements?	Y	N	X	
181	Do you expect process managers to identify test and inspection requirements?	Y	N	X	
182	Do you ask external providers to provide test specimens when required?	Y	N	X	
183	Do you expect them to provide test specimens for inspection purposes?	Y	N	X	
184	Do you expect them to provide test specimens for verification purposes?	Y	N	X	

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185	Do you expect them to provide test specimens for investigative purposes?	Y	N	X	
186	Do you expect them to provide test specimens for auditing purposes?	Y	N	X	
187	Do you expect process managers to identify part and component requirements?	Y	N	X	
188	Do you expect managers to prohibit the use of counterfeit parts and components?	Y	N	X	
189	Do you expect managers to ask external providers to prevent the use of counterfeit parts?	Y	N	X	
190	Do you expect process managers to identify outsourcing requirements?	Y	N	X	
191	Do you expect them to identify any external providers that external providers must use?	Y	N	X	
192	Do you expect them to identify any special providers that customers have pre-approved?	Y	N	X	
193	Do you expect them to identify any special providers that customers expect you to use?	Y	N	X	
194	Do you expect them to identify any specific processes that external providers must use?	Y	N	X	
195	Do you expect them to identify any process sources that external providers must employ?	Y	N	X	
196	Do you expect them to identify any "special process" requirements that must be met?	Y	N	X	
197	Do you expect process managers to identify supply chain requirements?	Y	N	X	
198	Do you expect them to identify your organization's supply chain access requirements?	Y	N	X	
199	Do you expect them to establish the right to access relevant areas throughout supply chain?	Y	N	X	
200	Do you expect them to establish your organization's right to access facilities and documents?	Y	N	X	
201	Do you expect them to establish your customers' right to access facilities and documents?	Y	N	X	
202	Do you expect them to identify your organization's supply chain flowdown requirements?	Y	N	X	
203	Do you expect them to identify important requirements that must flow down the supply chain?	Y	N	X	
204	Do you expect them to identify customer requirements that must flow down to suppliers?	Y	N	X	
205	Do you expect process managers to identify external staff awareness requirements?	Y	N	X	

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206	Do you expect them to ask external providers to emphasize the importance of safety?	Y	N	X	
207	Do you expect them to ask external providers to emphasize the importance of security?	Y	N	X	
208	Do you expect them to ask external providers to emphasize the importance of quality?	Y	N	X	
209	Do you expect them to ask providers to emphasize the importance of conformity?	Y	N	X	
210	Do you expect them to ask external providers to make their personnel aware of their contribution to product and service conformity?	Y	N	X	
211	Do you expect process managers to identify external competence requirements?	Y	N	X	
212	Do you expect them to specify external personnel qualification requirements?	Y	N	X	
213	Do you expect process managers to identify monitoring and control requirements?	Y	N	X	
214	Do you expect them to define how they plan to monitor performance of external providers?	Y	N	X	
215	Do you expect them to define how they plan to control performance of external providers?	Y	N	X	
216	Do you expect process managers to identify quality management requirements?	Y	N	X	
217	Do you expect them to identify quality management system implementation requirements?	Y	N	X	
218	Do you expect process managers to identify documentation requirements?	Y	N	X	
219	Do you expect them to ask external providers to retain documented information?	Y	N	X	
220	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

221	Do you expect process managers to verify that resources can produce required results?	Y	N	X	
222	Do you expect process managers to validate resources that will be used to operate process?	Y	N	X	
223	Do you expect managers to validate tools before they are used to operate process?	Y	N	X	
224	Do you expect managers to validate equipment before it is used to operate process?	Y	N	X	
225	Do you expect managers to validate software before it is used to operate process?	Y	N	X	

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226	Do you expect process managers to validate resources that will be used to automate process?	Y	N	X	
227	Do you expect managers to validate tools before they are used to automate process?	Y	N	X	
228	Do you expect managers to validate equipment before it is used to automate process?	Y	N	X	
229	Do you expect managers to validate software before it is used to automate process?	Y	N	X	
230	Do you expect process managers to validate resources that will be used to control process?	Y	N	X	
231	Do you expect managers to validate tools before they are used to control process?	Y	N	X	
232	Do you expect managers to validate equipment before it is used to control process?	Y	N	X	
233	Do you expect managers to validate software before it is used to control process?	Y	N	X	
234	Do you expect process managers to validate resources that will be used to monitor process?	Y	N	X	
235	Do you expect managers to validate tools before they are used to monitor process?	Y	N	X	
236	Do you expect managers to validate equipment before it is used to monitor process?	Y	N	X	
237	Do you expect managers to validate software before it is used to monitor process?	Y	N	X	
238	Do you expect process managers to validate resources that will be used to measure process?	Y	N	X	
239	Do you expect managers to validate tools before they are used to measure process?	Y	N	X	
240	Do you expect managers to validate equipment before it is used to measure process?	Y	N	X	
241	Do you expect managers to validate software before it is used to measure process?	Y	N	X	
242	Do you expect process managers to supervise and control all process personnel?	Y	N	X	
243	Do you expect process managers to plan and control all work transfer activities?	Y	N	X	
244	Do you expect them to ensure that risks are managed and requirements continue to be met?	Y	N	X	
245	Do you expect them to plan how they're going to manage and control the transfer of work?	Y	N	X	
246	Do you expect them to plan how they're going to transfer work within their own organization?	Y	N	X	
247	Do you expect them to plan how they're going to transfer work to and from external providers?	Y	N	X	

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248	Do you expect them to plan how they're going to transfer work between external providers?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
249	Do you expect process managers to control process documents and record keeping?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
250	Do you expect them to ensure that process documents and records are properly reviewed and approved?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
251	Do you expect them to ensure that authorized persons have been identified for each type of document and record?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
252	Do you expect them to ensure that approval methods have been identified for each type of document and record?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

3.2.7 EXPECT PROCESS MANAGERS TO MEASURE CONFORMANCE AND PERFORMANCE

253	Do you expect process managers to measure process performance and conformance?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
254	Do you expect process managers to measure output performance and conformance?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
255	Do you expect managers to measure output delivery performance and conformance?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
256	Do you expect managers to measure post-delivery performance and conformance?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

3.2.8 EXPECT PROCESS MANAGERS TO MEET EXPECTATIONS AND REQUIREMENTS

257	Do you expect process managers to ensure that legal expectations and requirements are met?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
258	Do you expect process managers to ensure that safety expectations and requirements are met?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
259	Do you expect process managers to ensure that quality expectations and requirements are met?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
260	Do you expect process managers to ensure that security expectations and requirements are met?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
261	Do you expect process managers to ensure that business expectations and requirements are met?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
262	Do you expect process managers to ensure that customer expectations and requirements are met?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

3.2.9 EXPECT PROCESS MANAGERS TO BE ACCOUNTABLE FOR THEIR PROCESS

263	Do you expect managers to ensure that process produces intended outputs?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
264	Do you expect managers to preserve outputs during process operations?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
265	Do you expect them to figure out how to preserve outputs during process operations?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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266	Do you expect them to consider using suitable identification methods to preserve outputs?	Y	N	X	
267	Do you expect them to consider using suitable packaging methods to preserve outputs?	Y	N	X	
268	Do you expect them to consider using suitable handling methods to preserve outputs?	Y	N	X	
269	Do you expect them to consider using suitable storage methods to preserve outputs?	Y	N	X	
270	Do you expect them to consider using suitable transmission methods to preserve outputs?	Y	N	X	
271	Do you expect them to consider using suitable transportation methods to preserve outputs?	Y	N	X	
272	Do you expect them to preserve outputs in accordance with official requirements?	Y	N	X	
273	Do you expect them to preserve outputs by establishing cleaning and sanitization practices?	Y	N	X	
274	Do you expect them to preserve outputs by establishing arrangements to control foreign objects?	Y	N	X	
275	Do you expect them to make arrangements to detect, prevent, and remove foreign objects?	Y	N	X	
276	Do you expect them to use arrangements to detect, prevent, and remove foreign objects?	Y	N	X	
277	Do you expect them to preserve outputs by establishing handling methods and storage facilities?	Y	N	X	
278	Do you expect them to use suitable methods and facilities to preserve sensitive products?	Y	N	X	
279	Do you expect them to use suitable methods and facilities to manage hazardous materials?	Y	N	X	
280	Do you expect them to preserve outputs by establishing marking methods and labeling practices?	Y	N	X	
281	Do you expect them to use safety warnings to preserve outputs during process operations?	Y	N	X	
282	Do you expect them to preserve outputs by establishing shelf life controls and rotating stock?	Y	N	X	
283	Do you expect managers to establish controlled conditions for output delivery?	Y	N	X	
284	Do you expect them to use documented information to control output delivery activities?	Y	N	X	
285	Do you expect them to document the characteristics of delivery activities to be provided?	Y	N	X	
286	Do you expect them to maintain and control documents defining delivery characteristics?	Y	N	X	
287	Do you expect them to document the output delivery results that you expect to achieve?	Y	N	X	

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288	Do you expect them to maintain and control documents defining expected delivery results?	Y	N	X	
289	Do you expect them to use suitable monitoring and measurement resources to control delivery?	Y	N	X	
290	Do you expect them to verify that output delivery process control criteria have been met?	Y	N	X	
291	Do you expect them to verify that your output delivery criteria have been met?	Y	N	X	
292	Do you expect them to verify that acceptance criteria for delivery have been met?	Y	N	X	
293	Do you expect them to verify acceptance before outputs are released?	Y	N	X	
294	Do you expect them to use a suitable process environment to control output delivery process?	Y	N	X	
295	Do you expect them to use a suitable infrastructure to control output delivery activities?	Y	N	X	
296	Do you expect them to use competent qualified personnel to control output delivery activities?	Y	N	X	
297	Do you expect them to take action to prevent human error during output delivery activities?	Y	N	X	
298	Do you expect managers to address post-delivery requirements for outputs?	Y	N	X	
299	Do you expect managers to develop controlled conditions for post-delivery?	Y	N	X	
300	Do you expect them to consider post-delivery requirements and commitments?	Y	N	X	
301	Do you expect them to identify activities that must be carried out after outputs are delivered?	Y	N	X	
302	Do you expect them to consider output requirements that customers want them to meet?	Y	N	X	
303	Do you expect them to consider nature and use of outputs and how long they could last?	Y	N	X	
304	Do you expect them to consider statutory and regulatory requirements affecting outputs?	Y	N	X	
305	Do you expect them to consider potential consequences that outputs could produce?	Y	N	X	
306	Do you expect them to consider feedback their customers provide about outputs?	Y	N	X	
307	Do you expect them to consider performance and reliability of their outputs?	Y	N	X	
308	Do you expect them to consider collecting and analyzing in-service data about outputs?	Y	N	X	
309	Do you expect them to consider reviewing the lessons they have learned about outputs?	Y	N	X	

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310	Do you expect them to consider the technical documentation needed to support outputs?	Y	N	X	
311	Do you expect them to consider the need to provide, update, and control output documents?	Y	N	X	
312	Do you expect them to consider documentation needed in order to use their outputs?	Y	N	X	
313	Do you expect them to consider documentation needed in order to maintain their outputs?	Y	N	X	
314	Do you expect them to consider documentation needed in order to overhaul their outputs?	Y	N	X	
315	Do you expect them to consider the documentation needed in order to repair their outputs?	Y	N	X	
316	Do you expect them to consider the external work that must be done to support outputs?	Y	N	X	
317	Do you expect them to consider how external work should be carried out and controlled?	Y	N	X	
318	Do you expect them to consider external resources that are needed to support outputs?	Y	N	X	
319	Do you expect them to consider agreements that they have made to support outputs?	Y	N	X	
320	Do you expect them to consider output warranty commitments that they have made?	Y	N	X	
321	Do you expect them to consider the need to provide replacement components?	Y	N	X	
322	Do you expect them to consider how, why, and when outputs will be obsolete?	Y	N	X	
323	Do you expect them to consider services that must be provided to support outputs?	Y	N	X	
324	Do you expect them to consider training that must be delivered to support outputs?	Y	N	X	
325	Do you expect them to consider follow-up queries that must be handled?	Y	N	X	
326	Do you expect them to consider maintenance that must be done to support outputs?	Y	N	X	
327	Do you expect them to consider disposal services that must be provided?	Y	N	X	
328	Do you expect them to consider recycling services that must be provided?	Y	N	X	
329	Do you expect them to consider the actions that must be taken after outputs are delivered?	Y	N	X	
330	Do you expect them to consider steps that must be taken when problems are detected?	Y	N	X	
331	Do you expect them to consider the investigations that must be carried out?	Y	N	X	

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332	Do you expect them to consider the reporting that must be carried out?	Y	N	X	
333	Do you expect managers to implement controlled conditions for post-delivery of outputs?	Y	N	X	
334	Do you expect them to implement controlled conditions for post-delivery of process outputs?	Y	N	X	
335	Do you expect them to use documented information to control post-delivery activities?	Y	N	X	
336	Do you expect them to document characteristics of post-delivery activities to be provided?	Y	N	X	
337	Do you expect them to keep and control documents defining post-delivery characteristics?	Y	N	X	
338	Do you expect them to document the post-delivery results that they expect to achieve?	Y	N	X	
339	Do you expect them to keep and control documents defining expected post-delivery results?	Y	N	X	
340	Do you expect them to use monitoring and measurement resources to control post-delivery?	Y	N	X	
341	Do you expect them to verify that post-delivery process control criteria are met?	Y	N	X	
342	Do you expect them to verify that post-delivery output criteria have been met?	Y	N	X	
343	Do you expect them to verify that acceptance criteria for post-delivery have been met?	Y	N	X	
344	Do you expect them to verify acceptance before post-delivery outputs are released?	Y	N	X	
345	Do you expect them to use a suitable process environment to control post-delivery activities?	Y	N	X	
346	Do you expect them to use a suitable infrastructure to control post-delivery activities?	Y	N	X	
347	Do you expect them to use competent qualified personnel to control post-delivery activities?	Y	N	X	
348	Do you expect them to take action to prevent human error during post-delivery activities?	Y	N	X	
349	Do you expect managers to identify and control nonconforming outputs?	Y	N	X	
350	Do you expect managers to evaluate nonconforming outputs?	Y	N	X	
351	Do you expect them to consider the nature of nonconforming output and to evaluate its effect?	Y	N	X	
352	Do you expect them to consider suspending or delaying the provision of products or services?	Y	N	X	
353	Do you expect them to consider correcting, containing, or segregating nonconforming outputs?	Y	N	X	

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354	Do you expect them to consider scrapping, discarding, or destroying nonconforming outputs?	Y	N	X	
355	Do you expect them to consider getting authorization to accept outputs under concession?	Y	N	X	
356	Do you expect them to consider telling customers about your nonconforming outputs?	Y	N	X	
357	Do you expect them to consider asking for the return of nonconforming products?	Y	N	X	
358	Do you expect managers to take action to control nonconforming outputs?	Y	N	X	
359	Do you expect them to prevent unintended use or delivery of nonconforming outputs?	Y	N	X	
360	Do you expect them to control nonconforming outputs that occur before outputs are delivered?	Y	N	X	
361	Do you expect them to control nonconforming outputs by correcting or containing them?	Y	N	X	
362	Do you expect them to verify conformity whenever nonconforming outputs are corrected?	Y	N	X	
363	Do you expect them to control nonconforming outputs by getting approval to accept them?	Y	N	X	
364	Do you expect them to get authorization from the customer or relevant authority?	Y	N	X	
365	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	
366	Do you expect managers to ask the customer to accept the nonconformity whenever it results in a departure from contractual requirements?	Y	N	X	
367	Do you expect them to control nonconforming outputs by scrapping or destroying them?	Y	N	X	
368	Do you expect them to control nonconforming outputs “dispositioned for scrap”?	Y	N	X	
369	Do you expect them to control scrapped outputs until they’re physically unusable?	Y	N	X	
370	Do you expect them to use output markings that are permanent and conspicuous?	Y	N	X	
371	Do you expect them to control nonconforming outputs that are or could be counterfeit?	Y	N	X	
372	Do you expect them to prevent counterfeit parts from reentering supply chains?	Y	N	X	

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373	Do you expect them to control nonconforming outputs that occur during output delivery?	Y	N	X	
374	Do you expect them to control nonconforming outputs that occur after output delivery?	Y	N	X	
375	Do you expect managers to document nonconforming process outputs?	Y	N	X	
376	Do you expect managers to document the actions and decisions taken to prevent the unintended use or delivery of nonconforming outputs?	Y	N	X	
377	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	
378	Do you expect them to retain documents describing nonconforming outputs and actions?	Y	N	X	
379	Do you expect them to control documents describing nonconforming outputs and actions?	Y	N	X	
380	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

381	Do you expect personnel to identify customer needs and expectations?	Y	N	X	
382	Do you expect personnel to identify customer assumptions and perceptions?	Y	N	X	
383	Do you expect personnel to understand customer needs and expectations?	Y	N	X	
384	Do you expect personnel to understand customer assumptions and perceptions?	Y	N	X	
385	Do you expect personnel to meet relevant customer needs and expectations?	Y	N	X	
386	Do you expect personnel to focus on enhancing customer satisfaction?	Y	N	X	

3.3.2 EXPECT PERSONNEL TO HANDLE RISKS AND OPPORTUNITIES

387	Do you expect personnel to identify their risks and opportunities?	Y	N	X	
388	Do you expect personnel to identify risks and opportunities related to outputs?	Y	N	X	
389	Do you expect them to identify the risks that could negatively influence their ability to provide compliant outputs to process customers?	Y	N	X	

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390	Do you expect them to identify the opportunities that could possibly enhance their ability to provide compliant outputs to process customers?	Y	N	X	
391	Do you expect personnel to identify risks and opportunities related to customer satisfaction?	Y	N	X	
392	Do you expect them to identify risks that could influence their ability to satisfy customers?	Y	N	X	
393	Do you expect them to identify opportunities that could enhance their ability to satisfy customers?	Y	N	X	
394	Do you expect personnel to address their risks and opportunities?	Y	N	X	
395	Do you expect personnel to address risks and opportunities related to outputs?	Y	N	X	
396	Do you expect them to address the risks that could negatively influence their ability to provide compliant outputs to process customers?	Y	N	X	
397	Do you expect them to address the opportunities that could enhance their ability to provide compliant outputs to process customers?	Y	N	X	
398	Do you expect personnel to address risks and opportunities related to customer satisfaction?	Y	N	X	
399	Do you expect them to address risks that could influence their ability to satisfy customers?	Y	N	X	
400	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

401	Do you expect personnel to apply process policies?	Y	N	X	
402	Do you expect them to apply safety policies?	Y	N	X	
403	Do you expect them to apply quality policies?	Y	N	X	
404	Do you expect them to apply security policies?	Y	N	X	
405	Do you expect them to apply business policies?	Y	N	X	
406	Do you expect them to apply continuity policies?	Y	N	X	
407	Do you expect them to apply environmental policies?	Y	N	X	
408	Do you expect personnel to apply process procedures?	Y	N	X	

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409	Do you expect them to apply safety procedures?	Y	N	X	
410	Do you expect them to apply quality procedures?	Y	N	X	
411	Do you expect them to apply security procedures?	Y	N	X	
412	Do you expect them to apply business procedures?	Y	N	X	
413	Do you expect them to apply continuity procedures?	Y	N	X	
414	Do you expect them to apply environmental procedures?	Y	N	X	

3.3.4 EXPECT PERSONNEL TO COMPLY WITH ALL RELEVANT REQUIREMENTS

415	Do you expect personnel to determine relevant requirements?	Y	N	X	
416	Do you expect them to identify customer requirements?	Y	N	X	
417	Do you expect them to identify legal requirements?	Y	N	X	
418	Do you expect them to identify statutory requirements?	Y	N	X	
419	Do you expect them to identify regulatory requirements?	Y	N	X	
420	Do you expect personnel to meet all relevant requirements?	Y	N	X	
421	Do you expect them to meet customer requirements?	Y	N	X	
422	Do you expect them to provide products that meet customer requirements?	Y	N	X	
423	Do you expect them to deliver services that meet customer requirements?	Y	N	X	
424	Do you expect them to meet legal requirements?	Y	N	X	
425	Do you expect them to provide products that meet legal requirements?	Y	N	X	
426	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

427	Do you expect personnel to take action when planned results aren't being achieved?	Y	N	X	
428	Do you expect personnel to take action when planned results won't be achieved?	Y	N	X	

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3. ASSESS PROCESS OPERATION ACTIVITIES

3.3.6 EXPECT PERSONNEL TO CONTROL PROCESS DOCUMENTS AND RECORDS

429	Do you expect personnel to retain and control process documents?	Y	N	X	
430	Do you expect personnel to maintain and control process records?	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 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. ASSESS PROCESS MAINTENANCE ACTIVITIES

4.1 PROVIDE THE RESOURCES NEEDED TO MAINTAIN PROCESS

4.1.1 PROVIDE THE EXPERTISE NEEDED TO MAINTAIN YOUR PROCESS

1	Do you provide the managers needed to maintain your process?	Y	N	X	
2	Do you acquire the knowledge that managers need in order to support process maintenance and achieve conformity of outputs?	Y	N	X	
3	Do you consider internal sources of knowledge about managing process maintenance?	Y	N	X	
4	Do you consider external sources of knowledge about managing process maintenance?	Y	N	X	
5	Do you share the knowledge that managers need so that they can support process maintenance and achieve conformity of outputs?	Y	N	X	
6	Do you deliver suitable training and awareness programmes to the people that manage process maintenance activities?	Y	N	X	
7	Do you provide the personnel needed to maintain your process?	Y	N	X	
8	Do you acquire the knowledge that personnel need in order to maintain process and achieve conformity of outputs?	Y	N	X	
9	Do you consider internal sources of knowledge about process maintenance?	Y	N	X	
10	Do you consider external sources of knowledge about process maintenance?	Y	N	X	
11	Do you share the knowledge that personnel need in order to maintain process and achieve conformity of outputs?	Y	N	X	
12	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

13	Do you provide the software needed to maintain your process?	Y	N	X	
14	Do you provide the software needed to support process maintenance and achieve conformity of outputs?	Y	N	X	
15	Do you provide the hardware needed to maintain your process?	Y	N	X	

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16	Do you provide the hardware needed to support process maintenance and achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
----	--	----------------------------	----------------------------	---------------------------------------	--

4.1.3 PROVIDE THE INFRASTRUCTURE NEEDED TO MAINTAIN YOUR PROCESS

17	Do you provide the infrastructure needed to support process maintenance and achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
----	--	----------------------------	----------------------------	---------------------------------------	--

4.2 USE AUTHORIZED METHODS TO MAINTAIN YOUR PROCESS**4.2.1 USE AUTHORIZED METHODS TO MAINTAIN PROCESS DOCUMENTS**

18	Do you maintain documents that describe how your process should be carried out?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
19	Do you maintain documents that show how process operations should be carried out?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
20	Do you maintain documents that show how process maintenance should be carried out?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
21	Do you maintain documents that show how process monitoring should be carried out?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
22	Do you maintain documents that show how process measurement should be carried out?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
23	Do you maintain documents that show how process control should be carried out?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
24	Do you maintain documents that show how process evaluation should be carried out?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
25	Do you maintain documents that show how process audits should be carried out?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
26	Do you maintain documents that show how process reviews should be carried out?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
27	Do you maintain documents that show how process modification should be carried out?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
28	Do you maintain documents that show how process correction should be carried out?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
29	Do you maintain documents that show how process improvement should be carried out?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

4.2.2 USE AUTHORIZED METHODS TO MAINTAIN PROCESS RECORDS

30	Do you maintain a record that describes the scope of your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
31	Do you maintain a record of process responsibilities and authorities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
32	Do you maintain a record of personnel performance and competence?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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33	Do you retain your documentation and use it as evidence to show that your process personnel are in fact competent?	Y	N	X	
34	Do you maintain a record showing that process is performing as planned?	Y	N	X	
35	Do you maintain records that show that process operations are carried out as planned?	Y	N	X	
36	Do you maintain records that show that process maintenance is carried out as planned?	Y	N	X	
37	Do you maintain records that show that process monitoring is carried out as planned?	Y	N	X	
38	Do you maintain records that show that process measurement is carried out as planned?	Y	N	X	
39	Do you maintain records that show that process control is carried out as planned?	Y	N	X	
40	Do you maintain records that show that process evaluation is carried out as planned?	Y	N	X	
41	Do you maintain records that show that process audits are carried out as planned?	Y	N	X	
42	Do you maintain records that show that process reviews are carried out as planned?	Y	N	X	
43	Do you maintain records that show that process modification is carried out as planned?	Y	N	X	
44	Do you maintain records that show that process corrections are carried out as planned?	Y	N	X	
45	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

46	Do you maintain process property owned by your customers and suppliers that is needed to achieve conformity of outputs?	Y	N	X	
47	Have you identified property belonging to customers and external providers?	Y	N	X	
48	Do you verify property belonging to customers and external providers?	Y	N	X	
49	Do you protect property belonging to customers and external providers?	Y	N	X	
50	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	
51	Do you safeguard other people's property whenever your process intends to use or incorporate it into its outputs?	Y	N	X	

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52	Do you report property belonging to your customers and external providers?	Y	N	X	
53	Do you report lost or damaged property to customers and external providers?	Y	N	X	
54	Do you report unsuitable property to customers and external providers?	Y	N	X	
55	Do you document property belonging to your customers and external providers?	Y	N	X	
56	Do you document the status of external property that is lost, damaged, or unsuitable?	Y	N	X	
57	Do you control and retain records documenting lost, damaged, or unsuitable property?	Y	N	X	
58	Do you maintain process property owned by your process that is needed to achieve conformity of process outputs?	Y	N	X	
59	Do you maintain equipment that process needs in order to achieve conformity of outputs?	Y	N	X	
60	Do you maintain software that process needs in order to achieve conformity of outputs?	Y	N	X	
61	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

62	Do you use authorized methods to maintain process management procedures?	Y	N	X	
63	Do you use authorized methods to maintain process control procedures?	Y	N	X	
64	Do you use authorized methods to maintain process operation procedures?	Y	N	X	
65	Do you use authorized methods to maintain process maintenance procedures?	Y	N	X	
66	Do you use authorized methods to maintain process monitoring procedures?	Y	N	X	
67	Do you use authorized methods to maintain process feedback procedures?	Y	N	X	
68	Do you use authorized methods to maintain process measurement procedures?	Y	N	X	
69	Do you use authorized methods to maintain equipment calibration procedures?	Y	N	X	
70	Do you use authorized methods to maintain process evaluation procedures?	Y	N	X	
71	Do you use authorized methods to maintain process audit procedures?	Y	N	X	

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72	Do you use authorized methods to maintain process review procedures?	Y	N	X	
73	Do you use authorized methods to maintain process modification procedures?	Y	N	X	
74	Do you use authorized methods to maintain process correction procedures?	Y	N	X	
75	Do you use authorized methods to maintain process improvement procedures?	Y	N	X	

4.2.5 USE AUTHORIZED METHODS TO MAINTAIN PROCESS PROGRAMMES

76	Do you use authorized methods to maintain process management programmes?	Y	N	X	
77	Do you use authorized methods to maintain risk management programme?	Y	N	X	
78	Do you use authorized methods to maintain safety management programme?	Y	N	X	
79	Do you use authorized methods to maintain quality management programme?	Y	N	X	
80	Do you use authorized methods to maintain configuration management programme?	Y	N	X	
81	Do you use authorized methods to maintain security management programme?	Y	N	X	
82	Do you use authorized methods to maintain personnel security management programme?	Y	N	X	
83	Do you use authorized methods to maintain information security management programme?	Y	N	X	
84	Do you use authorized methods to maintain component security management programme?	Y	N	X	
85	Do you use authorized methods to maintain counterfeit parts management programme?	Y	N	X	
86	Do you use authorized methods to maintain supplier management programme?	Y	N	X	
87	Do you use authorized methods to maintain environmental management programme?	Y	N	X	
88	Do you use authorized methods to maintain business continuity management programme?	Y	N	X	

4.2.6 USE AUTHORIZED METHODS TO MAINTAIN PROCESS COMPETENCE

89	Do you share information and knowledge with process personnel?	Y	N	X	
90	Do you make sure that they are aware of process policies?	Y	N	X	
91	Do you make sure that they are aware of process objectives?	Y	N	X	

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92	Do you make sure that they are aware of process procedures?	Y	N	X	
93	Do you make sure that they are aware of process documents and records?	Y	N	X	
94	Do you make sure that personnel stay abreast of all relevant changes?	Y	N	X	
95	Do you make sure that they are aware of the contribution they make?	Y	N	X	
96	Do you make sure that they understand how they affect process performance?	Y	N	X	
97	Do you make sure that they understand how they influence process outputs?	Y	N	X	
98	Do you make sure that they understand how they affect output quality?	Y	N	X	
99	Do you make sure that they understand how they affect output safety?	Y	N	X	
100	Do you make sure that they understand how they affect output security?	Y	N	X	
101	Do you make sure that they are aware of all relevant requirements?	Y	N	X	
102	Do you explain why compliance is important to your process?	Y	N	X	
103	Do you explain why they need to meet all relevant requirements?	Y	N	X	
104	Do you explain why they need to meet all output requirements?	Y	N	X	
105	Do you explain why they need to meet all process requirements?	Y	N	X	
106	Do you make sure that they are aware of how they can help?	Y	N	X	
107	Do you explain how they can help enhance process effectiveness?	Y	N	X	
108	Do you explain why it's important to improve process performance?	Y	N	X	
109	Do you acquire competence whenever shortcomings are discovered?	Y	N	X	
110	Do you acquire the necessary competence whenever process personnel fail to meet process competence requirements?	Y	N	X	
111	Do you consider helping your personnel to improve?	Y	N	X	
112	Do you consider providing suitable training?	Y	N	X	

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113	Do you consider offering mentoring services?	Y	N	X	
114	Do you consider hiring competent people?	Y	N	X	
115	Do you consider hiring competent employees?	Y	N	X	
116	Do you consider hiring competent contractors?	Y	N	X	
117	Do you consider reassigning unsuitable personnel?	Y	N	X	
118	Do you maintain the process knowledge that has been acquired?	Y	N	X	
119	Do you consider the need to protect and preserve lessons learned?	Y	N	X	
120	Do you consider the need to protect and preserve intellectual property?	Y	N	X	

4.2.7 USE AUTHORIZED METHODS TO MAINTAIN PROCESS TECHNOLOGIES

121	Do you maintain technology used to perform process operations?	Y	N	X	
122	Do you maintain tools used to perform process operations?	Y	N	X	
123	Do you define storage requirements for tools used for process operations?	Y	N	X	
124	Do you define how and when to check the status of tools used for process operations?	Y	N	X	
125	Do you maintain equipment used to perform process operations?	Y	N	X	
126	Do you define storage requirements for equipment used for process operations?	Y	N	X	
127	Do you define how and when to check the status of equipment used for process operations?	Y	N	X	
128	Do you maintain software used to perform process operations?	Y	N	X	
129	Do you define how and when to check the status of software used for process operations?	Y	N	X	
130	Do you maintain technology used to automate process operations?	Y	N	X	
131	Do you maintain tools used to automate process operations?	Y	N	X	
132	Do you define storage requirements for tools used to automate process operations?	Y	N	X	
133	Do you define how and when to check the status of tools used to automate operations?	Y	N	X	

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134	Do you maintain equipment used to automate process operations?	Y	N	X	
135	Do you define storage requirements for equipment used to automate process operations?	Y	N	X	
136	Do you define how and when to check the status of equipment used for automation?	Y	N	X	
137	Do you maintain software used to automate process operations?	Y	N	X	
138	Do you define how and when to check the status of software used for automation?	Y	N	X	
139	Do you maintain technology used to control process operations?	Y	N	X	
140	Do you maintain tools used to control process operations?	Y	N	X	
141	Do you define storage requirements for tools used to control process operations?	Y	N	X	
142	Do you define how and when to check status of tools used to control process operations?	Y	N	X	
143	Do you maintain equipment used to control process operations?	Y	N	X	
144	Do you define storage requirements for equipment used to control process operations?	Y	N	X	
145	Do you define how and when to check the status of process control equipment?	Y	N	X	
146	Do you maintain software used to control process operations?	Y	N	X	
147	Do you define how and when to check status of software used to control process operations?	Y	N	X	
148	Do you maintain technology used to monitor process operations?	Y	N	X	
149	Do you maintain tools used to monitor process operations?	Y	N	X	
150	Do you define storage requirements for tools used to monitor process operations?	Y	N	X	
151	Do you define how and when to check status of tools used to monitor process operations?	Y	N	X	
152	Do you maintain equipment used to monitor process operations?	Y	N	X	
153	Do you define storage requirements for equipment used to monitor process operations?	Y	N	X	
154	Do you define how and when to check the status of process monitoring equipment?	Y	N	X	
155	Do you maintain software used to monitor process operations?	Y	N	X	

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PROCESS BEING AUDITED:**4. ASSESS PROCESS MAINTENANCE ACTIVITIES**

156	Do you define how and when to check status of software used to monitor operations?	Y	N	X	
157	Do you maintain technology used to measure process operations?	Y	N	X	
158	Do you maintain software used to measure process operations?	Y	N	X	
159	Do you define how and when to check the status of software used to measure operations?	Y	N	X	
160	Do you maintain tools used to measure process operations?	Y	N	X	
161	Do you define storage requirements for tools used to measure process operations?	Y	N	X	
162	Do you define how and when to check the status of tools used to measure operations?	Y	N	X	
163	Do you maintain equipment used to measure process operations?	Y	N	X	
164	Do you define storage requirements for equipment used to measure process operations?	Y	N	X	
165	Do you define how and when to check the status of process measuring equipment?	Y	N	X	
166	Did you establish an identification system for measurement equipment?	Y	N	X	
167	Do you use it to ensure that your equipment calibration status is always clear?	Y	N	X	
168	Do you verify or calibrate your process measurement equipment?	Y	N	X	
169	Do you verify or calibrate equipment under suitable conditions?	Y	N	X	
170	Do you verify or calibrate your equipment at planned intervals or prior to use?	Y	N	X	
171	Do you verify or calibrate your equipment against measurement standards that are traceable to national or international measurement standards?	Y	N	X	
172	Do you document your verification and calibration methods whenever national or international measurement standards do not exist?	Y	N	X	
173	Do you control your verification and calibration documents?	Y	N	X	
174	Do you retain your verification and calibration documents?	Y	N	X	
175	Do you safeguard your process measurement equipment?	Y	N	X	
176	Do you protect your calibration status and measurement results?	Y	N	X	

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4. ASSESS PROCESS MAINTENANCE ACTIVITIES

177	Do you protect measurement equipment from damage or deterioration?	Y	N	X	
178	Do you protect measurement equipment from unauthorized adjustment?	Y	N	X	
179	Do you evaluate the validity of previous measurement results whenever you discover that measurement equipment is unfit for its intended purpose?	Y	N	X	
180	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

181	Do you maintain the infrastructure that process needs in order to achieve conformity of outputs?	Y	N	X	
182	Do you maintain the facilities that process needs in order to achieve conformity of outputs?	Y	N	X	
183	Do you maintain the utilities that process needs in order to achieve conformity of outputs?	Y	N	X	
184	Do you maintain the services that process needs in order to achieve conformity of outputs?	Y	N	X	
185	Do you maintain the technologies that process needs in order to achieve conformity of outputs?	Y	N	X	
186	Do you maintain the hardware that process needs in order to achieve conformity of outputs?	Y	N	X	
187	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

188	Do you use authorized methods to maintain internal process communications?	Y	N	X	
189	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. ASSESS PROCESS MEASUREMENT ACTIVITIES

5.1 PLAN HOW YOU'RE GOING TO MEASURE YOUR PROCESS

5.1.1 FIGURE OUT WHAT NEEDS TO BE MEASURED

1	Do you figure out what kind of process activities need to be measured?	Y	N	X	
2	Do you figure out what kind of process characteristics need to be measured?	Y	N	X	
3	Do you figure out what kind of inputs and outputs need to be measured?	Y	N	X	
4	Do you figure out what kind of output characteristics need to be measured?	Y	N	X	
5	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

6	Do you plan how you're going to measure process elements?	Y	N	X	
7	Do you plan how you're going to measure your process outputs?	Y	N	X	
8	Do you plan how you're going to measure your outputs against expectations?	Y	N	X	
9	Do you plan how you're going to measure how well outputs implement plans?	Y	N	X	
10	Do you plan how you're going to measure how well outputs achieve objectives?	Y	N	X	
11	Do you plan how you're going to measure how well outputs meet requirements?	Y	N	X	
12	Do you plan how you're going to measure how well outputs comply with policies?	Y	N	X	
13	Do you plan how you're going to measure your process inputs?	Y	N	X	
14	Do you plan how you're going to measure your inputs against expectations?	Y	N	X	
15	Do you plan how you're going to measure how well inputs implement plans?	Y	N	X	
16	Do you plan how you're going to measure how well inputs achieve objectives?	Y	N	X	
17	Do you plan how you're going to measure how well inputs meet requirements?	Y	N	X	
18	Do you plan how you're going to measure how well inputs comply with policies?	Y	N	X	
19	Do you plan how you're going to measure your process activities?	Y	N	X	

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20	Do you plan how you're going to measure process management activities?	Y	N	X	
21	Do you plan how to measure how well process management activities meet expectations?	Y	N	X	
22	Do you plan how to measure how well process management activities apply policies?	Y	N	X	
23	Do you plan how to measure how well process management activities implement plans?	Y	N	X	
24	Do you plan how to measure how well process management activities follow procedures?	Y	N	X	
25	Do you plan how to measure how well process management activities achieve objectives?	Y	N	X	
26	Do you plan how to measure how well process management activities meet requirements?	Y	N	X	
27	Do you plan how you're going to measure process operating activities?	Y	N	X	
28	Do you plan how to measure how well process operating activities meet expectations?	Y	N	X	
29	Do you plan how to measure how well process operating activities apply policies?	Y	N	X	
30	Do you plan how to measure how well process operating activities implement plans?	Y	N	X	
31	Do you plan how to measure how well process operating activities follow procedures?	Y	N	X	
32	Do you plan how to measure how well process operating activities achieve objectives?	Y	N	X	
33	Do you plan how to measure how well process operating activities meet requirements?	Y	N	X	
34	Do you plan how you're going to measure process maintenance activities?	Y	N	X	
35	Do you plan how to measure how well process maintenance activities meet expectations?	Y	N	X	
36	Do you plan how to measure how well process maintenance activities apply policies?	Y	N	X	
37	Do you plan how to measure how well process maintenance activities implement plans?	Y	N	X	
38	Do you plan how to measure how well process maintenance activities follow procedures?	Y	N	X	
39	Do you plan how to measure how well process maintenance activities achieve objectives?	Y	N	X	
40	Do you plan how to measure how well process maintenance activities meet requirements?	Y	N	X	
41	Do you plan how you're going to measure process monitoring activities?	Y	N	X	

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42	Do you plan how to measure how well process monitoring activities meet expectations?	Y	N	X	
43	Do you plan how to measure how well process monitoring activities apply policies?	Y	N	X	
44	Do you plan how to measure how well process monitoring activities implement plans?	Y	N	X	
45	Do you plan how to measure how well process monitoring activities follow procedures?	Y	N	X	
46	Do you plan how to measure how well process monitoring activities achieve objectives?	Y	N	X	
47	Do you plan how to measure how well process monitoring activities meet requirements?	Y	N	X	
48	Do you plan how you're going to measure process measurement activities?	Y	N	X	
49	Do you plan how to measure how well process measurement activities meet expectations?	Y	N	X	
50	Do you plan how to measure how well process measurement activities apply policies?	Y	N	X	
51	Do you plan how to measure how well process measurement activities implement plans?	Y	N	X	
52	Do you plan how to measure how well process measurement activities follow procedures?	Y	N	X	
53	Do you plan how to measure how well process measurement activities achieve objectives?	Y	N	X	
54	Do you plan how to measure how well process measurement activities meet requirements?	Y	N	X	
55	Do you plan how you're going to measure process control activities?	Y	N	X	
56	Do you plan how to measure how well process control activities meet expectations?	Y	N	X	
57	Do you plan how to measure how well process control activities apply policies?	Y	N	X	
58	Do you plan how to measure how well process control activities implement plans?	Y	N	X	
59	Do you plan how to measure how well process control activities follow procedures?	Y	N	X	
60	Do you plan how to measure how well process control activities achieve objectives?	Y	N	X	
61	Do you plan how to measure how well process control activities meet requirements?	Y	N	X	
62	Do you plan how you're going to measure process evaluation activities?	Y	N	X	
63	Do you plan how you're going to measure process audit activities?	Y	N	X	

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PROCESS BEING AUDITED:**5. ASSESS PROCESS MEASUREMENT ACTIVITIES**

64	Do you plan how to measure how well process audit activities meet expectations?	Y	N	X	
65	Do you plan how to measure how well process audit activities apply policies?	Y	N	X	
66	Do you plan how to measure how well process audit activities implement plans?	Y	N	X	
67	Do you plan how to measure how well process audit activities follow procedures?	Y	N	X	
68	Do you plan how to measure how well process audit activities achieve objectives?	Y	N	X	
69	Do you plan how to measure how well process audit activities meet requirements?	Y	N	X	
70	Do you plan how you're going to measure process review activities?	Y	N	X	
71	Do you plan how to measure how well process review activities meet expectations?	Y	N	X	
72	Do you plan how to measure how well process review activities apply policies?	Y	N	X	
73	Do you plan how to measure how well process review activities implement plans?	Y	N	X	
74	Do you plan how to measure how well process review activities follow procedures?	Y	N	X	
75	Do you plan how to measure how well process review activities achieve objectives?	Y	N	X	
76	Do you plan how to measure how well process review activities meet requirements?	Y	N	X	
77	Do you plan how you're going to measure process modification activities?	Y	N	X	
78	Do you plan how you're going to measure process correction activities?	Y	N	X	
79	Do you plan how to measure how well process correction activities meet expectations?	Y	N	X	
80	Do you plan how to measure how well process correction activities apply policies?	Y	N	X	
81	Do you plan how to measure how well process correction activities implement plans?	Y	N	X	
82	Do you plan how to measure how well process correction activities follow procedures?	Y	N	X	
83	Do you plan how to measure how well process correction activities achieve objectives?	Y	N	X	
84	Do you plan how to measure how well process correction activities meet requirements?	Y	N	X	
85	Do you plan how you're going to measure process improvement activities?	Y	N	X	

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86	Do you plan how to measure how well process improvement activities meet expectations?	Y	N	X	
87	Do you plan how to measure how well process improvement activities apply policies?	Y	N	X	
88	Do you plan how to measure how well process improvement activities implement plans?	Y	N	X	
89	Do you plan how to measure how well process improvement activities follow procedures?	Y	N	X	
90	Do you plan how to measure how well process improvement activities achieve objectives?	Y	N	X	
91	Do you plan how to measure how well process improvement activities meet requirements?	Y	N	X	
92	Do you plan how you're going to measure customer satisfaction?	Y	N	X	
93	Learn how your process customers feel about your process outputs?	Y	N	X	
94	Do you figure out how to gather information about customer satisfaction?	Y	N	X	
95	Do you figure out how to learn about customer satisfaction by doing customer surveys?	Y	N	X	
96	Do you figure out how to learn about customer satisfaction by using face-to-face meetings?	Y	N	X	
97	Do you figure out how to learn about customer satisfaction by studying customer feedback?	Y	N	X	
98	Do you figure out how to use information to evaluate customer satisfaction?	Y	N	X	
99	Do you figure out how to use output information to evaluate customer satisfaction?	Y	N	X	
100	Do you figure out how to use delivery information to evaluate customer satisfaction?	Y	N	X	
101	Do you figure out how to use post-delivery information to evaluate customer satisfaction?	Y	N	X	
102	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

103	Do you allocate responsibility and authority for measuring customer satisfaction?	Y	N	X	
104	Do you allocate responsibility and authority for carrying out customer surveys?	Y	N	X	
105	Do you allocate responsibility and authority for meeting with process customers?	Y	N	X	
106	Do you allocate responsibility and authority for studying feedback from customers?	Y	N	X	

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107	Do you allocate responsibility and authority for measuring process elements?	Y	N	X	
108	Do you allocate responsibility and authority for measuring process outputs?	Y	N	X	
109	Do you allocate responsibility and authority for measuring process inputs?	Y	N	X	
110	Do you allocate responsibility and authority for measuring process activities?	Y	N	X	
111	Do you allocate responsibility and authority for measuring process control activities?	Y	N	X	
112	Do you allocate responsibility and authority for measuring process operating activities?	Y	N	X	
113	Do you allocate responsibility and authority for measuring process maintenance activities?	Y	N	X	
114	Do you allocate responsibility and authority for measuring process measurement activities?	Y	N	X	
115	Do you allocate responsibility and authority for measuring process monitoring activities?	Y	N	X	
116	Do you allocate responsibility and authority for measuring process evaluation activities?	Y	N	X	
117	Do you allocate responsibility and authority for measuring process audit activities?	Y	N	X	
118	Do you allocate responsibility and authority for measuring process review activities?	Y	N	X	
119	Do you allocate responsibility and authority for measuring process modification activities?	Y	N	X	
120	Do you allocate responsibility and authority for measuring process correction activities?	Y	N	X	
121	Do you allocate responsibility and authority for measuring process improvement activities?	Y	N	X	

5.2 QUALIFY THE RESOURCES NEEDED TO MEASURE PROCESS

122	Do you select measurement resources that are fit for purpose?	Y	N	X	
123	Do you select measurement resources that will yield valid and reliable results?	Y	N	X	
124	Do you select measurement resources that will ensure that outputs meet requirements?	Y	N	X	
125	Do you validate measurement resources before you use them?	Y	N	X	
126	Do you validate resources that are used to measure process?	Y	N	X	
127	Do you validate software before it is used to measure process?	Y	N	X	

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128	Do you validate tools before they are used to measure process?	Y	N	X	
129	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**

130	Do you provide the expertise needed to ensure that measuring methods will yield valid and reliable results?	Y	N	X	
131	Do you provide the managers needed to measure your process?	Y	N	X	
132	Do you acquire the knowledge that process managers need to support process measurement activities?	Y	N	X	
133	Do you ensure that process managers get the knowledge they need to support process measurement activities?	Y	N	X	
134	Do you deliver suitable training and awareness programmes for managers of process measurement activities?	Y	N	X	
135	Do you provide the personnel needed to measure your process?	Y	N	X	
136	Do you acquire the knowledge that personnel need to measure your process?	Y	N	X	
137	Do you consider internal sources of knowledge about process measurement?	Y	N	X	
138	Do you consider external sources of knowledge about process measurement?	Y	N	X	
139	Do you ensure that personnel get the knowledge they need to measure your process?	Y	N	X	
140	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

141	Do you provide the technology needed to ensure that measurement methods yield valid and reliable results?	Y	N	X	
142	Do you provide the software needed to measure your process?	Y	N	X	
143	Do you provide the software needed to support process measurement activities?	Y	N	X	

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144	Do you provide the hardware needed to measure your process?	Y	N	X	
145	Do you provide the hardware needed to support process measurement activities?	Y	N	X	
146	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

147	Do you provide the infrastructure needed to ensure that measurement methods yield valid and reliable results?	Y	N	X	
148	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**

149	Do you use authorized methods to measure process outputs?	Y	N	X	
150	Do you measure your outputs against expectations?	Y	N	X	
151	Do you measure how well outputs meet requirements?	Y	N	X	
152	Do you measure how well outputs achieve objectives?	Y	N	X	
153	Do you measure how well outputs implement plans?	Y	N	X	
154	Do you use authorized methods to measure process inputs?	Y	N	X	
155	Do you measure your inputs against expectations?	Y	N	X	
156	Do you measure how well inputs meet requirements?	Y	N	X	
157	Do you measure how well inputs achieve objectives?	Y	N	X	
158	Do you measure how well inputs implement plans?	Y	N	X	
159	Do you use authorized methods to measure process activities?	Y	N	X	
160	Do you use authorized methods to measure process operating activities?	Y	N	X	
161	Do you measure how well process operating activities meet expectations?	Y	N	X	

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162	Do you measure how well process operating activities apply policies?	Y	N	X	
163	Do you measure how well process operating activities implement plans?	Y	N	X	
164	Do you measure how well process operating activities follow procedures?	Y	N	X	
165	Do you measure how well process operating activities achieve objectives?	Y	N	X	
166	Do you measure how well process operating activities comply with requirements?	Y	N	X	
167	Do you use authorized methods to measure process maintenance activities?	Y	N	X	
168	Do you measure how well process maintenance activities meet expectations?	Y	N	X	
169	Do you measure how well process maintenance activities apply policies?	Y	N	X	
170	Do you measure how well process maintenance activities implement plans?	Y	N	X	
171	Do you measure how well process maintenance activities follow procedures?	Y	N	X	
172	Do you measure how well process maintenance activities achieve objectives?	Y	N	X	
173	Do you measure how well process maintenance activities comply with requirements?	Y	N	X	
174	Do you use authorized methods to measure process measurement activities?	Y	N	X	
175	Do you measure how well process measurement activities meet expectations?	Y	N	X	
176	Do you measure how well process measurement activities apply policies?	Y	N	X	
177	Do you measure how well process measurement activities implement plans?	Y	N	X	
178	Do you measure how well process measurement activities follow procedures?	Y	N	X	
179	Do you measure how well process measurement activities achieve objectives?	Y	N	X	
180	Do you measure how well process measurement activities comply with requirements?	Y	N	X	
181	Do you use authorized methods to measure process monitoring activities?	Y	N	X	
182	Do you measure how well process monitoring activities meet expectations?	Y	N	X	
183	Do you measure how well process monitoring activities apply policies?	Y	N	X	

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184	Do you measure how well process monitoring activities implement plans?	Y	N	X	
185	Do you measure how well process monitoring activities follow procedures?	Y	N	X	
186	Do you measure how well process monitoring activities achieve objectives?	Y	N	X	
187	Do you measure how well process monitoring activities comply with requirements?	Y	N	X	
188	Do you use authorized methods to measure process control activities?	Y	N	X	
189	Do you measure how well process control activities meet expectations?	Y	N	X	
190	Do you measure how well process control activities apply policies?	Y	N	X	
191	Do you measure how well process control activities implement plans?	Y	N	X	
192	Do you measure how well process control activities follow procedures?	Y	N	X	
193	Do you measure how well process control activities achieve objectives?	Y	N	X	
194	Do you measure how well process control activities comply with requirements?	Y	N	X	
195	Do you use authorized methods to measure process evaluation activities?	Y	N	X	
196	Do you use authorized methods to measure process audit activities?	Y	N	X	
197	Do you measure how well process audit activities meet expectations?	Y	N	X	
198	Do you measure how well process audit activities apply policies?	Y	N	X	
199	Do you measure how well process audit activities implement plans?	Y	N	X	
200	Do you measure how well process audit activities follow procedures?	Y	N	X	
201	Do you measure how well process audit activities achieve objectives?	Y	N	X	
202	Do you measure how well process audit activities comply with requirements?	Y	N	X	
203	Do you use authorized methods to measure process review activities?	Y	N	X	
204	Do you measure how well process review activities meet expectations?	Y	N	X	
205	Do you measure how well process review activities apply policies?	Y	N	X	

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PROCESS BEING AUDITED:**5. ASSESS PROCESS MEASUREMENT ACTIVITIES**

206	Do you measure how well process review activities implement plans?	Y	N	X	
207	Do you measure how well process review activities follow procedures?	Y	N	X	
208	Do you measure how well process review activities achieve objectives?	Y	N	X	
209	Do you measure how well process review activities comply with requirements?	Y	N	X	
210	Do you use authorized methods to measure process modification activities?	Y	N	X	
211	Do you use authorized methods to measure process correction activities?	Y	N	X	
212	Do you measure how well process correction activities meet expectations?	Y	N	X	
213	Do you measure how well process correction activities apply policies?	Y	N	X	
214	Do you measure how well process correction activities implement plans?	Y	N	X	
215	Do you measure how well process correction activities follow procedures?	Y	N	X	
216	Do you measure how well process correction activities achieve objectives?	Y	N	X	
217	Do you measure how well process correction activities comply with requirements?	Y	N	X	
218	Do you use authorized methods to measure process improvement activities?	Y	N	X	
219	Do you measure how well process improvement activities meet expectations?	Y	N	X	
220	Do you measure how well process improvement activities apply policies?	Y	N	X	
221	Do you measure how well process improvement activities implement plans?	Y	N	X	
222	Do you measure how well process improvement activities follow procedures?	Y	N	X	
223	Do you measure how well process improvement activities achieve objectives?	Y	N	X	
224	Do you measure how well process improvement activities comply with requirements?	Y	N	X	

5.4.2 USE AUTHORIZED METHODS TO MEASURE PROCESS PERFORMANCE

225	Do you use authorized methods to measure the performance of process personnel?	Y	N	X	
226	Do you measure the competence and effectiveness of your process personnel?	Y	N	X	

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PROCESS BEING AUDITED:**5. ASSESS PROCESS MEASUREMENT ACTIVITIES**

227	Do you measure the process knowledge and skill that has been acquired?	Y	N	X	
228	Do you measure how well process personnel meet process expectations?	Y	N	X	
229	Do you measure how well process personnel apply process policies?	Y	N	X	
230	Do you measure how well process personnel implement process plans?	Y	N	X	
231	Do you measure how well process personnel follow process procedures?	Y	N	X	
232	Do you measure how well process personnel meet process requirements?	Y	N	X	
233	Do you measure how well process personnel achieve process objectives?	Y	N	X	
234	Do you measure how well process personnel achieve safety objectives?	Y	N	X	
235	Do you measure how well process personnel achieve quality objectives?	Y	N	X	
236	Do you measure how well process personnel achieve security objectives?	Y	N	X	
237	Do you measure how well process personnel achieve business objectives?	Y	N	X	
238	Do you measure how well process personnel achieve technical objectives?	Y	N	X	
239	Do you measure how well process personnel achieve continuity objectives?	Y	N	X	
240	Do you measure how well process personnel achieve environmental objectives?	Y	N	X	
241	Do you use authorized methods to measure the performance of process management?	Y	N	X	
242	Do you use authorized methods to measure process management activities?	Y	N	X	
243	Do you measure how well process management activities meet expectations?	Y	N	X	
244	Do you measure how well process management activities apply policies?	Y	N	X	
245	Do you measure how well process management activities implement plans?	Y	N	X	
246	Do you measure how well process management activities follow procedures?	Y	N	X	
247	Do you measure how well process management activities meet requirements?	Y	N	X	
248	Do you measure how well process management activities achieve objectives?	Y	N	X	

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249	Do you measure how well process managers achieve safety objectives?	Y	N	X	
250	Do you measure how well process managers achieve quality objectives?	Y	N	X	
251	Do you measure how well process managers achieve security objectives?	Y	N	X	
252	Do you measure how well process managers achieve business objectives?	Y	N	X	
253	Do you measure how well process managers achieve technical objectives?	Y	N	X	
254	Do you measure how well process managers achieve continuity objectives?	Y	N	X	
255	Do you measure how well process managers achieve environmental objectives?	Y	N	X	
256	Do you use authorized methods to measure process management programmes?	Y	N	X	
257	Do you use authorized methods to measure your risk management programme?	Y	N	X	
258	Do you use authorized methods to measure your safety management programme?	Y	N	X	
259	Do you use authorized methods to measure your quality management programme?	Y	N	X	
260	Do you use authorized methods to measure configuration management programme?	Y	N	X	
261	Do you use authorized methods to measure your security management programme?	Y	N	X	
262	Do you use authorized methods to measure personnel security management programme?	Y	N	X	
263	Do you use authorized methods to measure information management programme?	Y	N	X	
264	Do you use authorized methods to measure component management programme?	Y	N	X	
265	Do you use authorized methods to measure counterfeit parts management programme?	Y	N	X	
266	Do you use authorized methods to measure your supplier management programme?	Y	N	X	
267	Do you use authorized methods to measure your environmental management programme?	Y	N	X	
268	Do you use authorized methods to measure your business continuity management programme?	Y	N	X	
269	Do you use authorized methods to measure external providers?	Y	N	X	
270	Do you use authorized criteria to measure the performance of external providers?	Y	N	X	

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271	Do you measure the performance of external process, product, and service providers?	Y	N	X	
272	Do you use data and criteria to measure the performance of your external providers?	Y	N	X	
273	Do you document performance measuring activities and retain these documents?	Y	N	X	
274	Do you control documents that describe your performance measuring activities?	Y	N	X	
275	Do you measure external process, product, and service verification activities?	Y	N	X	
276	Do you measure verifications whenever they are delegated to external providers?	Y	N	X	
277	Do you use authorized methods to measure internal providers?	Y	N	X	
278	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**

279	Do you control the procedures needed to measure your process and its outputs?	Y	N	X	
280	Do you control the instructions needed to measure your process and its outputs?	Y	N	X	
281	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

282	Do you control the software needed to measure your process and its outputs?	Y	N	X	
283	Do you control the hardware needed to measure your process and its outputs?	Y	N	X	
284	Do you control the tools needed to measure your process and its outputs?	Y	N	X	
285	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

286	Do you establish records for process measurement activities and resources?	Y	N	X	
287	Do you use records to control your process measuring activities and resources?	Y	N	X	

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288	Do you establish a register of process measurement activities and resources?	Y	N	X	
289	Do you use register to record the identity of measurement resources?	Y	N	X	
290	Do you use your register to describe the type or kind of resources being used?	Y	N	X	
291	Do you use your register to describe your test hardware and software?	Y	N	X	
292	Do you use your register to document automated test equipment (ATE)?	Y	N	X	
293	Do you use your register to identify plotters used to produce verification data?	Y	N	X	
294	Do you use your register to list equipment used to provide evidence of conformity?	Y	N	X	
295	Do you use register to list personally owned equipment used to verify conformity?	Y	N	X	
296	Do you use register to list customer supplied equipment used to verify conformity?	Y	N	X	
297	Do you use your register to specify a unique identifier for each piece of equipment?	Y	N	X	
298	Do you use register to specify the location of your measurement tools and equipment?	Y	N	X	
299	Do you use register to control the calibration of your measurement tools and equipment?	Y	N	X	
300	Do you use your register to record calibration or verification methods and results?	Y	N	X	
301	Do you use your register to record calibration or verification acceptance criteria?	Y	N	X	
302	Do you use your register to specify equipment calibration or verification frequency?	Y	N	X	
303	Do you maintain a register of your process measurement activities and resources?	Y	N	X	
304	Do you maintain records that show that measurement resources are still fit for purpose?	Y	N	X	
305	Do you control records that show that measurement resources are still fit for purpose?	Y	N	X	
306	Do you use records to keep track of measurement activities and resources?	Y	N	X	
307	Do you establish suitable measurement traceability methods?	Y	N	X	
308	Do you maintain suitable measurement traceability resources?	Y	N	X	

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PROCESS BEING AUDITED:**5. ASSESS PROCESS MEASUREMENT ACTIVITIES**

309	Do you establish recall methods for your measurement equipment?	Y	N	X	
310	Do you implement recall methods for your measurement equipment?	Y	N	X	
311	Do you recall measurement equipment that must be verified or calibrated?	Y	N	X	
312	Do you maintain recall records for your process measurement equipment?	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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PROCESS BEING AUDITED:

6. ASSESS PROCESS MONITORING ACTIVITIES

6.1 PLAN HOW YOU'RE GOING TO MONITOR YOUR PROCESS

6.1.1 FIGURE OUT WHAT NEEDS TO BE MONITORED

1	Do you figure out what kind of policies and plans need to be monitored?	Y	N	X	
2	Do you figure out what kind of practices and procedures need to be monitored?	Y	N	X	
3	Do you figure out what kind of issues, factors, and concerns need to be monitored?	Y	N	X	
4	Do you figure out what kind of internal issues and factors need to be monitored?	Y	N	X	
5	Do you figure out what kind of external issues and factors need to be monitored?	Y	N	X	
6	Do you figure out what kind of participants and providers need to be monitored?	Y	N	X	
7	Do you figure out what kind of process participants need to be monitored?	Y	N	X	
8	Do you figure out what kind of process managers need to be monitored?	Y	N	X	
9	Do you figure out what kind of process personnel need to be monitored?	Y	N	X	
10	Do you figure out what kind of process providers need to be monitored?	Y	N	X	
11	Do you figure out what kind of internal process providers need to be monitored?	Y	N	X	
12	Do you figure out what kind of external process providers need to be monitored?	Y	N	X	
13	Do you figure out what kind of process inputs and outputs need to be monitored?	Y	N	X	
14	Do you figure out what kind of output characteristics need to be monitored?	Y	N	X	
15	Do you figure out what kind of input characteristics need to be monitored?	Y	N	X	
16	Do you figure out what kind of internal process resources need to be monitored?	Y	N	X	
17	Do you figure out what kind of data and information needs to be monitored?	Y	N	X	
18	Do you figure out what kind of documents and records need to be monitored?	Y	N	X	
19	Do you figure out what kind of hardware and software needs to be monitored?	Y	N	X	

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20	Do you figure out what kind of parts and components need to be monitored?	Y	N	X	
21	Do you figure out what kind of products and services need to be monitored?	Y	N	X	
22	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

23	Do you plan how you're going to monitor customer satisfaction?	Y	N	X	
24	Do you plan how to monitor customer feelings about process outputs?	Y	N	X	
25	Do you plan how to monitor information about customer satisfaction?	Y	N	X	
26	Do you plan how you're going to monitor process performance?	Y	N	X	
27	Do you plan how you're going to monitor process outputs?	Y	N	X	
28	Do you plan how you're going to monitor output deliveries?	Y	N	X	
29	Do you plan how to monitor post-delivery performance?	Y	N	X	
30	Do you plan how you're going to monitor output characteristics?	Y	N	X	
31	Do you plan how you're going to monitor process activities?	Y	N	X	
32	Do you plan how you're going to monitor process management activities?	Y	N	X	
33	Do you plan how to monitor how well process management activities meet expectations?	Y	N	X	
34	Do you plan how to monitor how well process management activities apply policies?	Y	N	X	
35	Do you plan how to monitor how well process management activities implement plans?	Y	N	X	
36	Do you plan how to monitor how well process management activities follow procedures?	Y	N	X	
37	Do you plan how to monitor how well process management activities achieve objectives?	Y	N	X	
38	Do you plan how to monitor how well process management activities meet requirements?	Y	N	X	
39	Do you plan how you're going to monitor process operating activities?	Y	N	X	

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40	Do you plan how to monitor how well process operating activities meet expectations?	Y	N	X	
41	Do you plan how to monitor how well process operating activities apply policies?	Y	N	X	
42	Do you plan how to monitor how well process operating activities implement plans?	Y	N	X	
43	Do you plan how to monitor how well process operating activities follow procedures?	Y	N	X	
44	Do you plan how to monitor how well process operating activities achieve objectives?	Y	N	X	
45	Do you plan how to monitor how well process operating activities meet requirements?	Y	N	X	
46	Do you plan how you're going to monitor process maintenance activities?	Y	N	X	
47	Do you plan how to monitor how well process maintenance activities meet expectations?	Y	N	X	
48	Do you plan how to monitor how well process maintenance activities apply policies?	Y	N	X	
49	Do you plan how to monitor how well process maintenance activities implement plans?	Y	N	X	
50	Do you plan how to monitor how well process maintenance activities follow procedures?	Y	N	X	
51	Do you plan how to monitor how well process maintenance activities achieve objectives?	Y	N	X	
52	Do you plan how to monitor how well process maintenance activities meet requirements?	Y	N	X	
53	Do you plan how you're going to monitor process monitoring activities?	Y	N	X	
54	Do you plan how to monitor how well process monitoring activities meet expectations?	Y	N	X	
55	Do you plan how to monitor how well process monitoring activities apply policies?	Y	N	X	
56	Do you plan how to monitor how well process monitoring activities implement plans?	Y	N	X	
57	Do you plan how to monitor how well process monitoring activities follow procedures?	Y	N	X	
58	Do you plan how to monitor how well process monitoring activities achieve objectives?	Y	N	X	
59	Do you plan how to monitor how well process monitoring activities meet requirements?	Y	N	X	
60	Do you plan how you're going to monitor process measurement activities?	Y	N	X	

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61	Do you plan how to monitor how well process measurement activities meet expectations?	Y	N	X	
62	Do you plan how to monitor how well process measurement activities apply policies?	Y	N	X	
63	Do you plan how to monitor how well process measurement activities implement plans?	Y	N	X	
64	Do you plan how to monitor how well process measurement activities follow procedures?	Y	N	X	
65	Do you plan how to monitor how well process measurement activities achieve objectives?	Y	N	X	
66	Do you plan how to monitor how well process measurement activities meet requirements?	Y	N	X	
67	Do you plan how you're going to monitor process control activities?	Y	N	X	
68	Do you plan how to monitor how well process control activities meet expectations?	Y	N	X	
69	Do you plan how to monitor how well process control activities apply policies?	Y	N	X	
70	Do you plan how to monitor how well process control activities implement plans?	Y	N	X	
71	Do you plan how to monitor how well process control activities follow procedures?	Y	N	X	
72	Do you plan how to monitor how well process control activities achieve objectives?	Y	N	X	
73	Do you plan how to monitor how well process control activities meet requirements?	Y	N	X	
74	Do you plan how you're going to monitor process evaluation activities?	Y	N	X	
75	Do you plan how you're going to monitor process audit activities?	Y	N	X	
76	Do you plan how to monitor how well process audit activities meet expectations?	Y	N	X	
77	Do you plan how to monitor how well process audit activities apply policies?	Y	N	X	
78	Do you plan how to monitor how well process audit activities implement plans?	Y	N	X	
79	Do you plan how to monitor how well process audit activities follow procedures?	Y	N	X	
80	Do you plan how to monitor how well process audit activities achieve objectives?	Y	N	X	
81	Do you plan how to monitor how well process audit activities meet requirements?	Y	N	X	
82	Do you plan how you're going to monitor process review activities?	Y	N	X	

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83	Do you plan how to monitor how well process review activities meet expectations?	Y	N	X	
84	Do you plan how to monitor how well process review activities apply policies?	Y	N	X	
85	Do you plan how to monitor how well process review activities implement plans?	Y	N	X	
86	Do you plan how to monitor how well process review activities follow procedures?	Y	N	X	
87	Do you plan how to monitor how well process review activities achieve objectives?	Y	N	X	
88	Do you plan how to monitor how well process review activities meet requirements?	Y	N	X	
89	Do you plan how you're going to monitor process modification activities?	Y	N	X	
90	Do you plan how you're going to monitor process correction activities?	Y	N	X	
91	Do you plan how to monitor how well process correction activities meet expectations?	Y	N	X	
92	Do you plan how to monitor how well process correction activities apply policies?	Y	N	X	
93	Do you plan how to monitor how well process correction activities implement plans?	Y	N	X	
94	Do you plan how to monitor how well process correction activities follow procedures?	Y	N	X	
95	Do you plan how to monitor how well process correction activities achieve objectives?	Y	N	X	
96	Do you plan how to monitor how well process correction activities meet requirements?	Y	N	X	
97	Do you plan how you're going to monitor process improvement activities?	Y	N	X	
98	Do you plan how to monitor how well process improvement activities meet expectations?	Y	N	X	
99	Do you plan how to monitor how well process improvement activities apply policies?	Y	N	X	
100	Do you plan how to monitor how well process improvement activities implement plans?	Y	N	X	
101	Do you plan how to monitor how well process improvement activities follow procedures?	Y	N	X	
102	Do you plan how to monitor how well process improvement activities achieve objectives?	Y	N	X	
103	Do you plan how to monitor how well process improvement activities meet requirements?	Y	N	X	
104	Do you plan how you're going to monitor process resources?	Y	N	X	

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105	Do you plan how you're going to monitor process parts?	Y	N	X	
106	Do you plan how you're going to monitor process plans?	Y	N	X	
107	Do you plan how you're going to monitor process policies?	Y	N	X	
108	Do you plan how you're going to monitor process supplies?	Y	N	X	
109	Do you plan how you're going to monitor process hardware?	Y	N	X	
110	Do you plan how you're going to monitor process software?	Y	N	X	
111	Do you plan how you're going to monitor process services?	Y	N	X	
112	Do you plan how you're going to monitor process products?	Y	N	X	
113	Do you plan how you're going to monitor process property?	Y	N	X	
114	Do you plan how you're going to monitor process providers?	Y	N	X	
115	Do you plan how you're going to monitor process documents?	Y	N	X	
116	Do you plan how you're going to monitor process components?	Y	N	X	
117	Do you plan how you're going to monitor process infrastructure?	Y	N	X	
118	Do you plan how you're going to monitor process participants?	Y	N	X	
119	Do you plan how you're going to monitor process procedures?	Y	N	X	
120	Do you plan how you're going to monitor process practices?	Y	N	X	
121	Do you plan how you're going to monitor process records?	Y	N	X	
122	Do you plan how you're going to monitor process inputs?	Y	N	X	
123	Do you plan how you're going to monitor internal process inputs?	Y	N	X	
124	Do you plan how you're going to monitor external process inputs?	Y	N	X	
125	Do you plan how you're going to monitor reports about counterfeit parts?	Y	N	X	

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126	Do you plan how you're going to monitor process technologies?	Y	N	X	
127	Do you plan how you're going to monitor process tools and equipment?	Y	N	X	
128	Do you plan how you're going to monitor process monitoring tools and equipment?	Y	N	X	
129	Do you plan how you're going to recall monitoring tools and equipment that must be recalibrated or reverified?	Y	N	X	
130	Do you plan how you're going to monitor process measurement tools and equipment?	Y	N	X	
131	Do you plan how you're going to recall measurement tools and equipment that must be recalibrated or reverified?	Y	N	X	
132	Do you plan how you're going to monitor process environment?	Y	N	X	
133	Do you plan how you're going to monitor your process's external context?	Y	N	X	
134	Do you figure out how you're going to monitor the external issues and factors that could affect your process?	Y	N	X	
135	Do you figure out how you're going to monitor the external interested parties that could affect your process?	Y	N	X	
136	Do you plan how you're going to monitor your process's internal context?	Y	N	X	
137	Do you figure out how you're going to monitor the internal issues and factors that could affect your process?	Y	N	X	
138	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

139	Do you allocate responsibility and authority for monitoring process plans?	Y	N	X	
140	Do you allocate responsibility and authority for monitoring process policies?	Y	N	X	
141	Do you allocate responsibility and authority for monitoring process outputs?	Y	N	X	
142	Do you allocate responsibility and authority for monitoring process supplies?	Y	N	X	

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PROCESS BEING AUDITED:**6. ASSESS PROCESS MONITORING ACTIVITIES**

143	Do you allocate responsibility and authority for monitoring process materials?	Y	N	X	
144	Do you allocate responsibility and authority for monitoring process hardware?	Y	N	X	
145	Do you allocate responsibility and authority for monitoring process software?	Y	N	X	
146	Do you allocate responsibility and authority for monitoring process services?	Y	N	X	
147	Do you allocate responsibility and authority for monitoring process products?	Y	N	X	
148	Do you allocate responsibility and authority for monitoring process property?	Y	N	X	
149	Do you allocate responsibility and authority for monitoring process providers?	Y	N	X	
150	Do you allocate responsibility and authority for monitoring process objectives?	Y	N	X	
151	Do you allocate responsibility and authority for monitoring process documents?	Y	N	X	
152	Do you allocate responsibility and authority for monitoring process participants?	Y	N	X	
153	Do you allocate responsibility and authority for monitoring process components?	Y	N	X	
154	Do you allocate responsibility and authority for monitoring process technologies?	Y	N	X	
155	Do you allocate responsibility and authority for monitoring process characteristics?	Y	N	X	
156	Do you allocate responsibility and authority for monitoring process requirements?	Y	N	X	
157	Do you allocate responsibility and authority for monitoring process infrastructure?	Y	N	X	
158	Do you allocate responsibility and authority for monitoring process environment?	Y	N	X	
159	Do you allocate responsibility and authority for monitoring process procedures?	Y	N	X	
160	Do you allocate responsibility and authority for monitoring process practices?	Y	N	X	
161	Do you allocate responsibility and authority for monitoring process records?	Y	N	X	
162	Do you allocate responsibility and authority for monitoring process parties?	Y	N	X	
163	Do you allocate responsibility and authority for monitoring process inputs?	Y	N	X	

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PROCESS BEING AUDITED:**6. ASSESS PROCESS MONITORING ACTIVITIES****6.2 QUALIFY THE RESOURCES NEEDED TO MONITOR PROCESS**

164	Do you select monitoring resources that are fit for purpose?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
165	Do you select monitoring resources that will yield valid and reliable results?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
166	Do you select resources that will help ensure that outputs meet requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
167	Do you validate monitoring resources before you use them?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
168	Do you validate tools before they are used to monitor process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
169	Do you validate equipment before it is used to monitor process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
170	Do you validate software before it is used to monitor process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

6.3 PROVIDE THE RESOURCES NEEDED TO MONITOR PROCESS**6.3.1 PROVIDE THE EXPERTISE NEEDED TO MONITOR YOUR PROCESS**

171	Do you provide the expertise needed to ensure that monitoring methods will consistently yield valid and reliable results?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
172	Do you provide the managers needed to monitor your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
173	Do you acquire the knowledge that managers need to support process monitoring and achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
174	Do you share the knowledge that managers need so that they can support process monitoring and achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
175	Do you deliver suitable training and awareness programmes for managers of process monitoring activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
176	Do you provide the personnel needed to monitor your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
177	Do you acquire the knowledge that personnel need to monitor your process and achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
178	Do you consider internal sources of knowledge about process monitoring?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
179	Do you consider external sources of knowledge about process monitoring?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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180	Do you share the knowledge that personnel need to monitor your process and achieve conformity of outputs?	Y	N	X	
181	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

182	Do you provide the technology needed to ensure that your monitoring methods will yield valid and reliable results?	Y	N	X	
183	Do you provide the software needed to monitor your process?	Y	N	X	
184	Do you provide the software needed to support process monitoring and achieve conformity of outputs?	Y	N	X	
185	Do you provide the hardware needed to monitor your process?	Y	N	X	
186	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

187	Do you provide the infrastructure needed to ensure that your monitoring methods will yield valid and reliable results?	Y	N	X	
188	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

189	Do you use authorized methods to monitor process management activities?	Y	N	X	
190	Do you monitor how well process management activities meet expectations?	Y	N	X	
191	Do you monitor how well process management activities apply policies?	Y	N	X	
192	Do you monitor how well process management activities implement plans?	Y	N	X	
193	Do you monitor how well process management activities follow procedures?	Y	N	X	

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194	Do you monitor how well process management activities achieve objectives?	Y	N	X	
195	Do you monitor how well process management activities comply with requirements?	Y	N	X	
196	Do you use authorized methods to monitor process operating activities?	Y	N	X	
197	Do you monitor how well process operating activities meet expectations?	Y	N	X	
198	Do you monitor how well process operating activities apply policies?	Y	N	X	
199	Do you monitor how well process operating activities implement plans?	Y	N	X	
200	Do you monitor how well process operating activities follow procedures?	Y	N	X	
201	Do you monitor how well process operating activities achieve objectives?	Y	N	X	
202	Do you monitor how well process operating activities comply with requirements?	Y	N	X	
203	Do you use authorized methods to monitor process maintenance activities?	Y	N	X	
204	Do you monitor how well process maintenance activities meet expectations?	Y	N	X	
205	Do you monitor how well process maintenance activities apply policies?	Y	N	X	
206	Do you monitor how well process maintenance activities implement plans?	Y	N	X	
207	Do you monitor how well process maintenance activities follow procedures?	Y	N	X	
208	Do you monitor how well process maintenance activities achieve objectives?	Y	N	X	
209	Do you monitor how well process maintenance activities comply with requirements?	Y	N	X	
210	Do you use authorized methods to monitor process measurement activities?	Y	N	X	
211	Do you monitor how well process measurement activities meet expectations?	Y	N	X	
212	Do you monitor how well process measurement activities apply policies?	Y	N	X	
213	Do you monitor how well process measurement activities implement plans?	Y	N	X	
214	Do you monitor how well process measurement activities follow procedures?	Y	N	X	

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215	Do you monitor how well process measurement activities achieve objectives?	Y	N	X	
216	Do you monitor how well process measurement activities comply with requirements?	Y	N	X	
217	Do you use authorized methods to monitor process monitoring activities?	Y	N	X	
218	Do you monitor how well process monitoring activities meet expectations?	Y	N	X	
219	Do you monitor how well process monitoring activities apply policies?	Y	N	X	
220	Do you monitor how well process monitoring activities implement plans?	Y	N	X	
221	Do you monitor how well process monitoring activities follow procedures?	Y	N	X	
222	Do you monitor how well process monitoring activities achieve objectives?	Y	N	X	
223	Do you monitor how well process monitoring activities comply with requirements?	Y	N	X	
224	Do you use authorized methods to monitor process control activities?	Y	N	X	
225	Do you monitor how well process control activities meet expectations?	Y	N	X	
226	Do you monitor how well process control activities apply policies?	Y	N	X	
227	Do you monitor how well process control activities implement plans?	Y	N	X	
228	Do you monitor how well process control activities follow procedures?	Y	N	X	
229	Do you monitor how well process control activities achieve objectives?	Y	N	X	
230	Do you monitor how well process control activities comply with requirements?	Y	N	X	
231	Do you use authorized methods to monitor process evaluation activities?	Y	N	X	
232	Do you use authorized methods to monitor process audit activities?	Y	N	X	
233	Do you monitor how well process audit activities meet expectations?	Y	N	X	
234	Do you monitor how well process audit activities apply policies?	Y	N	X	
235	Do you monitor how well process audit activities implement plans?	Y	N	X	
236	Do you monitor how well process audit activities follow procedures?	Y	N	X	

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237	Do you monitor how well process audit activities achieve objectives?	Y	N	X	
238	Do you monitor how well process audit activities comply with requirements?	Y	N	X	
239	Do you use authorized methods to monitor process review activities?	Y	N	X	
240	Do you monitor how well process review activities meet expectations?	Y	N	X	
241	Do you monitor how well process review activities apply policies?	Y	N	X	
242	Do you monitor how well process review activities implement plans?	Y	N	X	
243	Do you monitor how well process review activities follow procedures?	Y	N	X	
244	Do you monitor how well process review activities achieve objectives?	Y	N	X	
245	Do you monitor how well process review activities comply with requirements?	Y	N	X	
246	Do you use authorized methods to monitor process modification activities?	Y	N	X	
247	Do you use authorized methods to monitor process correction activities?	Y	N	X	
248	Do you monitor how well process correction activities meet expectations?	Y	N	X	
249	Do you monitor how well process correction activities apply policies?	Y	N	X	
250	Do you monitor how well process correction activities implement plans?	Y	N	X	
251	Do you monitor how well process correction activities follow procedures?	Y	N	X	
252	Do you monitor how well process correction activities achieve objectives?	Y	N	X	
253	Do you monitor how well process correction activities comply with requirements?	Y	N	X	
254	Do you use authorized methods to monitor process improvement activities?	Y	N	X	
255	Do you monitor how well process improvement activities meet expectations?	Y	N	X	
256	Do you monitor how well process improvement activities apply policies?	Y	N	X	
257	Do you monitor how well process improvement activities implement plans?	Y	N	X	

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258	Do you monitor how well process improvement activities follow procedures?	Y	N	X	
259	Do you monitor how well process improvement activities achieve objectives?	Y	N	X	
260	Do you monitor how well process improvement activities comply with requirements?	Y	N	X	

6.4.2 USE AUTHORIZED METHODS TO MONITOR PROCESS OUTPUTS

261	Do you monitor how well process outputs meet expectations?	Y	N	X	
262	Do you monitor how well process outputs apply policies?	Y	N	X	
263	Do you monitor how well process outputs implement plans?	Y	N	X	
264	Do you monitor how well process outputs follow procedures?	Y	N	X	
265	Do you monitor how well process outputs achieve objectives?	Y	N	X	
266	Do you monitor how well process outputs comply with requirements?	Y	N	X	
267	Do you monitor how well process outputs meet customer requirements?	Y	N	X	
268	Do you monitor how well process outputs meet regulatory requirements?	Y	N	X	
269	Do you monitor how well process outputs meet corporate requirements?	Y	N	X	

6.4.3 USE AUTHORIZED METHODS TO MONITOR PROCESS INPUTS

270	Do you monitor supplies that have or could have a major impact on outputs?	Y	N	X	
271	Do you monitor services that have or could have a major impact on outputs?	Y	N	X	
272	Do you monitor materials that have or could have a major impact on outputs?	Y	N	X	
273	Do you monitor products that have or could have a major impact on outputs?	Y	N	X	
274	Do you monitor components that have or could have a major impact on outputs?	Y	N	X	
275	Do you monitor all of your “critical items” and “key characteristics”?	Y	N	X	
276	Do you monitor all relevant counterfeit parts and components?	Y	N	X	
277	Do you monitor external reports about counterfeit parts?	Y	N	X	

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6.4.4 USE AUTHORIZED METHODS TO MONITOR PROCESS DOCUMENTS

278	Do you monitor documents that specify how your process should be operated?	Y	N	X	
279	Do you monitor documents that specify how your process should be maintained?	Y	N	X	
280	Do you monitor documents that specify how your process should be monitored?	Y	N	X	
281	Do you monitor documents that specify how your process should be measured?	Y	N	X	
282	Do you monitor documents that specify how your process should be controlled?	Y	N	X	
283	Do you monitor documents that specify how your process should be audited?	Y	N	X	
284	Do you monitor documents that specify how your process should be reviewed?	Y	N	X	
285	Do you monitor documents that specify how your process should be corrected?	Y	N	X	
286	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

287	Do you monitor records of personnel performance and competence?	Y	N	X	
288	Do you retain records of personnel performance and competence?	Y	N	X	
289	Do you use records to show that personnel know how to perform process tasks?	Y	N	X	
290	Do you monitor records that track the performance of your process?	Y	N	X	
291	Do you monitor records that keep track of process operations?	Y	N	X	
292	Do you monitor records that keep track of process outputs?	Y	N	X	
293	Do you monitor records that keep track of process activities?	Y	N	X	
294	Do you monitor records that keep track of process inputs?	Y	N	X	
295	Do you monitor records that keep track of process maintenance?	Y	N	X	
296	Do you monitor records that keep track of process measurement?	Y	N	X	

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297	Do you monitor records that keep track of process monitoring?	Y	N	X	
298	Do you monitor records that keep track of process controls?	Y	N	X	
299	Do you monitor records that keep track of process audits?	Y	N	X	
300	Do you monitor records that keep track of process reviews?	Y	N	X	
301	Do you monitor records that keep track of process corrections?	Y	N	X	
302	Do you monitor records that keep track of process improvements?	Y	N	X	

6.4.6 USE AUTHORIZED METHODS TO MONITOR PROCESS PROPERTY

303	Do you monitor process property owned by customers and suppliers that is needed to achieve conformity of outputs?	Y	N	X	
304	Do you report problematic property to your customers and external providers?	Y	N	X	
305	Do you report unsuitable property to customers and external providers?	Y	N	X	
306	Do you report lost or damaged property to customers and external providers?	Y	N	X	
307	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

308	Do you use authorized methods to monitor process personnel?	Y	N	X	
309	Do you monitor the process objectives that process personnel must achieve?	Y	N	X	
310	Do you monitor the safety objectives that process personnel must achieve?	Y	N	X	
311	Do you monitor the quality objectives that process personnel must achieve?	Y	N	X	
312	Do you monitor the security objectives that process personnel must achieve?	Y	N	X	
313	Do you monitor the business objectives that process personnel must achieve?	Y	N	X	
314	Do you monitor the technical objectives that process personnel must achieve?	Y	N	X	
315	Do you monitor the continuity objectives that process personnel must achieve?	Y	N	X	

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316	Do you monitor the environmental objectives that process personnel must achieve?	Y	N	X	
317	Do you monitor the competence and performance of process personnel?	Y	N	X	
318	Do you monitor the process knowledge and skill that has been acquired?	Y	N	X	
319	Do you consider the need to protect and preserve process lessons learned?	Y	N	X	
320	Do you consider the need to protect and preserve your intellectual property?	Y	N	X	
321	Do you monitor changes and trends in process knowledge and information?	Y	N	X	
322	Do you use authorized methods to monitor process management?	Y	N	X	
323	Do you use authorized methods to monitor process management personnel?	Y	N	X	
324	Do you use authorized methods to monitor process management programmes?	Y	N	X	
325	Do you use authorized methods to monitor risk management programme?	Y	N	X	
326	Do you use authorized methods to monitor safety management programme?	Y	N	X	
327	Do you use authorized methods to monitor quality management programme?	Y	N	X	
328	Do you use authorized methods to monitor configuration management programme?	Y	N	X	
329	Do you use authorized methods to monitor security management programme?	Y	N	X	
330	Do you use authorized methods to monitor personnel security management programme?	Y	N	X	
331	Do you use authorized methods to monitor information security management programme?	Y	N	X	
332	Do you use authorized methods to monitor component security management programme?	Y	N	X	
333	Do you use authorized methods to monitor counterfeit parts management programme?	Y	N	X	
334	Do you use authorized methods to monitor supplier management programme?	Y	N	X	
335	Do you use authorized methods to monitor environmental management programme?	Y	N	X	
336	Do you use authorized methods to monitor business continuity management programme?	Y	N	X	
337	Do you use authorized methods to monitor external providers?	Y	N	X	

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338	Do you use authorized criteria to monitor the performance of external providers?	Y	N	X	
339	Do you use criteria to monitor verification activities delegated to external providers?	Y	N	X	
340	Do you use authorized methods to monitor interested parties?	Y	N	X	
341	Do you monitor the external parties that could influence your process?	Y	N	X	
342	Do you monitor performance of external process, product, and service providers?	Y	N	X	
343	Do you expect process managers to use data and criteria to monitor the performance of their external providers?	Y	N	X	
344	Do you expect process managers to document performance monitoring activities and retain these documents?	Y	N	X	
345	Do you expect process managers to control documents that describe their performance monitoring activities?	Y	N	X	
346	Do you monitor external process, product, and service verification activities?	Y	N	X	
347	Do you monitor verifications whenever they are delegated to external providers?	Y	N	X	
348	Do you monitor the internal parties that could influence your process?	Y	N	X	

6.4.8 USE AUTHORIZED METHODS TO MONITOR PROCESS TECHNOLOGIES

349	Do you monitor technology used to perform process operations?	Y	N	X	
350	Do you monitor software used to perform process operations?	Y	N	X	
351	Do you monitor hardware used to perform process operations?	Y	N	X	
352	Do you monitor technology used to automate process operations?	Y	N	X	
353	Do you monitor software used to automate process operations?	Y	N	X	
354	Do you monitor hardware used to automate process operations?	Y	N	X	
355	Do you monitor technology used to maintain process operations?	Y	N	X	
356	Do you monitor software used to maintain process operations?	Y	N	X	

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357	Do you monitor hardware used to maintain process operations?	Y	N	X	
358	Do you monitor technology used to monitor process operations?	Y	N	X	
359	Do you monitor software used to monitor process operations?	Y	N	X	
360	Do you monitor hardware used to monitor process operations?	Y	N	X	
361	Do you recall monitoring equipment that must be recalibrated or reverified?	Y	N	X	
362	Do you monitor technology used to measure process operations?	Y	N	X	
363	Do you monitor software used to measure process operations?	Y	N	X	
364	Do you monitor hardware used to measure process operations?	Y	N	X	
365	Do you recall measuring equipment that must be recalibrated or reverified?	Y	N	X	
366	Do you monitor technology used to control process operations?	Y	N	X	
367	Do you monitor software used to control process operations?	Y	N	X	
368	Do you monitor hardware used to control process operations?	Y	N	X	

6.4.9 USE AUTHORIZED METHODS TO MONITOR PROCESS ENVIRONMENT

369	Do you use authorized methods to monitor your process's external environment?	Y	N	X	
370	Do you use authorized methods to monitor external interested parties and their requirements?	Y	N	X	
371	Do you use authorized methods to monitor your process's internal environment?	Y	N	X	
372	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

373	Do you use authorized methods to monitor process networks and communications?	Y	N	X	
374	Do you use authorized methods to monitor internal process networks and communications?	Y	N	X	
375	Do you use authorized methods to monitor external process networks and communications?	Y	N	X	
376	Do you use authorized methods to monitor process utilities and support services?	Y	N	X	

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6.5 CONTROL THE RESOURCES NEEDED TO MONITOR PROCESS

377	Do you control the technology needed to monitor your process?	Y	N	X	
378	Do you control the tools needed to monitor your process?	Y	N	X	
379	Do you control the software needed to monitor your process?	Y	N	X	
380	Do you control the equipment needed to monitor your process?	Y	N	X	
381	Do you control the records needed to monitor your process?	Y	N	X	
382	Did you establish a register of your process monitoring resources?	Y	N	X	
383	Do you ensure that your monitoring resources continue to be fit for purpose?	Y	N	X	
384	Do you ensure that register describes the type of monitoring tools and equipment in use?	Y	N	X	
385	Do you ensure that register specifies the location of your monitoring tools and equipment?	Y	N	X	
386	Do you ensure that register tracks the calibration of your monitoring tools and equipment?	Y	N	X	
387	Do you ensure that your register records equipment calibration or verification methods?	Y	N	X	
388	Do you ensure that your register records calibration or verification acceptance criteria?	Y	N	X	
389	Do you ensure that register specifies equipment calibration or verification frequency?	Y	N	X	
390	Do you maintain a register of your process monitoring resources?	Y	N	X	
391	Do you maintain records that show that monitoring resources are still fit for purpose?	Y	N	X	
392	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.

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PROCESS BEING AUDITED:

7. ASSESS PROCESS CONTROL ACTIVITIES

7.1 PLAN HOW YOU'RE GOING TO CONTROL PROCESS

7.1.1 CONSIDER HOW TO CONTROL YOUR PROCESS OUTPUTS

1	Do you figure out how you're going to control your process outputs?	Y	N	X	
2	Do you consider process output requirements as you develop output controls?	Y	N	X	
3	Do you consider output safety requirements as you develop output controls?	Y	N	X	
4	Do you consider personnel safety requirements as you develop output controls?	Y	N	X	
5	Do you consider output quality requirements as you develop output controls?	Y	N	X	
6	Do you consider output reliability requirements as you develop output controls?	Y	N	X	
7	Do you consider output purity requirements as you develop output controls?	Y	N	X	
8	Do you consider the need to control undesirable foreign objects?	Y	N	X	
9	Do you consider the need to detect undesirable foreign objects?	Y	N	X	
10	Do you consider the need to remove undesirable foreign objects?	Y	N	X	
11	Do you consider the need to prevent undesirable foreign objects?	Y	N	X	
12	Do you consider output suitability requirements as you develop output controls?	Y	N	X	
13	Do you consider suitability requirements for parts and materials to be used in outputs?	Y	N	X	
14	Do you consider suitability requirements for software to be embedded in outputs?	Y	N	X	
15	Do you consider suitability requirements for software that you plan to purchase?	Y	N	X	
16	Do you consider suitability requirements for software that you plan to develop?	Y	N	X	
17	Do you consider output maintenance requirements as you develop output controls?	Y	N	X	
18	Do you consider output maintainability requirements as you develop output controls?	Y	N	X	
19	Do you consider output security requirements as you develop output controls?	Y	N	X	
20	Do you consider output handling requirements as you develop output controls?	Y	N	X	

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PROCESS BEING AUDITED:

7. ASSESS PROCESS CONTROL ACTIVITIES

21	Do you consider output packaging requirements as you develop output controls?	Y	N	X	
22	Do you consider output availability requirements as you develop output controls?	Y	N	X	
23	Do you consider output preservation requirements as you develop output controls?	Y	N	X	
24	Do you consider output obsolescence requirements as you develop output controls?	Y	N	X	
25	Do you consider output recycling requirements as you develop output controls?	Y	N	X	
26	Do you consider output disposal requirements as you develop output controls?	Y	N	X	
27	Do you consider final disposal requirements as you develop output controls?	Y	N	X	
28	Do you consider output production requirements as you develop output controls?	Y	N	X	
29	Do you consider output producibility requirements as you develop output controls?	Y	N	X	
30	Do you consider output measurement requirements as you develop output controls?	Y	N	X	
31	Do you consider output monitoring requirements as you develop output controls?	Y	N	X	
32	Do you consider output inspectability requirements as you develop output controls?	Y	N	X	

7.1.2 CONSIDER HOW TO CONTROL YOUR PROCESS INPUTS

33	Do you figure out how you're going to control your process inputs?	Y	N	X	
34	Do you consider process input requirements as you develop input controls?	Y	N	X	
35	Do you consider input safety requirements as you develop input controls?	Y	N	X	
36	Do you consider input security requirements as you develop input controls?	Y	N	X	
37	Do you consider input quality requirements as you develop input controls?	Y	N	X	
38	Do you consider input reliability requirements as you develop input controls?	Y	N	X	
39	Do you consider input purity requirements as you develop input controls?	Y	N	X	
40	Do you consider the need to control foreign objects that could compromise inputs?	Y	N	X	
41	Do you consider the need to detect foreign objects that could compromise inputs?	Y	N	X	

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PROCESS BEING AUDITED:

7. ASSESS PROCESS CONTROL ACTIVITIES

42	Do you consider the need to remove foreign objects that could compromise inputs?	Y	N	X	
43	Do you consider the need to prevent foreign objects that could compromise inputs?	Y	N	X	
44	Do you consider input availability requirements as you develop input controls?	Y	N	X	
45	Do you consider input suitability requirements as you develop input controls?	Y	N	X	
46	Do you consider suitability requirements for parts and materials to be used by process?	Y	N	X	
47	Do you consider suitability requirements for software programmes to be used by process?	Y	N	X	
48	Do you consider input storage requirements as you develop input controls?	Y	N	X	
49	Do you consider input handling requirements as you develop input controls?	Y	N	X	
50	Do you consider input monitoring requirements as you develop input controls?	Y	N	X	
51	Do you consider input maintenance requirements as you develop input controls?	Y	N	X	
52	Do you consider input measurement requirements as you develop input controls?	Y	N	X	
53	Do you consider input preservation requirements as you develop input controls?	Y	N	X	

7.1.3 CONSIDER HOW TO CONTROL YOUR PROCESS ACTIVITIES

54	Do you figure out how you're going to control your process activities?	Y	N	X	
55	Do you consider process safety requirements as you develop process controls?	Y	N	X	
56	Do you consider process quality requirements as you develop process controls?	Y	N	X	
57	Do you consider process security requirements as you develop process controls?	Y	N	X	
58	Do you consider process reliability requirements as you develop process controls?	Y	N	X	
59	Do you consider process monitoring requirements as you develop process controls?	Y	N	X	
60	Do you consider process measurement requirements as you develop process controls?	Y	N	X	
61	Do you consider process improvement requirements as you develop process controls?	Y	N	X	
62	Do you consider process maintenance requirements as you develop process controls?	Y	N	X	

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PROCESS BEING AUDITED:

7. ASSESS PROCESS CONTROL ACTIVITIES

63	Do you consider process evaluation requirements as you develop process controls?	Y	N	X	
64	Do you consider process correction requirements as you develop process controls?	Y	N	X	
65	Do you consider process reporting requirements as you develop process controls?	Y	N	X	
66	Do you consider process review requirements as you develop process controls?	Y	N	X	
67	Do you consider process audit requirements as you develop process controls?	Y	N	X	

7.1.4 CONSIDER HOW TO CONTROL YOUR PROCESS PROVIDERS

68	Do you figure out how you're going to control your external providers?	Y	N	X	
69	Do you consider the requirements that external process providers must meet?	Y	N	X	
70	Do you consider the requirements that external product providers must meet?	Y	N	X	
71	Do you consider the requirements that external service providers must meet?	Y	N	X	
72	Do you figure out how you're going to control your internal providers?	Y	N	X	
73	Do you consider the requirements that internal process providers must meet?	Y	N	X	
74	Do you consider the requirements that internal product providers must meet?	Y	N	X	
75	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

76	Do you develop controlled conditions for process outputs?	Y	N	X	
77	Do you develop ways of controlling your process outputs?	Y	N	X	
78	Do you develop ways of controlling the quality of process outputs?	Y	N	X	
79	Do you develop ways of controlling the reliability of process outputs?	Y	N	X	
80	Do you develop ways of controlling the suitability of process outputs?	Y	N	X	
81	Do you develop ways of controlling suitability of parts and materials to be used in outputs?	Y	N	X	

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82	Do you develop ways of controlling suitability of software to be embedded into outputs?	Y	N	X	
83	Do you develop ways of controlling the suitability of software that you plan to purchase?	Y	N	X	
84	Do you develop ways of controlling the suitability of software that you plan to develop?	Y	N	X	
85	Do you develop ways of controlling the purity of process outputs?	Y	N	X	
86	Do you develop ways of controlling foreign objects that could affect your outputs?	Y	N	X	
87	Do you develop ways of detecting foreign objects that may compromise output quality?	Y	N	X	
88	Do you develop ways of removing foreign objects that may compromise output quality?	Y	N	X	
89	Do you develop ways of preventing foreign objects that may compromise output quality?	Y	N	X	
90	Do you develop ways of controlling the safety of outputs?	Y	N	X	
91	Do you develop ways of ensuring that outputs can be safely produced?	Y	N	X	
92	Do you develop ways of ensuring that outputs can be safely packaged?	Y	N	X	
93	Do you develop ways of ensuring that outputs can be safely delivered?	Y	N	X	
94	Do you develop ways of ensuring that outputs can be safely handled?	Y	N	X	
95	Do you develop ways of ensuring that outputs can be safely stored?	Y	N	X	
96	Do you develop ways of ensuring that outputs can be safely used?	Y	N	X	
97	Do you develop ways of ensuring that outputs can be safely repaired?	Y	N	X	
98	Do you develop ways of ensuring that outputs can be safely maintained?	Y	N	X	
99	Do you develop ways of ensuring that outputs can be safely preserved?	Y	N	X	
100	Do you develop ways of ensuring that outputs can be safely destroyed?	Y	N	X	
101	Do you develop ways of ensuring that outputs can be safely recycled?	Y	N	X	
102	Do you develop ways of controlling the security of outputs?	Y	N	X	
103	Do you develop ways of ensuring that outputs can be securely produced?	Y	N	X	

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104	Do you develop ways of ensuring that outputs can be securely packaged?	Y	N	X	
105	Do you develop ways of ensuring that outputs can be securely delivered?	Y	N	X	
106	Do you develop ways of ensuring that outputs can be securely handled?	Y	N	X	
107	Do you develop ways of ensuring that outputs can be securely stored?	Y	N	X	
108	Do you develop ways of ensuring that outputs can be securely used?	Y	N	X	
109	Do you develop ways of ensuring that outputs can be securely repaired?	Y	N	X	
110	Do you develop ways of ensuring that outputs can be securely maintained?	Y	N	X	
111	Do you develop ways of ensuring that outputs can be securely preserved?	Y	N	X	
112	Do you develop ways of ensuring that outputs can be securely destroyed?	Y	N	X	
113	Do you develop controlled conditions for process inputs?	Y	N	X	
114	Do you develop ways of controlling your process inputs?	Y	N	X	
115	Do you develop ways of controlling the quality of process inputs?	Y	N	X	
116	Do you develop ways of controlling the purity of process inputs?	Y	N	X	
117	Do you develop ways of controlling foreign objects that compromise input quality?	Y	N	X	
118	Do you develop ways of detecting foreign objects that compromise input quality?	Y	N	X	
119	Do you develop ways of removing foreign objects that compromise input quality?	Y	N	X	
120	Do you develop ways of preventing foreign objects that compromise input quality?	Y	N	X	
121	Do you develop ways of controlling the suitability of process inputs?	Y	N	X	
122	Do you develop ways of controlling suitability of parts and materials to be used as inputs?	Y	N	X	
123	Do you develop ways of controlling suitability of software that is embedded in inputs?	Y	N	X	
124	Do you develop ways of controlling the acceptability of process inputs?	Y	N	X	

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125	Do you develop acceptance criteria for your process inputs?	Y	N	X	
126	Do you develop methods and procedures for testing process inputs?	Y	N	X	
127	Do you develop methods and procedures for inspecting process inputs?	Y	N	X	
128	Do you develop methods and procedures for monitoring process inputs?	Y	N	X	
129	Do you develop methods and procedures for measuring process inputs?	Y	N	X	
130	Do you develop methods and procedures for evaluating process inputs?	Y	N	X	
131	Do you develop ways of controlling the security of process inputs?	Y	N	X	
132	Do you develop ways of controlling the safety of process inputs?	Y	N	X	
133	Do you develop controlled conditions for process activities?	Y	N	X	
134	Do you develop ways of controlling your process activities?	Y	N	X	
135	Do you develop ways of controlling process testing activities?	Y	N	X	
136	Do you develop ways of controlling process control activities?	Y	N	X	
137	Do you develop ways of controlling process inspection activities?	Y	N	X	
138	Do you develop ways of controlling process management activities?	Y	N	X	
139	Do you develop ways of controlling process measurement activities?	Y	N	X	
140	Do you develop ways of controlling process maintenance activities?	Y	N	X	
141	Do you develop ways of controlling process production activities?	Y	N	X	
142	Do you develop ways of controlling process monitoring activities?	Y	N	X	
143	Do you develop ways of controlling process evaluation activities?	Y	N	X	
144	Do you develop ways of controlling process audit activities?	Y	N	X	
145	Do you develop ways of controlling process review activities?	Y	N	X	
146	Do you develop ways of controlling process modification activities?	Y	N	X	

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147	Do you develop ways of controlling process correction activities?	Y	N	X	
148	Do you develop ways of controlling process improvement activities?	Y	N	X	
149	Do you develop controlled conditions for process programmes?	Y	N	X	
150	Do you develop ways of controlling your risk management programme?	Y	N	X	
151	Do you develop ways of controlling your safety management programme?	Y	N	X	
152	Do you develop ways of controlling your quality management programme?	Y	N	X	
153	Do you develop ways of controlling your configuration management programme?	Y	N	X	
154	Do you develop ways of controlling your security management programme?	Y	N	X	
155	Do you develop ways of controlling your personnel security management programme?	Y	N	X	
156	Do you develop ways of controlling your information security management programme?	Y	N	X	
157	Do you develop ways of controlling your component security management programme?	Y	N	X	
158	Do you develop ways of controlling your counterfeit parts management programme?	Y	N	X	
159	Do you develop ways of controlling your supplier management programme?	Y	N	X	
160	Do you develop ways of controlling your environmental management programme?	Y	N	X	
161	Do you develop ways of controlling your business continuity management programme?	Y	N	X	

7.2.2 DEVELOP WAYS OF CONTROLLING PROCESS PROVIDERS

162	Do you develop ways of controlling external providers?	Y	N	X	
163	Do you plan how to control external processes, products, and services?	Y	N	X	
164	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	
165	Do you consider the potential impact on your ability to meet customer requirements?	Y	N	X	
166	Do you consider the potential impact on statutory and regulatory requirements?	Y	N	X	

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PROCESS BEING AUDITED:**7. ASSESS PROCESS CONTROL ACTIVITIES**

167	Do you consider the controls that external process, product, and service providers have implemented and think about how effective their controls actually are?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
168	Do you create controls for external processes, products, and services?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
169	Do you develop controls for processes that your organization is outsourcing?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
170	Do you ensure that outsourced processes remain within your organization's control?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
171	Do you figure out how you're going to control external process providers?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
172	Do you consider the potential impact that external process providers could have on your ability to consistently meet customer and legal requirements?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
173	Do you consider the controls that external process providers have implemented and think about how effective their process controls really are in practice?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
174	Do you develop controls for products that your organization is outsourcing?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
175	Do you ensure that outsourced products remain within your organization's control?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
176	Do you figure out how you're going to control external product providers?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
177	Do you consider the potential impact that external product providers could have on your ability to consistently meet customer and legal requirements?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
178	Do you consider the controls that external product providers have implemented and think about how effective their process controls really are in practice?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
179	Do you develop controls for services that your organization is outsourcing?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
180	Do you ensure that outsourced services remain within your organization's control?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
181	Do you figure out how you're going to control external service providers?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
182	Do you consider the potential impact that external service providers could have on your ability to consistently meet customer and legal requirements?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
183	Do you consider the controls that external service providers have implemented and think about how effective their process controls really are in practice?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
184	Do you design external process, product, and service verification methods?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	

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185	Do you plan your external process, product, and service verification activities?	Y	N	X	
186	Do you define the scope and extent of external verification and testing activities?	Y	N	X	
187	Do you define requirements whenever verifications are delegated to external providers?	Y	N	X	
188	Do you maintain a register of verification activities delegated to external providers?	Y	N	X	
189	Do you consider risks when you carry out external verification and testing activities?	Y	N	X	
190	Do you consider the risk of external process, product, and service nonconformities?	Y	N	X	
191	Do you consider the risk that counterfeit parts and components are being used?	Y	N	X	
192	Do you consider the risk that raw materials might fail to meet requirements?	Y	N	X	
193	Do you use objective evidence to verify external processes, products, and services?	Y	N	X	
194	Do you use documents and records to verify processes, products, and services?	Y	N	X	
195	Do you examine related test documents and records?	Y	N	X	
196	Do you examine related statistical documents and records?	Y	N	X	
197	Do you examine related process control documents and records?	Y	N	X	
198	Do you examine related conformance documents and records?	Y	N	X	
199	Do you examine the associated certificates of conformity?	Y	N	X	
200	Do you examine related production documents and records?	Y	N	X	
201	Do you review production verification activities and results?	Y	N	X	
202	Do you assess any changes to production process activities?	Y	N	X	
203	Do you review data related to production part approval process?	Y	N	X	
204	Do you develop a process to evaluate the accuracy of test data and test reports?	Y	N	X	
205	Do you validate test data when it is used to verify externally provided products?	Y	N	X	

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206	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?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
207	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?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
208	Do you develop ways of controlling internal providers?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
209	Do you plan how to control internal processes, products, and services?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
210	Do you consider the potential impact that internally provided processes, products, and services could have on your ability to consistently meet internal requirements?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
211	Do you consider the potential impact on your ability to meet customer requirements?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
212	Do you consider the potential impact on statutory and regulatory requirements?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
213	Do you consider the controls that internal process, product, and service providers have implemented and think about how effective their controls actually are?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
214	Do you create controls for internal processes, products, and services?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
215	Do you design internal process, product, and service verification methods?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
216	Do you plan your internal process, product, and service verification activities?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
217	Do you define the scope and extent of internal verification and testing activities?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
218	Do you consider risks when you carry out internal verification and testing activities?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
219	Do you use objective evidence to verify internal processes, products, and services?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
220	Do you develop a process to evaluate the accuracy of test data and test reports?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	

7.3 PROVIDE RESOURCES NEEDED TO CONTROL PROCESS

221	Do you provide the people that are needed in order to control your process?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
222	Do you provide the training that is needed in order to control your process?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
223	Do you provide the policies that are needed in order to control your process?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	

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224	Do you provide the knowledge that is needed in order to control your process?	Y	N	X	
225	Do you provide the procedures that are needed in order to control your process?	Y	N	X	
226	Do you provide the technologies that are needed in order to control your process?	Y	N	X	
227	Do you provide the methodologies that are needed in order to control your process?	Y	N	X	
228	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

229	Do you control the unique identity of your process inputs?	Y	N	X	
230	Do you establish suitable means for identifying your process inputs?	Y	N	X	
231	Do you specify the identity of inputs when conformity must be ensured?	Y	N	X	
232	Have you identified inputs whenever input conformity must be ensured?	Y	N	X	
233	Have you identified the monitoring and measurement status of inputs?	Y	N	X	
234	Do you record the identity of inputs when traceability is a requirement?	Y	N	X	
235	Do you clarify your organization's specific input traceability requirements?	Y	N	X	
236	Do you retain the documents and records that are needed to facilitate traceability?	Y	N	X	
237	Do you make arrangements to verify inputs at appropriate stages?	Y	N	X	
238	Do you verify that input requirements were met at all appropriate stages?	Y	N	X	
239	Do you retain evidence that shows that input acceptance criteria were met?	Y	N	X	
240	Do you retain evidence that shows that your input meets defined requirements?	Y	N	X	
241	Have you identified the people who may authorize the release of inputs for production?	Y	N	X	
242	Do you retain and control records to facilitate traceability of input releases?	Y	N	X	

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243	Do you release inputs only if verifications are finished or if authorized to do so?	Y	N	X	
244	Do you verify that your input acceptance criteria are being met?	Y	N	X	
245	Do you verify acceptance before inputs are officially released?	Y	N	X	
246	Do you establish a record of your input acceptance activities?	Y	N	X	
247	Do you document your criteria for input acceptance and rejection?	Y	N	X	
248	Do you document where in the sequence input verification is performed?	Y	N	X	
249	Do you document and retain your input monitoring and measuring results?	Y	N	X	
250	Do you maintain a record of input acceptance and rejection activities?	Y	N	X	
251	Do you document how input monitoring and measuring must be carried out?	Y	N	X	
252	Do you document all required input monitoring and measuring instructions?	Y	N	X	
253	Do you document all required input monitoring and measuring equipment?	Y	N	X	
254	Do you verify that critical input items are being controlled?	Y	N	X	
255	Do you control critical input items in accordance with established methods?	Y	N	X	
256	Do you verify that key input characteristics are being controlled?	Y	N	X	
257	Do you control key input characteristics in accordance with established methods?	Y	N	X	
258	Do you verify that inputs being used in the process are being controlled?	Y	N	X	
259	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	
260	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	
261	Do you verify that all input inspection and verification activities have been completed?	Y	N	X	
262	Do you maintain a record of input inspection and verification activities and results?	Y	N	X	
263	Do you use records to show that input inspections and verifications were completed?	Y	N	X	

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7.4.2 USE AUTHORIZED METHODS TO CONTROL PROCESS OUTPUTS

264	Do you control output design and development activities?	Y	N	X	
265	Do you control how output design and development results are defined?	Y	N	X	
266	Do you control how output design and development reviews are carried out?	Y	N	X	
267	Do you ask representatives from all relevant functions to participate in reviews?	Y	N	X	
268	Do you include people concerned with the design and development stage under review?	Y	N	X	
269	Do you evaluate how well design and development results meet requirements?	Y	N	X	
270	Do you control actions taken to address problems identified during reviews?	Y	N	X	
271	Do you control how output design and development verifications are performed?	Y	N	X	
272	Do you verify that design and development outputs meet input requirements?	Y	N	X	
273	Do you control actions taken to address problems identified during verifications?	Y	N	X	
274	Do you control how output design and development validations are performed?	Y	N	X	
275	Do you confirm that your outputs meet intended use requirements?	Y	N	X	
276	Do you verify that all intended use or application requirements are being met?	Y	N	X	
277	Do you control actions taken to address problems identified during validations?	Y	N	X	
278	Do you reverify your outputs if changes occur that invalidate previous results?	Y	N	X	
279	Do you control how output design and development progression is authorized?	Y	N	X	
280	Do you control progression to the next stage of output design and development?	Y	N	X	
281	Do you control how output design and development work is documented?	Y	N	X	
282	Do you control output design and development documents and records?	Y	N	X	
283	Do you control outputs while process is being carried out?	Y	N	X	
284	Do you establish suitable means and methods for identifying process outputs?	Y	N	X	

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285	Do you control how acceptance authority media are used to identify outputs?	Y	N	X	
286	Do you specify the identity of outputs whenever conformity must be ensured?	Y	N	X	
287	Do you identify outputs whenever output conformity must be ensured?	Y	N	X	
288	Do you establish the specific identity of your output configurations?	Y	N	X	
289	Do you specify the unique identity of all required output configurations?	Y	N	X	
290	Do you specify the unique identity of all actual output configurations?	Y	N	X	
291	Do you maintain the unique identity of your output configurations?	Y	N	X	
292	Do you determine differences between required and actual configurations?	Y	N	X	
293	Do you identify the monitoring and measurement status of outputs throughout production?	Y	N	X	
294	Do you record the unique identity of outputs when traceability is a requirement?	Y	N	X	
295	Do you clarify your organization's unique output traceability requirements?	Y	N	X	
296	Do you consider whether identities must be maintained throughout output life cycle?	Y	N	X	
297	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	
298	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	
299	Do you consider whether or not you need to maintain sequential assembly records?	Y	N	X	
300	Do you consider whether or not you need to maintain sequential inspection records?	Y	N	X	
301	Do you consider whether or not you need to maintain sequential verification records?	Y	N	X	
302	Do you consider whether or not you need to maintain sequential manufacturing records?	Y	N	X	
303	Do you consider whether components need to be traceable to final assemblies?	Y	N	X	
304	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	
305	Do you retain the documents and records that are needed to facilitate traceability?	Y	N	X	

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306	Do you verify that input items, characteristics, and activities are being controlled?	Y	N	X	
307	Do you verify that “critical items” and “key characteristics” are being controlled?	Y	N	X	
308	Do you control identified “critical items” in accordance with established methods?	Y	N	X	
309	Do you control “key characteristics” in accordance with established methods?	Y	N	X	
310	Do you verify that inputs being used in the process are being controlled?	Y	N	X	
311	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	
312	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	
313	Do you verify that all inspection and verification activities have been completed?	Y	N	X	
314	Do you maintain a record of your inspection and verification activities and results?	Y	N	X	
315	Do you use records to show that inspections and verifications were completed?	Y	N	X	
316	Do you control how outputs are officially released?	Y	N	X	
317	Do you verify acceptance before outputs are officially released?	Y	N	X	
318	Do you implement arrangements to verify your process outputs?	Y	N	X	
319	Do you verify that output requirements were met at all appropriate stages?	Y	N	X	
320	Do you retain evidence that shows that output acceptance criteria were met?	Y	N	X	
321	Do you retain evidence that shows that your output meets defined requirements?	Y	N	X	
322	Do you identify people who may authorize release of outputs to process customers?	Y	N	X	
323	Do you retain and control records to facilitate the traceability of output releases?	Y	N	X	
324	Do you release outputs only if verifications are finished or if authorized to do so?	Y	N	X	
325	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	

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326	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	
327	Do you use sampling to see if outputs are acceptable (when applicable)?	Y	N	X	
328	Do you use recognized statistical principles to justify your sampling plans?	Y	N	X	
329	Do you make sure that your sampling plans are appropriate for use?	Y	N	X	
330	Do you make sure that sampling plans consider process capability?	Y	N	X	
331	Do you make sure that sampling plans consider the criticality of the output?	Y	N	X	
332	Do you establish a record of your output acceptance activities?	Y	N	X	
333	Do you document your criteria for output acceptance and rejection?	Y	N	X	
334	Do you document where in the sequence output verification is performed?	Y	N	X	
335	Do you document and retain your output monitoring and measuring results?	Y	N	X	
336	Do you maintain a record of output acceptance and rejection activities?	Y	N	X	
337	Do you document how output monitoring and measuring must be carried out?	Y	N	X	
338	Do you document all required output monitoring and measuring instructions?	Y	N	X	
339	Do you document all required output monitoring and measuring equipment?	Y	N	X	

7.4.3 USE AUTHORIZED METHODS TO CONTROL PROCESS ACTIVITIES

340	Do you use authorized methods to control normal process activities?	Y	N	X	
341	Do you use authorized methods to control process control activities?	Y	N	X	
342	Do you use authorized methods to control process management activities?	Y	N	X	
343	Do you use authorized methods to control process maintenance activities?	Y	N	X	
344	Do you use authorized methods to control process measurement activities?	Y	N	X	
345	Do you use authorized methods to control process monitoring activities?	Y	N	X	

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346	Do you use authorized methods to control process evaluation activities?	Y	N	X	
347	Do you use authorized methods to control process audit activities?	Y	N	X	
348	Do you use authorized methods to control process review activities?	Y	N	X	
349	Do you use authorized methods to control process modification activities?	Y	N	X	
350	Do you use authorized methods to control process correction activities?	Y	N	X	
351	Do you use authorized methods to control process improvement activities?	Y	N	X	
352	Do you use authorized methods to control “special process” activities?	Y	N	X	
353	Do you establish methods for managing “special process” activities?	Y	N	X	
354	Do you validate “special process” activities and results?	Y	N	X	
355	Do you validate your ability to achieve planned results whenever outputs cannot be verified by subsequent monitoring or measurement?	Y	N	X	
356	Have you identified in-process inspection and verification points whenever adequate verification of conformity cannot be performed at subsequent stages?	Y	N	X	
357	Do you control “special process” activities and results?	Y	N	X	
358	Do you make arrangements to control special process activities?	Y	N	X	
359	Do you use criteria to control your special process activities?	Y	N	X	
360	Do you use criteria to control how special activities are reviewed?	Y	N	X	
361	Do you use criteria to control how special activities are approved?	Y	N	X	
362	Do you specify the conditions that must be met in order to maintain approvals?	Y	N	X	
363	Do you use approvals to control your special process activities?	Y	N	X	
364	Do you approve equipment before it is used by special process activities?	Y	N	X	
365	Do you approve facilities before they are used by special process activities?	Y	N	X	
366	Do you approve personnel before they are assigned to special process activities?	Y	N	X	

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367	Do you approve qualifications before assigning them to special process activities?	Y	N	X	
368	Do you use procedures to control your special process activities?	Y	N	X	
369	Follow specific procedures when implementing special process activities?	Y	N	X	
370	Follow specific procedures when maintaining special process activities?	Y	N	X	
371	Follow specific procedures when monitoring special process activities?	Y	N	X	
372	Follow specific procedures when measuring special process activities?	Y	N	X	
373	Follow specific procedures when controlling special process activities?	Y	N	X	
374	Do you use methods to control your special process activities?	Y	N	X	
375	Follow specific methods when implementing special process activities?	Y	N	X	
376	Follow specific methods when maintaining special process activities?	Y	N	X	
377	Follow specific methods when monitoring special process activities?	Y	N	X	
378	Follow specific methods when measuring special process activities?	Y	N	X	
379	Follow specific methods when controlling special process activities?	Y	N	X	
380	Do you use documents to control your special process activities?	Y	N	X	
381	Do you specify retention requirements for these documents?	Y	N	X	
382	Do you use records to control your special process activities?	Y	N	X	
383	Do you specify retention requirements for these records?	Y	N	X	

7.4.4 USE AUTHORIZED METHODS TO CONTROL PROCESS TECHNOLOGY

384	Do you control process equipment, tools, and software programmes?	Y	N	X	
385	Do you validate technology prior to final release for process operations?	Y	N	X	
386	Do you validate technology that is used to perform process operations?	Y	N	X	
387	Do you validate tools before they are used to perform process operations?	Y	N	X	

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388	Do you validate equipment before it is used to perform process operations?	Y	N	X	
389	Do you validate software before it is used to perform process operations?	Y	N	X	
390	Do you validate technology that is used to automate process operations?	Y	N	X	
391	Do you validate tools before they are used to automate process operations?	Y	N	X	
392	Do you validate equipment before it is used to automate process operations?	Y	N	X	
393	Do you validate software before it is used to automate process operations?	Y	N	X	
394	Do you validate technology that is used to maintain process operations?	Y	N	X	
395	Do you validate tools before they are used to maintain process operations?	Y	N	X	
396	Do you validate equipment before it is used to maintain process operations?	Y	N	X	
397	Do you validate software before it is used to maintain process operations?	Y	N	X	
398	Do you validate technology that is used to monitor process operations?	Y	N	X	
399	Do you validate tools before they are used to monitor process operations?	Y	N	X	
400	Do you validate equipment before it is used to monitor process operations?	Y	N	X	
401	Do you validate software before it is used to monitor process operations?	Y	N	X	
402	Do you validate technology that is used to measure process operations?	Y	N	X	
403	Do you validate tools before they are used to measure process operations?	Y	N	X	
404	Do you validate equipment before it is used to measure process operations?	Y	N	X	
405	Do you validate software before it is used to measure process operations?	Y	N	X	
406	Do you validate technology that is used to control process operations?	Y	N	X	
407	Do you validate tools before they are used to control process operations?	Y	N	X	
408	Do you validate equipment before it is used to control process operations?	Y	N	X	
409	Do you validate software before it is used to control process operations?	Y	N	X	

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410	Do you use authorized methods to control risk management programme?	Y	N	X	
411	Do you use authorized methods to control safety management programme?	Y	N	X	
412	Do you use authorized methods to control quality management programme?	Y	N	X	
413	Do you use authorized methods to control security management programme?	Y	N	X	
414	Do you use authorized methods to control personnel security management programme?	Y	N	X	
415	Do you use authorized methods to control information security management programme?	Y	N	X	
416	Do you use authorized methods to control component security management programme?	Y	N	X	
417	Do you use authorized methods to control your counterfeit parts programme?	Y	N	X	
418	Do you use authorized methods to control supplier management programme?	Y	N	X	
419	Do you use authorized methods to control environmental management programme?	Y	N	X	
420	Do you use authorized methods to control business continuity management programme?	Y	N	X	

7.4.6 USE AUTHORIZED METHODS TO CONTROL PROCESS PERFORMANCE

421	Do you use authorized methods to control internal personnel?	Y	N	X	
422	Have you identified the people who can affect process performance?	Y	N	X	
423	Do you qualify the people who can affect process performance?	Y	N	X	
424	Do you make sure that they have the competence they need?	Y	N	X	
425	Do you make sure that they have the appropriate training?	Y	N	X	
426	Do you make sure that they have the appropriate education?	Y	N	X	
427	Do you make sure that they have the appropriate experience?	Y	N	X	
428	Do you supervise the people who can affect process performance?	Y	N	X	
429	Do you use authorized methods to control external providers?	Y	N	X	

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430	Do you establish control of all externally provided processes, products, and services?	Y	N	X	
431	Do you ensure that external processes, products, and services meet requirements?	Y	N	X	
432	Do you ensure that externally provided products and services meet requirements if they are incorporated into your process outputs?	Y	N	X	
433	Do you ensure that externally provided products and services meet requirements if external providers deliver them directly to your process customers?	Y	N	X	
434	Do you ensure that externally provided processes and functions meet requirements?	Y	N	X	
435	Do you ensure that outsourced parts of processes and functions meet requirements?	Y	N	X	
436	Do you control the use of externally provided processes, products, and services?	Y	N	X	
437	Do you use customer-designated or customer-approved external providers if required?	Y	N	X	
438	Do you use customer-designated or customer-approved external process sources?	Y	N	X	
439	Do you use customer-designated or customer-approved "special processes"?	Y	N	X	
440	Do you manage risks associated with the selection and use of external providers?	Y	N	X	
441	Do you manage risks related to externally provided processes, products, and services?	Y	N	X	
442	Do you tell external providers to control their direct and sub-tier external providers?	Y	N	X	
443	Do you tell your providers to ensure that their own providers meet requirements?	Y	N	X	
444	Do you perform external process, product, and service verification activities?	Y	N	X	
445	Do you carry out product inspections and service verifications upon receipt?	Y	N	X	
446	Do you carry out periodic inspections and audits at external provider's premises?	Y	N	X	
447	Do you accept external processes, products, and services only if they meet requirements?	Y	N	X	
448	Do you complete verifications before processes, products, and services are accepted?	Y	N	X	
449	Do you complete all verifications before accepting products for use in production?	Y	N	X	
450	Do you identify externally provided products that are released for use in production?	Y	N	X	

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451	Do you record externally provided products that have been released for use in production pending completion of required verification activities?	Y	N	X	
452	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

453	Do you control how process documents and records are controlled?	Y	N	X	
454	Do you control how process documents and records are created?	Y	N	X	
455	Do you make sure that process documents and records are suitable for use?	Y	N	X	
456	Do you make sure that documents and records are properly identified and described?	Y	N	X	
457	Do you make sure that they have the right names and descriptive titles?	Y	N	X	
458	Do you make sure that they have the right dates and reference numbers?	Y	N	X	
459	Do you make sure that documents and records are properly formatted and presented?	Y	N	X	
460	Do you make sure that process documents and records use the appropriate media?	Y	N	X	
461	Do you make sure that process documents and records use the appropriate graphics?	Y	N	X	
462	Do you make sure that process documents and records use the appropriate language?	Y	N	X	
463	Do you make sure that process documents and records use the appropriate software?	Y	N	X	
464	Do you control how process documents and records are identified?	Y	N	X	
465	Do you control how internal documents and records are identified and described?	Y	N	X	
466	Do you control how external documents and records are identified and described?	Y	N	X	
467	Do you control how process documents and records are distributed?	Y	N	X	
468	Do you control how process documents and records are stored?	Y	N	X	
469	Do you control how process documents and records are retrieved?	Y	N	X	
470	Do you control how process documents and records are accessed?	Y	N	X	

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471	Do you prevent unauthorized access to documents and records?	Y	N	X	
472	Do you make sure that documents and records are available for use where needed?	Y	N	X	
473	Do you make sure that documents and records are available for use when needed?	Y	N	X	
474	Do you control how process documents and records are used?	Y	N	X	
475	Do you control how active process documents and records are used?	Y	N	X	
476	Do you control how documents and records are used to plan your process?	Y	N	X	
477	Do you control how internal documents and records are used to plan your process?	Y	N	X	
478	Do you control how external documents and records are used to plan your process?	Y	N	X	
479	Do you control how documents and records are used to operate your process?	Y	N	X	
480	Do you control how internal documents and records are used to operate process?	Y	N	X	
481	Do you control how external documents and records are used to operate process?	Y	N	X	
482	Do you control how documents and records are used to implement your process?	Y	N	X	
483	Do you control how internal documents and records are used to implement process?	Y	N	X	
484	Do you control how external documents and records are used to implement process?	Y	N	X	
485	Do you control how documents and records are used to maintain your process?	Y	N	X	
486	Do you control how internal documents and records are used to maintain process?	Y	N	X	
487	Do you control how external documents and records are used to maintain process?	Y	N	X	
488	Do you control how documents and records are used to monitor your process?	Y	N	X	
489	Do you control how internal documents and records are used to monitor process?	Y	N	X	
490	Do you control how external documents and records are used to monitor process?	Y	N	X	
491	Do you control how documents and records are used to measure your process?	Y	N	X	
492	Do you control how internal documents and records are used to measure process?	Y	N	X	

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493	Do you control how external documents and records are used to measure process?	Y	N	X	
494	Do you control how documents and records are used to control your process?	Y	N	X	
495	Do you control how internal documents and records are used to control process?	Y	N	X	
496	Do you control how external documents and records are used to control process?	Y	N	X	
497	Do you control how documents and records are used to evaluate your process?	Y	N	X	
498	Do you control how documents and records are used to audit your process?	Y	N	X	
499	Do you control how internal documents and records are used to audit process?	Y	N	X	
500	Do you control how external documents and records are used to audit process?	Y	N	X	
501	Do you control how documents and records are used to review your process?	Y	N	X	
502	Do you control how internal documents and records are used to review process?	Y	N	X	
503	Do you control how external documents and records are used to review process?	Y	N	X	
504	Do you control how documents and records are used to modify your process?	Y	N	X	
505	Do you control how documents and records are used to correct your process?	Y	N	X	
506	Do you control how internal documents and records are used to correct process?	Y	N	X	
507	Do you control how external documents and records are used to correct process?	Y	N	X	
508	Do you control how documents and records are used to improve your process?	Y	N	X	
509	Do you control how internal documents and records are used to improve process?	Y	N	X	
510	Do you control how external documents and records are used to improve process?	Y	N	X	
511	Do you control how inactive process documents and records are used?	Y	N	X	
512	Do you control how obsolete process documents and records are used?	Y	N	X	
513	Do you prevent the unintended use of obsolete documented information?	Y	N	X	
514	Do you identify obsolete process documents and records?	Y	N	X	

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PROCESS BEING AUDITED:**7. ASSESS PROCESS CONTROL ACTIVITIES**

515	Do you control obsolete process documents and records?	Y	N	X	
516	Do you remove obsolete process documents and records?	Y	N	X	
517	Do you control how process documents and records are protected?	Y	N	X	
518	Do you control how paper documents and records are protected?	Y	N	X	
519	Do you ensure that paper documents and records are protected?	Y	N	X	
520	Do you protect the integrity of your paper documents and records?	Y	N	X	
521	Do you prevent unauthorized or improper use of paper documents and records?	Y	N	X	
522	Do you protect the confidentiality of paper documents and records?	Y	N	X	
523	Do you protect the legibility of paper documents and records?	Y	N	X	
524	Do you control how electronic documents and records are protected?	Y	N	X	
525	Do you ensure that electronic documents and records are protected?	Y	N	X	
526	Do you define and develop suitable data protection methods?	Y	N	X	
527	Do you protect process documents and records from loss?	Y	N	X	
528	Do you protect process documents and records from corruption?	Y	N	X	
529	Do you protect process documents and records from physical damage?	Y	N	X	
530	Do you protect process documents and records from unauthorized access?	Y	N	X	
531	Do you protect process documents and records from unintended alteration?	Y	N	X	
532	Do you protect process documents and records from inappropriate changes?	Y	N	X	
533	Do you control how process documents and records are changed?	Y	N	X	
534	Do you control how paper documents and records are changed?	Y	N	X	
535	Do you use version control to manage changes to paper documents and records?	Y	N	X	

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PROCESS BEING AUDITED:**7. ASSESS PROCESS CONTROL ACTIVITIES**

536	Do you prevent unintended alterations or modifications of paper documents and records that are maintained as evidence of conformity?	Y	N	X	
537	Do you control how electronic documents and records are changed?	Y	N	X	
538	Do you control how process documents and records are preserved?	Y	N	X	
539	Do you control the retention of documents and records?	Y	N	X	
540	Do you control the disposal of documents and records?	Y	N	X	
541	Do you control all the process documents and records that you need?	Y	N	X	
542	Do you control all the internal documents and records that your process needs?	Y	N	X	
543	Do you control information that your process needs in order to be effective?	Y	N	X	
544	Do you control all the documents and records needed to operate your process?	Y	N	X	
545	Do you control documents and records used to facilitate process operations?	Y	N	X	
546	Do you control documents and records used to facilitate output compliance?	Y	N	X	
547	Do you control all the documents and records needed to maintain your process?	Y	N	X	
548	Do you control documents and records used to maintain process operations?	Y	N	X	
549	Do you control documents and records used to maintain output compliance?	Y	N	X	
550	Do you control all the documents and records needed to monitor your process?	Y	N	X	
551	Do you control documents and records used to monitor process operations?	Y	N	X	
552	Do you control documents and records used to monitor output compliance?	Y	N	X	
553	Do you control all the documents and records needed to measure your process?	Y	N	X	
554	Do you control documents and records used to measure process operations?	Y	N	X	
555	Do you control documents and records used to measure output compliance?	Y	N	X	
556	Do you control all the documents and records needed to control your process?	Y	N	X	

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PROCESS BEING AUDITED:

7. ASSESS PROCESS CONTROL ACTIVITIES

557	Do you control documents and records used to control process operations?	Y	N	X	
558	Do you control documents and records used to control output compliance?	Y	N	X	
559	Do you control all the documents and records needed to evaluate your process?	Y	N	X	
560	Do you control documents and records needed to audit your process?	Y	N	X	
561	Do you control documents and records used to audit process operations?	Y	N	X	
562	Do you control documents and records used to audit output compliance?	Y	N	X	
563	Do you control all the documents and records needed to review your process?	Y	N	X	
564	Do you control documents and records used to review process operations?	Y	N	X	
565	Do you control documents and records used to review output compliance?	Y	N	X	
566	Do you control all the documents and records needed to modify your process?	Y	N	X	
567	Do you control documents and records needed to correct your process?	Y	N	X	
568	Do you control documents and records used to correct process operations?	Y	N	X	
569	Do you control documents and records used to correct output compliance?	Y	N	X	
570	Do you control documents and records needed to improve your process?	Y	N	X	
571	Do you control documents and records used to improve process operations?	Y	N	X	
572	Do you control documents and records used to improve output compliance?	Y	N	X	
573	Do you control all the external documents and records that your process needs?	Y	N	X	
574	Do you control all external documented information needed in order to plan process?	Y	N	X	
575	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.

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PROCESS BEING AUDITED:

8. ASSESS PROCESS EVALUATION ACTIVITIES

8.1 PLAN HOW YOU'RE GOING TO EVALAUTE PROCESS

8.1.1 PLAN HOW YOU'RE GOING TO AUDIT YOUR PROCESS

1	Have you developed an internal audit programme?	Y	N	X	
2	Did you develop a programme that can find out if your process meets requirements?	Y	N	X	
3	Do you make sure it can determine how well your process meets corporate expectations?	Y	N	X	
4	Do you make sure it can determine how well your process meets international standards?	Y	N	X	
5	Did you develop a programme that can determine if your process is actually effective?	Y	N	X	
6	Do you make sure that your programme is capable of producing valid results?	Y	N	X	
7	Did you establish an internal audit programme?	Y	N	X	
8	Do you assign internal audit responsibilities?	Y	N	X	
9	Do you develop your internal audit methods?	Y	N	X	
10	Do you clarify your internal audit standards?	Y	N	X	
11	Do you expect auditors to be objective?	Y	N	X	
12	Do you expect auditors to be impartial?	Y	N	X	
13	Do you specify internal audit planning requirements?	Y	N	X	
14	Do you expect auditors to consider the results of previous audits?	Y	N	X	
15	Do you expect auditors to consider the impact proposed changes could have?	Y	N	X	
16	Do you expect auditors to consider the importance of the processes being audited?	Y	N	X	
17	Do you define internal audit reporting requirements?	Y	N	X	
18	Do you expect auditors to report results to management?	Y	N	X	
19	Do you formulate internal audit schedules?	Y	N	X	
20	Do you expect audits to be done at planned intervals?	Y	N	X	

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PROCESS BEING AUDITED:

8. ASSESS PROCESS EVALUATION ACTIVITIES

8.1.2 PLAN HOW YOU'RE GOING TO ANALYZE YOUR PROCESS

21	Do you plan how you're going to analyze the opinions and satisfaction of process customers?	Y	N	X	
22	Do you plan how you're going to use your analytical results to evaluate satisfaction?	Y	N	X	
23	Do you plan how you're going to analyze the degree of customer satisfaction?	Y	N	X	
24	Do you plan how you're going to use your analytical results to evaluate effectiveness?	Y	N	X	
25	Do you plan how you're going to analyze the effectiveness of process operations?	Y	N	X	
26	Do you plan how you're going to determine if you need to improve effectiveness?	Y	N	X	
27	Do you plan how you're going to analyze the effectiveness of your process planning?	Y	N	X	
28	Do you plan how you're going to determine if plans are effectively implemented?	Y	N	X	
29	Do you plan how you're going to analyze the effectiveness of actions taken by managers?	Y	N	X	
30	Do you plan how to analyze the effectiveness of actions taken to address risks?	Y	N	X	
31	Do you plan how to analyze the effectiveness of actions taken to exploit opportunities?	Y	N	X	
32	Do you plan how you're going to analyze the conformance and effectiveness of your process?	Y	N	X	
33	Do you plan how you're going to use analytical results to evaluate conformance?	Y	N	X	
34	Do you plan how you're going to analyze the conformity of process outputs?	Y	N	X	
35	Do you plan how you're going to analyze your process output problems?	Y	N	X	
36	Do you plan how to analyze output problems reported by external sources?	Y	N	X	
37	Do you plan how to analyze output problems reported using advisories?	Y	N	X	
38	Do you plan how to analyze output problems reported by means of alerts?	Y	N	X	
39	Do you plan how to analyze problems reported by means of industry alerts?	Y	N	X	
40	Do you plan how to analyze problems reported by means of government alerts?	Y	N	X	

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PROCESS BEING AUDITED:**8. ASSESS PROCESS EVALUATION ACTIVITIES**

41	Do you plan how to analyze output problems revealed by internal sources?	Y	N	X	
42	Do you plan how you're going to use analytical results to evaluate effectiveness?	Y	N	X	
43	Do you plan how to analyze the effectiveness of your process operations?	Y	N	X	
44	Do you plan how to determine if you need to improve its effectiveness?	Y	N	X	
45	Do you plan how you're going to analyze the competence and performance of process personnel?	Y	N	X	
46	Do you plan how to analyze the effectiveness of actions taken to acquire competence?	Y	N	X	
47	Do you plan how you're going to analyze the conformance and performance of external providers?	Y	N	X	
48	Do you plan how to analyze process, product, and service conformity of each external provider?	Y	N	X	
49	Do you plan how to analyze the on-time delivery performance of each external provider?	Y	N	X	
50	Do you plan how to analyze the approval status of each external provider?	Y	N	X	
51	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

52	Do you consider how you're going to review your process?	Y	N	X	
53	Do you consider how you're going to review the suitability of your process?	Y	N	X	
54	Do you consider how you're going to review the adequacy of your process?	Y	N	X	
55	Do you consider how you're going to review the effectiveness of your process?	Y	N	X	
56	Do you consider the issues that are relevant to your process?	Y	N	X	
57	Do you consider changes in the external issues that influence your process?	Y	N	X	
58	Do you consider changes in the internal issues that influence your process?	Y	N	X	
59	Do you consider the status of your previous management reviews?	Y	N	X	
60	Do you consider the status of the actions that were previously taken?	Y	N	X	

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PROCESS BEING AUDITED:**8. ASSESS PROCESS EVALUATION ACTIVITIES****8.2 PROVIDE RESOURCES NEEDED TO EVALUATE PROCESS****8.2.1 PROVIDE THE PEOPLE THAT YOU NEED TO EVALAUTE YOUR PROCESS**

61	Do you provide the people that you need in order to audit your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
62	Do you provide the people that you need in order to analyze your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
63	Do you provide the people that you need in order to review your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

8.2.2 PROVIDE THE KNOWLEDGE THAT YOU NEED TO EVALUATE YOUR PROCESS

64	Do you provide the knowledge that you need in order to audit your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
65	Do you provide the knowledge that you need in order to analyze your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
66	Do you provide the knowledge that you need in order to review your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

8.2.3 PROVIDE THE TECHNOLOGY THAT YOU NEED TO EVALUATE YOUR PROCESS

67	Do you provide the technology that you need in order to audit your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
68	Do you provide the technology that you need in order to analyze your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
69	Do you provide the technology that you need in order to review your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

8.2.4 PROVIDE THE INFRASTRUCTURE THAT YOU NEED TO EVALUATE YOUR PROCESS

70	Do you provide the infrastructure that you need in order to audit your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
71	Do you provide the infrastructure that you need in order to analyze your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
72	Do you provide the infrastructure that you need in order to review your process?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

8.3 USE AUTHORIZED METHODS TO EVALUATE PROCESS**8.3.1 USE AUTHORIZED METHODS TO AUDIT YOUR PROCESS**

73	Do you plan your internal process audit activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
74	Do you define the scope for each internal process audit?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
75	Do you specify audit criteria for each internal process audit?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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76	Do you clarify internal process audit methods and techniques?	Y	N	X	
77	Do you select impartial and objective internal process auditors?	Y	N	X	
78	Do you schedule internal process audits at planned intervals?	Y	N	X	
79	Do you carry out internal process audits at planned intervals?	Y	N	X	
80	Do you conduct internal conformance audits of your process?	Y	N	X	
81	Do you determine if your process meets relevant requirements?	Y	N	X	
82	Do you determine if your process meets internal requirements?	Y	N	X	
83	Do you determine if your process meets external requirements?	Y	N	X	
84	Do you determine if your process meets external customer requirements?	Y	N	X	
85	Do you determine if your process meets external statutory requirements?	Y	N	X	
86	Do you determine if your process meets external regulatory requirements?	Y	N	X	
87	Do you determine if your process complies with government regulations?	Y	N	X	
88	Do you determine if your process complies with international standards?	Y	N	X	
89	Do you determine how well process meets safety management requirements?	Y	N	X	
90	Do you determine how well process meets security management requirements?	Y	N	X	
91	Do you determine how well process meets quality management requirements?	Y	N	X	
92	Do you determine how well process meets environmental management requirements?	Y	N	X	
93	Do you determine how well process meets continuity management requirements?	Y	N	X	
94	Do you conduct internal effectiveness audits of your process?	Y	N	X	
95	Do you determine how effective process implementation was?	Y	N	X	
96	Do you use performance indicators to see if process is effectively implemented?	Y	N	X	

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PROCESS BEING AUDITED:**8. ASSESS PROCESS EVALUATION ACTIVITIES**

97	Do you determine how effective process operations are?	Y	N	X	
98	Do you use performance indicators to see if process is effectively operated?	Y	N	X	
99	Do you determine how effective process control is?	Y	N	X	
100	Do you use performance indicators to see if process is effectively controlled?	Y	N	X	
101	Do you determine how effective process maintenance is?	Y	N	X	
102	Do you use performance indicators to see if process is effectively maintained?	Y	N	X	
103	Do you determine how effective process monitoring is?	Y	N	X	
104	Do you use performance indicators to see if process is effectively monitored?	Y	N	X	
105	Do you determine how effective process measurement is?	Y	N	X	
106	Do you use performance indicators to see if process is effectively measured?	Y	N	X	
107	Do you determine how effective process evaluations are?	Y	N	X	
108	Do you use performance indicators to see if process is effectively evaluated?	Y	N	X	
109	Do you use performance indicators to see if process is effectively audited?	Y	N	X	
110	Do you use performance indicators to see if process is effectively reviewed?	Y	N	X	
111	Do you determine how effective process modifications are?	Y	N	X	
112	Do you use performance indicators to see if process is effectively modified?	Y	N	X	
113	Do you use performance indicators to see if process corrections are effective?	Y	N	X	
114	Do you use performance indicators to see if process improvements are effective?	Y	N	X	
115	Do you report process audit results to management?	Y	N	X	
116	Do you maintain your internal process audit programme?	Y	N	X	
117	Do you retain documented information about your process audit programme?	Y	N	X	
118	Do you retain your internal process audit results and control these results?	Y	N	X	

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8. ASSESS PROCESS EVALUATION ACTIVITIES

8.3.2 USE AUTHORIZED METHODS TO ANALYZE YOUR PROCESS

119	Do you analyze the opinions of process customers?	Y	N	X	
120	Do you use your analytical results to evaluate satisfaction?	Y	N	X	
121	Do you evaluate the degree of customer satisfaction?	Y	N	X	
122	Do you analyze the performance of your process?	Y	N	X	
123	Do you use your results to analyze conformance?	Y	N	X	
124	Do you analyze the conformity of process outputs?	Y	N	X	
125	Do you analyze your process output problems?	Y	N	X	
126	Do you analyze output problems reported by external sources?	Y	N	X	
127	Do you analyze output problems reported using advisories?	Y	N	X	
128	Do you analyze output problems reported by means of alerts?	Y	N	X	
129	Do you analyze problems reported by means of industry alerts?	Y	N	X	
130	Do you analyze problems reported by means of government alerts?	Y	N	X	
131	Do you analyze output problems revealed by internal sources?	Y	N	X	
132	Do you use your results to analyze effectiveness?	Y	N	X	
133	Do you analyze the effectiveness of your process operations?	Y	N	X	
134	Do you determine if you need to improve its effectiveness?	Y	N	X	
135	Do you analyze the effectiveness of your process?	Y	N	X	
136	Do you use your results to analyze process effectiveness?	Y	N	X	
137	Do you analyze the effectiveness of process operations?	Y	N	X	
138	Do you determine if you need to improve process operations?	Y	N	X	
139	Do you analyze the effectiveness of process maintenance?	Y	N	X	

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PROCESS BEING AUDITED:**8. ASSESS PROCESS EVALUATION ACTIVITIES**

140	Do you determine if you need to improve process maintenance?	Y	N	X	
141	Do you analyze the effectiveness of process monitoring?	Y	N	X	
142	Do you determine if you need to improve process monitoring?	Y	N	X	
143	Do you analyze the effectiveness of process measurement?	Y	N	X	
144	Do you determine if you need to improve process measurement?	Y	N	X	
145	Do you analyze the effectiveness of process evaluations?	Y	N	X	
146	Do you analyze the effectiveness of process audits?	Y	N	X	
147	Do you determine if you need to improve process audits?	Y	N	X	
148	Do you analyze the effectiveness of process reviews?	Y	N	X	
149	Do you determine if you need to improve process reviews?	Y	N	X	
150	Do you analyze the effectiveness of process modifications?	Y	N	X	
151	Do you analyze the effectiveness of process corrections?	Y	N	X	
152	Do you determine if you need to improve process correction activities?	Y	N	X	
153	Do you analyze the effectiveness of process improvements?	Y	N	X	
154	Do you determine if you need to improve process improvement activities?	Y	N	X	
155	Do you use your results to analyze process management?	Y	N	X	
156	Do you analyze the effectiveness of actions taken by managers?	Y	N	X	
157	Do you analyze the effectiveness of actions taken to address process risks?	Y	N	X	
158	Do you analyze the effectiveness of actions taken to address process opportunities?	Y	N	X	
159	Do you analyze the effectiveness of actions taken to address process nonconformities?	Y	N	X	
160	Do you analyze the effectiveness of actions taken to address process performance problems?	Y	N	X	
161	Do you analyze the competence of process participants?	Y	N	X	

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PROCESS BEING AUDITED:**8. ASSESS PROCESS EVALUATION ACTIVITIES**

162	Do you analyze the competence and performance of process personnel?	Y	N	X	
163	Do you analyze the effectiveness of actions taken to acquire competence?	Y	N	X	
164	Do you analyze the competence and performance of external providers?	Y	N	X	
165	Do you analyze the process, product, and service conformity of each external provider?	Y	N	X	
166	Do you analyze the on-time delivery performance of each external provider?	Y	N	X	
167	Do you analyze the approval status of each external provider?	Y	N	X	
168	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

169	Do you review the performance of your process?	Y	N	X	
170	Do you review your process nonconformities?	Y	N	X	
171	Do you review process output nonconformities?	Y	N	X	
172	Do you review customer perceptions and satisfaction?	Y	N	X	
173	Do you use output conformity information to review customer satisfaction?	Y	N	X	
174	Do you use on-time delivery performance to review customer satisfaction?	Y	N	X	
175	Do you use corrective action requests to review customer satisfaction?	Y	N	X	
176	Do you use customer complaints to review customer satisfaction?	Y	N	X	
177	Do you review the performance of process personnel?	Y	N	X	
178	Do you review how well objectives are being met?	Y	N	X	
179	Do you review the competence of process personnel?	Y	N	X	
180	Do you review process management activities and results?	Y	N	X	
181	Do you review process control methods and results?	Y	N	X	
182	Do you review process operations methods and results?	Y	N	X	

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PROCESS BEING AUDITED:**8. ASSESS PROCESS EVALUATION ACTIVITIES**

183	Do you review process monitoring methods and results?	Y	N	X	
184	Do you review process measurement methods and results?	Y	N	X	
185	Do you review process maintenance methods and results?	Y	N	X	
186	Do you review process evaluation methods and results?	Y	N	X	
187	Do you review process audit activities and results?	Y	N	X	
188	Do you review process analysis activities and results?	Y	N	X	
189	Do you review process modification methods and results?	Y	N	X	
190	Do you review actual process modifications?	Y	N	X	
191	Do you review actions taken to modify your process?	Y	N	X	
192	Do you review the effectiveness of actions taken to improve process?	Y	N	X	
193	Do you review the effectiveness of corrective and preventive actions?	Y	N	X	
194	Do you review corrective actions taken to address process nonconformities?	Y	N	X	
195	Do you review preventive actions taken to address process nonconformities?	Y	N	X	
196	Do you review potential process modifications?	Y	N	X	
197	Do you review potential improvement opportunities?	Y	N	X	
198	Do you review potential corrective and preventive actions?	Y	N	X	
199	Do you review process risks and opportunities?	Y	N	X	
200	Do you review actions taken to address risks and opportunities?	Y	N	X	
201	Do you review the effectiveness of the actions that were taken?	Y	N	X	
202	Do you review suitability of process environment?	Y	N	X	
203	Do you review external process, product, and service providers?	Y	N	X	
204	Do you review your external process, product, and service verification activities?	Y	N	X	

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8. ASSESS PROCESS EVALUATION ACTIVITIES

205	Do you review verifications whenever they are delegated to external providers?	Y	N	X	
206	Do you review the issues that could influence process performance?	Y	N	X	
207	Do you review and evaluate the issues and concerns of interested parties?	Y	N	X	
208	Do you review and evaluate their changing needs and expectations?	Y	N	X	
209	Do you review the adequacy of process resources?	Y	N	X	
210	Do you generate suitable management review outputs?	Y	N	X	

8.4 RECORD THE RESULTS OF PROCESS EVALUATIONS

211	Do you record your process audit activities and results?	Y	N	X	
212	Do you maintain and control your process audit records?	Y	N	X	
213	Do you record your process analysis activities and results?	Y	N	X	
214	Do you maintain and control your process analysis records?	Y	N	X	
215	Do you record your process review activities and results?	Y	N	X	
216	Do you maintain and control your process review records?	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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PROCESS BEING AUDITED:

9. ASSESS PROCESS MODIFICATION ACTIVITIES

9.1 ESTABLISH YOUR PROCESS MODIFICATION METHODS

9.1.1 ESTABLISH METHODS FOR CORRECTING PROCESS AND OUTPUTS

1	Do you establish appropriate corrective action methods and procedures?	Y	N	X	
2	Do you document your corrective action methods and procedures?	Y	N	X	
3	Do you maintain documents that describe corrective action methods and procedures?	Y	N	X	
4	Do you establish appropriate corrective action record keeping methods?	Y	N	X	
5	Do you figure out how to record the actions taken to correct process and outputs?	Y	N	X	
6	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

7	Do you establish appropriate process and output improvement methods and procedures?	Y	N	X	
8	Do you document your process and output improvement methods and procedures?	Y	N	X	
9	Do you keep documents describing process and output improvement methods and procedures?	Y	N	X	
10	Do you establish appropriate process and output improvement record keeping methods?	Y	N	X	
11	Do you figure out how to record the actions taken to improve process and outputs?	Y	N	X	
12	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

13	Do you discover opportunities to correct your process and its outputs?	Y	N	X	
14	Do you discover opportunities to make corrections by examining audit reports?	Y	N	X	
15	Do you discover opportunities to make corrections by examining review results?	Y	N	X	
16	Do you discover opportunities to make corrections by examining best practices?	Y	N	X	
17	Do you discover opportunities to make corrections by examining lessons learned?	Y	N	X	

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18	Do you discover opportunities to make corrections by examining nonconformities?	Y	N	X	
19	Do you discover opportunities to make corrections by examining customer feedback?	Y	N	X	
20	Do you discover opportunities to improve your process and its outputs?	Y	N	X	
21	Do you discover improvement opportunities by examining audit reports?	Y	N	X	
22	Do you discover improvement opportunities by examining review results?	Y	N	X	
23	Do you discover improvement opportunities by examining best practices?	Y	N	X	
24	Do you discover improvement opportunities by examining lessons learned?	Y	N	X	
25	Do you discover improvement opportunities by examining nonconformities?	Y	N	X	
26	Do you discover improvement opportunities by examining customer feedback?	Y	N	X	

9.2.2 DEFINE OPPORTUNITIES TO MODIFY YOUR PROCESS AND OUTPUTS

27	Do you define opportunities to correct and improve process outputs?	Y	N	X	
28	Do you define opportunities to correct and improve the quality of your outputs?	Y	N	X	
29	Do you define opportunities to correct and improve the safety of your outputs?	Y	N	X	
30	Do you define opportunities to correct and improve the security of your outputs?	Y	N	X	
31	Do you define opportunities to correct and improve process performance?	Y	N	X	
32	Do you define opportunities to correct and improve process operations?	Y	N	X	
33	Do you define opportunities to correct and improve process maintenance?	Y	N	X	
34	Do you define opportunities to correct and improve process monitoring?	Y	N	X	
35	Do you define opportunities to correct and improve process measurement?	Y	N	X	
36	Do you define opportunities to correct and improve process controls?	Y	N	X	
37	Do you define opportunities to correct and improve process evaluations?	Y	N	X	
38	Do you define opportunities to correct and improve process audits?	Y	N	X	

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PROCESS BEING AUDITED:

9. ASSESS PROCESS MODIFICATION ACTIVITIES

39	Do you define opportunities to correct and improve process reviews?	Y	N	X	
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9.2.3 CONFIRM THAT PROCESS AND OUTPUT MODIFICATIONS ARE NEEDED

40	Do you confirm that proposed process modifications are necessary?	Y	N	X	
41	Do you confirm that proposed process modifications would be feasible?	Y	N	X	
42	Do you confirm that proposed process modifications would be appropriate?	Y	N	X	
43	Do you confirm that proposed process modifications would be effective?	Y	N	X	
44	Do you confirm that proposed process modifications would be cost-effective?	Y	N	X	
45	Do you confirm that proposed output modifications would be necessary?	Y	N	X	
46	Do you confirm that proposed output modifications would be feasible?	Y	N	X	
47	Do you confirm that proposed output modifications would be appropriate?	Y	N	X	
48	Do you confirm that proposed output modifications would be effective?	Y	N	X	
49	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

50	Do you authorize proposed process corrections and improvements?	Y	N	X	
51	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

52	Do you plan how you're going to apply your corrective action methods and procedures?	Y	N	X	
53	Do you plan how you're going to react to your process and output nonconformities?	Y	N	X	
54	Do you plan how you're going to control and correct process and output nonconformities?	Y	N	X	
55	Do you plan how you're going to deal with all relevant effects and consequences?	Y	N	X	
56	Do you plan how you're going to document your corrective action activities and results?	Y	N	X	

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57	Do you plan how you're going to document the actions taken and the results achieved?	Y	N	X	
58	Do you plan how you're going to retain and control your record of actions and results?	Y	N	X	
59	Do you plan how you're going to evaluate the need to eliminate causes?	Y	N	X	
60	Do you plan how you're going to review and analyze the nonconformity?	Y	N	X	
61	Do you plan how you're going to determine the causes of the nonconformity?	Y	N	X	
62	Do you plan how to determine if human factors are responsible for the nonconformity?	Y	N	X	
63	Do you plan how to determine if external providers are responsible for nonconformity?	Y	N	X	
64	Do you plan how to flow down corrective action requirements to external providers?	Y	N	X	
65	Do you plan how you're going to decide if corrective action should be taken?	Y	N	X	
66	Do you plan how you're going to develop corrective actions to address causes?	Y	N	X	
67	Do you plan how you're going to make sure that your actions are feasible?	Y	N	X	
68	Do you plan how you're going to make sure that your actions are appropriate?	Y	N	X	
69	Do you plan how you're going to make sure that actions also consider consequences?	Y	N	X	
70	Do you plan how you're going to make sure that your actions are effective?	Y	N	X	
71	Do you plan how you're going to make sure that your actions are cost-effective?	Y	N	X	
72	Do you plan how you're going to get managers to authorize corrective action?	Y	N	X	
73	Do you plan how you're going to submit corrective action requests?	Y	N	X	
74	Do you plan how you're going to take corrective actions to deal with causes?	Y	N	X	
75	Do you plan how you're going to correct your process and its outputs?	Y	N	X	
76	Do you plan how you're going to review the effectiveness of corrective actions?	Y	N	X	
77	Do you plan how you're going to respond when correction actions aren't taken?	Y	N	X	
78	Do you plan how you're going to update your list of process and output risks?	Y	N	X	

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PROCESS BEING AUDITED:

9. ASSESS PROCESS MODIFICATION ACTIVITIES

9.3.2 PLAN HOW YOU'RE GOING TO IMPROVE PROCESS AND ITS OUTPUTS

79	Do you plan improvements and other changes to your process?	Y	N	X	
80	Have you identified people authorized to approve changes in your process?	Y	N	X	
81	Do you use your process purpose and scope to guide process improvements?	Y	N	X	
82	Do you use process policy statements to guide process improvements?	Y	N	X	
83	Do you use your quality policy to guide your process improvements?	Y	N	X	
84	Do you use your quality objectives to guide process improvements?	Y	N	X	
85	Do you use your safety policy to guide your process improvements?	Y	N	X	
86	Do you use your safety objectives to guide process improvements?	Y	N	X	
87	Do you use your security policy to guide your process improvements?	Y	N	X	
88	Do you use your security objectives to guide process improvements?	Y	N	X	
89	Do you use your environmental policy to guide your process improvements?	Y	N	X	
90	Do you use your environmental objectives to guide process improvements?	Y	N	X	
91	Do you use your business continuity policy to guide your process improvements?	Y	N	X	
92	Do you use your business continuity objectives to guide process improvements?	Y	N	X	
93	Do you consider improvements and other changes to your process?	Y	N	X	
94	Do you consider the purpose and effects of the changes you intend to make?	Y	N	X	
95	Do you consider responsibilities and authorities whenever you make changes?	Y	N	X	
96	Do you consider allocating or reallocating responsibilities and authorities?	Y	N	X	
97	Do you consider the consequences that changes could potentially produce?	Y	N	X	
98	Do you consider the availability of resources whenever you make changes?	Y	N	X	
99	Do you consider the integrity of your process whenever you make changes?	Y	N	X	

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9. ASSESS PROCESS MODIFICATION ACTIVITIES

100	Do you figure out how you're going to control changes in your process?	Y	N	X	
101	Do you ensure that process continues to work properly even though changes are being made?	Y	N	X	
102	Do you plan improvements and other changes to process outputs?	Y	N	X	
103	Have you identified people authorized to approve changes in process outputs?	Y	N	X	
104	Do you use your process purpose and scope to guide output improvements?	Y	N	X	
105	Do you use process policy statements to guide process improvements?	Y	N	X	
106	Do you use your quality policy to guide your output improvements?	Y	N	X	
107	Do you use your quality objectives to guide output improvements?	Y	N	X	
108	Do you use your safety policy to guide your output improvements?	Y	N	X	
109	Do you use your safety objectives to guide output improvements?	Y	N	X	
110	Do you use your security policy to guide your output improvements?	Y	N	X	
111	Do you use your security objectives to guide output improvements?	Y	N	X	
112	Do you use your environmental policy to guide your output improvements?	Y	N	X	
113	Do you use your environmental objectives to guide output improvements?	Y	N	X	
114	Do you consider improvements and other changes to your outputs?	Y	N	X	
115	Do you consider the purpose and effects of the output changes you intend to make?	Y	N	X	
116	Do you consider responsibilities and authorities whenever you make output changes?	Y	N	X	
117	Do you consider the consequences that output changes could potentially produce?	Y	N	X	
118	Do you consider the availability of resources whenever you make output changes?	Y	N	X	
119	Do you consider the integrity of your outputs whenever you make changes?	Y	N	X	
120	Do you figure out how you're going to control changes in your process outputs?	Y	N	X	
121	Do you ensure that outputs still meet requirements even though changes are being made?	Y	N	X	

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9. ASSESS PROCESS MODIFICATION ACTIVITIES

9.4 USE AUTHORIZED METHODS TO MODIFY YOUR PROCESS

9.4.1 USE AUTHORIZED METHODS TO CORRECT PROCESS AND OUTPUTS

122	Do you apply your corrective action methods and procedures?	Y	N	X	
123	Do you evaluate the need to eliminate causes of nonconformity?	Y	N	X	
124	Do you review and analyze your process and output nonconformities?	Y	N	X	
125	Do you determine the causes of process and output nonconformities?	Y	N	X	
126	Do you determine if human factors are responsible for nonconformity?	Y	N	X	
127	Do you determine if external providers are responsible for nonconformity?	Y	N	X	
128	Do you flow down corrective action requirements to your external providers?	Y	N	X	
129	Do you decide if the causes of process or output nonconformity must be addressed?	Y	N	X	
130	Do you develop corrective actions to address causes of nonconformity?	Y	N	X	
131	Do you make sure that your corrective actions are feasible?	Y	N	X	
132	Do you make sure that your corrective actions are appropriate?	Y	N	X	
133	Do you make sure that actions also consider effects and consequences?	Y	N	X	
134	Do you make sure that your corrective actions are effective?	Y	N	X	
135	Do you make sure that your corrective actions are cost-effective?	Y	N	X	
136	Do you take corrective action to address the causes of nonconformity?	Y	N	X	
137	Do you provide the resources needed to correct process and outputs?	Y	N	X	
138	Do you provide suitable resources needed to correct process outputs?	Y	N	X	
139	Do you provide suitable resources needed to correct process activities?	Y	N	X	
140	Do you control your corrective action activities and results?	Y	N	X	
141	Do you monitor your corrective action activities and results?	Y	N	X	

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142	Do you record your corrective action activities and results?	Y	N	X	
143	Do you document the actions taken and the results achieved?	Y	N	X	
144	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

145	Do you apply process and output improvement methods and procedures?	Y	N	X	
146	Do you evaluate the need to make process and output improvements?	Y	N	X	
147	Do you provide the resources needed to make process and output improvements?	Y	N	X	
148	Do you provide suitable resources needed to improve your process outputs?	Y	N	X	
149	Do you provide suitable resources needed to improve your process activities?	Y	N	X	
150	Do you develop improvements to your process and process outputs?	Y	N	X	
151	Do you make sure that your process and output improvements are feasible?	Y	N	X	
152	Do you make sure that your process and output improvements are appropriate?	Y	N	X	
153	Do you make sure that process and output improvements also consider effects?	Y	N	X	
154	Do you make sure that your process and output improvements are effective?	Y	N	X	
155	Do you make sure that your process and output improvements are cost-effective?	Y	N	X	
156	Do you implement improvements to your process and process outputs?	Y	N	X	
157	Do you improve the suitability, adequacy, and effectiveness of your process?	Y	N	X	
158	Do you improve the quality, safety, and security of your process outputs?	Y	N	X	
159	Do you control improvements to your process and process outputs?	Y	N	X	
160	Do you control improvements and other changes affecting process software?	Y	N	X	
161	Do you control improvements and other changes affecting process operations?	Y	N	X	
162	Do you control improvements and other changes affecting process equipment?	Y	N	X	

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9. ASSESS PROCESS MODIFICATION ACTIVITIES

163	Do you control improvements and other changes affecting process tools?	Y	N	X	
164	Do you monitor improvements to your process and process outputs?	Y	N	X	
165	Do you monitor the implementation of process and output improvement activities?	Y	N	X	
166	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

167	Do you review and evaluate actions taken to correct your process?	Y	N	X	
168	Do you document your process correction reviews and the actions that are taken?	Y	N	X	
169	Do you establish and maintain records of process correction reviews and actions taken?	Y	N	X	
170	Do you review and evaluate actions taken to correct outputs?	Y	N	X	
171	Do you document your output correction reviews and the actions that are taken?	Y	N	X	
172	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

173	Do you review and evaluate improvements and changes to your process?	Y	N	X	
174	Do you document your process improvement reviews and the actions that are taken?	Y	N	X	
175	Do you establish a record of process improvement reviews and the actions taken?	Y	N	X	
176	Do you review and evaluate improvements and changes to process outputs?	Y	N	X	
177	Do you document your output improvement reviews and the actions that are taken?	Y	N	X	
178	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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