

Audit Tool for Quality Management Systems

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PLAIN ENGLISH AUDIT TOOL FOR QUALITY MANAGEMENT SYSTEMS

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PLAIN ENGLISH QMS AUDIT TOOL

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PLAIN ENGLISH AUDIT TOOL FOR QUALITY MANAGEMENT SYSTEMS

I. INTRODUCTION TO AUDIT TOOL

INTRODUCTION TO OUR AUDIT METHODOLOGY

For each audit 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 management requirements that make up our QMS 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 Framework and your organization's practices and processes while N/A answers point to items that may be ignored or excluded.

Once you've completed all seven questionnaires, study your NO answers, your observations, and our questions and then use this information to formulate actions or steps that need to be taken in order to improve your organization's management practices and processes. Use this information to develop your own unique *Quality Management System Improvement Plan*.

Before you start your audit, please fill out the form entitled *Profile of Audit Project* (Part II, below). First record the name of the organization being audited, its address, and a brief description of the actual scope or focus of the audit. Also record the names of your audit team members and your start date. Once you've completed the audit, use the same form to record when the audit was finished, who reviewed the audit and when, and any review comments.

We've also provided a mini audit checklist (Part III) that you can use to carry out a quick audit or to decide what general areas need more detailed attention. If you're not clear about what one of the items is talking about, simply go to our more detailed audit tool and study the relevant section.

Plain English QMS Audit Tool

Overview of Quality Management System (QMS) Audit Tool



The diagram on the left provides a quick overview of our audit tool.

PLAIN ENGLISH AUDIT TOOL FOR QUALITY MANAGEMENT SYSTEMS

I. INTRODUCTION TO AUDIT TOOL

OUTLINE OF PLAIN ENGLISH QMS AUDIT TOOL

1. ASSESS QMS OPERATIONS MANAGEMENT PROCESS	1.1 Assess how well operational resources are being used 1.2 Assess how well operational functions are being managed 1.3 Assess how well operational activities are being carried out
2. ASSESS QMS MAINTENANCE MANAGEMENT PROCESS	2.1 Assess how well resources are used to maintain system 2.2 Assess how well management system is being maintained
3. ASSESS QMS MEASUREMENT MANAGEMENT PROCESS	3.1 Assess how well measurement activities are planned 3.2 Assess how well measurement methods are performing 3.3 Assess how well resources are used to measure system 3.4 Assess how well management system is being measured 3.5 Assess how well measurement resources are being controlled
4. ASSESS QMS MONITORING MANAGEMENT PROCESS	4.1 Assess how well monitoring activities are planned 4.2 Assess how well monitoring methods are performing 4.3 Assess how well resources are used to monitor system 4.4 Assess how well management system is being monitored 4.5 Assess how well monitoring resources are being controlled
5. ASSESS QMS CONTROL MANAGEMENT PROCESS	5.1 Assess how well control activities are being planned 5.2 Assess how well controls are designed and developed 5.3 Assess how well resources are used to control system 5.4 Assess how well management system is controlled
6. ASSESS QMS EVALUATION MANAGEMENT PROCESS	6.1 Assess how well evaluation activities are being planned 6.2 Assess how well resources are used to evaluate system 6.3 Assess how well management system is being evaluated 6.4 Assess how well evaluation activities are being recorded
7. ASSESS QMS CHANGE MANAGEMENT PROCESS	7.1 Assess how well systemic change is being managed 7.2 Assess how well change opportunities are identified 7.3 Assess how well systemic changes are being planned 7.4 Assess how well management system is being changed 7.5 Assess how well changes are reviewed and evaluated

PROFILE OF QMS AUDIT PROJECT

II. PROFILE OF AUDIT PROJECT

QMS AUDIT SCOPE

NAME OF ORGANIZATION BEING AUDITED

ADDRESS OF ORGANIZATION BEING AUDITED

SCOPE OF YOUR ORGANIZATION'S QMS AUDIT

AUDITORS

AUDIT MANAGER

AUDIT STAFF

AUDIT SCHEDULE

AUDIT START DATE

AUDIT FINISH DATE

AUDIT REVIEWER

AUDIT REVIEWED BY

DATE AUDIT REVIEWED

AUDIT REVIEW COMMENTS

PLAIN ENGLISH AUDIT TOOL FOR QUALITY MANAGEMENT SYSTEMS

III. MINI QMS AUDIT CHECKLIST

		DO	DN	NA	
1	1. ASSESS QMS OPERATIONS MANAGEMENT PROCESS				
2	1.1 Assess how well operational resources are being used	DO	DN	NA	
3	1.1.1 Assess the expertise used to operate your system	DO	DN	NA	
4	1.1.2 Assess the technology used to operate your system	DO	DN	NA	
5	1.1.3 Assess the infrastructure used to operate your system	DO	DN	NA	
6	1.2 Assess how well operational functions are being managed	DO	DN	NA	
7	1.2.1 Assess how well system managers address risks and opportunities	DO	DN	NA	
8	1.2.2 Assess how well system managers implement policies and procedures	DO	DN	NA	
9	1.2.3 Assess how well system managers specify output requirements and capabilities	DO	DN	NA	
10	1.2.4 Assess how well system managers communicate with system customers	DO	DN	NA	
11	1.2.5 Assess how well system managers evaluate and select their external providers	DO	DN	NA	
12	1.2.6 Assess how well system managers supervise and control system activities	DO	DN	NA	
13	1.2.7 Assess how well system managers measure conformance and performance	DO	DN	NA	
14	1.2.8 Assess how well system managers meet expectations and requirements	DO	DN	NA	
15	1.2.9 Assess how well system managers understand their responsibilities	DO	DN	NA	
16	1.3 Assess how well operational activities are being carried out	DO	DN	NA	
17	1.3.1 Assess how well personnel focus on system customers	DO	DN	NA	
18	1.3.2 Assess how well personnel handle risks and opportunities	DO	DN	NA	
19	1.3.3 Assess how well personnel implement policies and procedures	DO	DN	NA	
20	1.3.4 Assess how well personnel comply with all relevant requirements	DO	DN	NA	
21	1.3.5 Assess how well personnel take appropriate action when necessary	DO	DN	NA	
22	1.3.6 Assess how well personnel control system documents and records	DO	DN	NA	

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III. MINI QMS AUDIT CHECKLIST

23	2. ASSESS QMS MAINTENANCE MANAGEMENT PROCESS	DO	DN	NA	
24	2.1 Assess how well resources are used to maintain system	DO	DN	NA	
25	2.1.1 Assess the expertise used to maintain your system	DO	DN	NA	
26	2.1.2 Assess the technology used to maintain your system	DO	DN	NA	
27	2.2 Assess how well management system is being maintained	DO	DN	NA	
28	2.2.1 Assess the methods used to maintain your documents	DO	DN	NA	
29	2.2.2 Assess the methods used to maintain your records	DO	DN	NA	
30	2.2.3 Assess the methods used to maintain your property	DO	DN	NA	
31	2.2.4 Assess the methods used to maintain your procedures	DO	DN	NA	
32	2.2.5 Assess the methods used to maintain your competence	DO	DN	NA	
33	2.2.6 Assess the methods used to maintain your technologies	DO	DN	NA	
34	2.2.7 Assess the methods used to maintain your infrastructure	DO	DN	NA	
35	2.2.8 Assess the methods used to maintain your communications	DO	DN	NA	
36	3. ASSESS QMS MEASUREMENT MANAGEMENT PROCESS	DO	DN	NA	
37	3.1 Assess how well measurement activities are planned	DO	DN	NA	
38	3.1.1 Assess how well measurement resources are targeted	DO	DN	NA	
39	3.1.2 Assess how well measurement methods are designed	DO	DN	NA	
40	3.1.3 Assess how well measurement duties are distributed	DO	DN	NA	
41	3.2 Assess how well measurement methods are performing	DO	DN	NA	
42	3.2.1 Assess how effective measurement methods are	DO	DN	NA	
43	3.2.2 Assess how accurate measurement methods are	DO	DN	NA	

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44	3.3 Assess how well resources are used to measure system	DO	DN	NA	
45	3.3.1 Assess the expertise used to measure your system	DO	DN	NA	
46	3.3.2 Assess the technology used to measure your system	DO	DN	NA	
47	3.3.3 Assess the infrastructure used to measure your system	DO	DN	NA	
48	3.4 Assess how well management system is being measured	DO	DN	NA	
49	3.4.1 Assess the methods used to measure system elements	DO	DN	NA	
50	3.4.2 Assess the methods used to measure system performance	DO	DN	NA	
51	3.5 Assess how well measurement resources are being controlled	DO	DN	NA	
52	3.5.1 Assess how well measurement documents are being controlled	DO	DN	NA	
53	3.5.2 Assess how well measurement technologies are being controlled	DO	DN	NA	
54	3.5.3 Assess how well measurement records are being controlled	DO	DN	NA	
55	4. ASSESS QMS MONITORING MANAGEMENT PROCESS	DO	DN	NA	
56	4.1 Assess how well monitoring activities are planned	DO	DN	NA	
57	4.1.1 Assess how well monitoring resources are targeted	DO	DN	NA	
58	4.1.2 Assess how well monitoring methods are designed	DO	DN	NA	
59	4.1.3 Assess how well monitoring duties are distributed	DO	DN	NA	
60	4.2 Assess how well monitoring methods are performing	DO	DN	NA	
61	4.2.1 Assess how effective monitoring methods are	DO	DN	NA	
62	4.2.2 Assess how accurate monitoring methods are	DO	DN	NA	
63	4.3 Assess how well resources are used to monitor system	DO	DN	NA	
64	4.3.1 Assess the expertise used to monitor your system	DO	DN	NA	
65	4.3.2 Assess the technology used to monitor your system	DO	DN	NA	
66	4.3.3 Assess the infrastructure used to monitor your system	DO	DN	NA	

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67	4.4 Assess how well management system is being monitored	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
68	4.4.1 Assess the methods used to monitor system activities	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
69	4.4.2 Assess the methods used to monitor system outputs	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
70	4.4.3 Assess the methods used to monitor system inputs	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
71	4.4.4 Assess the methods used to monitor system documents	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
72	4.4.5 Assess the methods used to monitor system records	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
73	4.4.6 Assess the methods used to monitor system property	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
74	4.4.7 Assess the methods used to monitor system participants	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
75	4.4.8 Assess the methods used to monitor system technologies	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
76	4.4.9 Assess the methods used to monitor system environment	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
77	4.4.10 Assess the methods used to monitor system infrastructure	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
78	4.5 Assess how well monitoring resources are being controlled	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
79	4.5.1 Assess how well monitoring technologies are being controlled	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
80	4.5.2 Assess how well monitoring records are being controlled	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
81	5. ASSESS QMS CONTROL MANAGEMENT PROCESS	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
82	5.1 Assess how well control activities are being planned	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
83	5.1.1 Assess the steps taken to plan how outputs are controlled	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
84	5.1.2 Assess the steps taken to plan how inputs are controlled	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
85	5.1.3 Assess the steps taken to plan how activities are controlled	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
86	5.1.4 Assess the steps taken to plan how providers are controlled	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
87	5.2 Assess how well controls are designed and developed	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
88	5.2.1 Assess the steps taken to develop ways of controlling elements	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
89	5.2.2 Assess the steps taken to develop ways of controlling providers	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	

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90	5.3 Assess how well resources are used to control system	DO	DN	NA	
91	5.3.1 Assess the human resources used to control system	DO	DN	NA	
92	5.3.2 Assess the technical resources used to control system	DO	DN	NA	
93	5.4 Assess how well management system is controlled	DO	DN	NA	
94	5.4.1 Assess the methods used to control system inputs	DO	DN	NA	
95	5.4.2 Assess the methods used to control system outputs	DO	DN	NA	
96	5.4.3 Assess the methods used to control system activities	DO	DN	NA	
97	5.4.4 Assess the methods used to control system technology	DO	DN	NA	
98	5.4.5 Assess the methods used to control system performance	DO	DN	NA	
99	5.4.6 Assess the methods used to control system documentation	DO	DN	NA	
100	6. ASSESS QMS EVALUATION MANAGEMENT PROCESS	DO	DN	NA	
101	6.1 Assess how well evaluation activities are being planned	DO	DN	NA	
102	6.1.1 Assess how well audit activities are being planned	DO	DN	NA	
103	6.1.2 Assess how well analytical activities are being planned	DO	DN	NA	
104	6.1.3 Assess how well review activities are being planned	DO	DN	NA	
105	6.2 Assess how well resources are used to evaluate system	DO	DN	NA	
106	6.2.1 Assess the personnel used to evaluate your system	DO	DN	NA	
107	6.2.2 Assess the knowledge used to evaluate your system	DO	DN	NA	
108	6.2.3 Assess the technology used to evaluate your system	DO	DN	NA	
109	6.2.4 Assess the infrastructure used to evaluate your system	DO	DN	NA	
110	6.3 Assess how well management system is being evaluated	DO	DN	NA	
111	6.3.1 Assess the methods used to audit your system	DO	DN	NA	
112	6.3.2 Assess the methods used to analyze your system	DO	DN	NA	
113	6.3.3 Assess the methods used to review your system	DO	DN	NA	

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114	6.4 Assess how well evaluation activities are being recorded	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
115	6.4.1 Assess how well system audits are being recorded	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
116	6.4.2 Assess how well system analyses are being recorded	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
117	6.4.3 Assess how well system reviews are being recorded	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
118	7. ASSESS QMS CHANGE MANAGEMENT PROCESS	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
119	7.1 Assess how well systemic change is being managed	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
120	7.1.1 Assess the methods used to manage systemic corrections	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
121	7.1.2 Assess the methods used to manage systemic improvements	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
122	7.2 Assess how well change opportunities are identified	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
123	7.2.1 Assess the methods used to discover opportunities to change system	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
124	7.2.2 Assess the methods used to confirm that changes are actually needed	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
125	7.2.3 Assess the methods used to approve opportunities to change system	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
126	7.3 Assess how well systemic changes are being planned	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
127	7.3.1 Assess the methods used to plan systemic corrections	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
128	7.3.2 Assess the methods used to plan systemic improvements	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
129	7.4 Assess how well management system is being changed	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
130	7.4.1 Assess the methods used to correct management system	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
131	7.4.2 Assess the methods used to improve management system	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
132	7.5 Assess how well changes are reviewed and evaluated	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
133	7.5.1 Assess the methods used to review and evaluate corrections	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
134	7.5.2 Assess the methods used to review and evaluate improvements	<input type="checkbox"/> DO	<input type="checkbox"/> DN	<input type="checkbox"/> NA	
<p>Consider each audit task and select a response. If you haven't done it and it needs to be done, select DO. If you've already done it, select DN. If the task is not applicable in your situation and you can justify and explain why it should be ignored or excluded, select NA.</p> <p>In the spaces below, please enter the name and location of your organization, who completed this page, who reviewed it, and the dates.</p>					

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1. ASSESS QMS OPERATIONS MANAGEMENT PROCESS

1.1 ASSESS HOW WELL OPERATIONAL RESOURCES ARE BEING USED

1.1.1 ASSESS THE EXPERTISE USED TO OPERATE YOUR SYSTEM

1	Do you provide the personnel needed to manage system operations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
2	Do you acquire the knowledge that managers need to manage system operations and achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
3	Do you consider internal sources of knowledge about managing systems?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
4	Do you consider external sources of knowledge about managing systems?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
5	Do you share the knowledge that managers need to manage system operations and achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
6	Do you deliver suitable system management training and awareness programmes to system managers?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
7	Do you provide the personnel needed to operate your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
8	Do you acquire the knowledge that personnel need to operate your system and achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
9	Do you consider internal sources of knowledge about system operations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
10	Do you consider external sources of knowledge about system operations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
11	Do you share the knowledge that personnel need to operate your system and achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
12	Do you deliver system training and awareness programmes to support system operations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

1.1.2 ASSESS THE TECHNOLOGY USED TO OPERATE YOUR SYSTEM

13	Do you provide the software needed to operate your quality management system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
14	Do you provide software needed to support operations and achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
15	Do you provide the hardware needed to operate your quality management system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
16	Do you provide hardware needed to support operations and achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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1. ASSESS QMS OPERATIONS MANAGEMENT PROCESS

1.1.3 ASSESS THE INFRASTRUCTURE USED TO OPERATE YOUR SYSTEM

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

1.2 ASSESS HOW WELL OPERATIONAL FUNCTIONS ARE BEING MANAGED

1.2.1 ASSESS HOW WELL SYSTEM MANAGERS ADDRESS RISKS AND OPPORTUNITIES

22	Do system managers identify risks and opportunities?	Y	N	X	
23	Do system managers identify the operational risks that could affect their ability to meet requirements?	Y	N	X	
24	Do system managers identify the operational opportunities that could improve their ability to meet requirements?	Y	N	X	
25	Do system managers address risks and opportunities?	Y	N	X	
26	Do system managers manage and control risks?	Y	N	X	
27	Do system managers consider all of their risk treatment options?	Y	N	X	
28	Do system managers consider avoiding or reducing their risk?	Y	N	X	
29	Do system managers consider eliminating the source of their risk?	Y	N	X	
30	Do system managers consider retaining the risk or sharing it with others?	Y	N	X	

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1. ASSESS QMS OPERATIONS MANAGEMENT PROCESS

31	Do system managers consider modifying the probabilities or consequences?	Y	N	X	
32	Do system managers define actions to address risks and opportunities?	Y	N	X	
33	Do system managers define actions that they can take to address the risks that could weaken the performance of their system or disrupt or damage operations?	Y	N	X	
34	Do system managers consider the potential impact on outputs when they define the actions they plan to take to address system risks?	Y	N	X	
35	Do system managers figure out how they're going to implement these actions and how they're going to make them part of the system?	Y	N	X	
36	Do system managers figure out how they're going to evaluate the effectiveness of the actions they take to address system risks?	Y	N	X	
37	Do system managers exploit system improvement opportunities?	Y	N	X	
38	Do managers define actions to exploit system improvement opportunities?	Y	N	X	

1.2.2 ASSESS HOW WELL SYSTEM MANAGERS IMPLEMENT POLICIES AND PROCEDURES

39	Do system managers implement system policies?	Y	N	X	
40	Do system managers implement business policies?	Y	N	X	
41	Do system managers implement quality policies?	Y	N	X	
42	Do system managers implement safety policies?	Y	N	X	
43	Do system managers implement privacy policies?	Y	N	X	
44	Do system managers implement security policies?	Y	N	X	
45	Do system managers implement continuity policies?	Y	N	X	
46	Do system managers implement system procedures?	Y	N	X	
47	Do system managers implement business procedures?	Y	N	X	

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1. ASSESS QMS OPERATIONS MANAGEMENT PROCESS

48	Do system managers implement quality procedures?	Y	N	X	
49	Do system managers implement safety procedures?	Y	N	X	
50	Do system managers implement privacy procedures?	Y	N	X	
51	Do system managers implement security procedures?	Y	N	X	
52	Do system managers implement continuity procedures?	Y	N	X	
53	Do system managers implement system plans?	Y	N	X	
54	Do system managers implement business plans?	Y	N	X	
55	Do system managers implement quality plans?	Y	N	X	
56	Do system managers implement safety plans?	Y	N	X	
57	Do system managers implement privacy plans?	Y	N	X	
58	Do system managers implement security plans?	Y	N	X	
59	Do system managers implement continuity plans?	Y	N	X	

1.2.3 ASSESS HOW WELL SYSTEM MANAGERS SPECIFY OUTPUT REQUIREMENTS AND CAPABILITIES

60	Do system managers determine requirements for outputs offered to customers?	Y	N	X	
61	Do system managers determine statutory and regulatory requirements for outputs?	Y	N	X	
62	Do system managers determine your organization's own requirements for outputs?	Y	N	X	
63	Do system managers determine any additional "special requirements" for outputs?	Y	N	X	
64	Do system managers review output requirements before accepting orders?	Y	N	X	
65	Do managers review requirements before agreeing to supply outputs to customers?	Y	N	X	
66	Do system managers coordinate reviews with other functions within your organization?	Y	N	X	

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67	Do system managers review all documented requirements before accepting orders?	Y	N	X	
68	Do system managers review output requirements specified by your system's customers?	Y	N	X	
69	Do system managers review delivery and post-delivery requirements before proceeding?	Y	N	X	
70	Do system managers review output requirements specified by regulatory bodies?	Y	N	X	
71	Do system managers review output requirements specified by interested parties?	Y	N	X	
72	Do system managers review output requirements specified by your organization?	Y	N	X	
73	Do system managers review all undocumented requirements before accepting orders?	Y	N	X	
74	Do system managers clarify differences between original proposals and final orders?	Y	N	X	
75	Do system managers review orders and contractual requirements that were modified?	Y	N	X	
76	Do system managers resolve all differences between original proposals and final orders?	Y	N	X	
77	Do system managers confirm that they can meet output requirements?	Y	N	X	
78	Do system managers confirm that they can meet undocumented customer requirements before making a commitment to supply outputs?	Y	N	X	
79	Do system managers document the review of output requirements?	Y	N	X	
80	Do system managers document the results of output requirement reviews?	Y	N	X	
81	Do system managers retain documents that record results of their reviews?	Y	N	X	
82	Do system managers control documents that record results of their reviews?	Y	N	X	
83	Do system managers document any new or changed output requirements?	Y	N	X	
84	Do system managers retain documents that record new or changed requirements?	Y	N	X	
85	Do system managers control documents that record new or changed requirements?	Y	N	X	
86	Do system managers amend documents when output requirements change?	Y	N	X	
87	Do system managers control documents that record changes in output requirements?	Y	N	X	

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1. ASSESS QMS OPERATIONS MANAGEMENT PROCESS

1.2.4 ASSESS HOW WELL SYSTEM MANAGERS COMMUNICATE WITH SYSTEM CUSTOMERS

88	Do system managers provide information to customers?	Y	N	X	
89	Do system managers share information about outputs?	Y	N	X	
90	Do system managers obtain information from customers?	Y	N	X	
91	Do system managers obtain information about customer orders and contracts?	Y	N	X	
92	Do system managers receive information about changes to orders and contracts?	Y	N	X	
93	Do system managers obtain information about system outputs?	Y	N	X	
94	Do system managers gather customer feedback about system outputs?	Y	N	X	
95	Do system managers gather complaints about system outputs?	Y	N	X	
96	Do system managers obtain information about property supplied by customers?	Y	N	X	
97	Do system managers manage and control property supplied by customers?	Y	N	X	

1.2.5 ASSESS HOW WELL SYSTEM MANAGERS EVALUATE AND SELECT THEIR EXTERNAL PROVIDERS

98	Do system managers accept responsibility for externally provided processes, products, and services?	Y	N	X	
99	Do system managers accept responsibility for conformity of external processes, products, and services?	Y	N	X	
100	Do system managers identify risks related to the external provision of processes, products, and services?	Y	N	X	
101	Do system managers identify risks related to the selection and use of external providers and external sources?	Y	N	X	
102	Do system managers define data and criteria to manage external process, product, and service providers?	Y	N	X	
103	Do system managers use data and criteria to evaluate external process, product, and service providers?	Y	N	X	

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104	Do system managers use data and criteria to select external process, product, and service providers?	Y	N	X	
105	Do system managers specify what they expect from external process, product, and service providers?	Y	N	X	
106	Do system managers identify external process requirements?	Y	N	X	
107	Do system managers identify external process approval requirements?	Y	N	X	
108	Do system managers identify product requirements?	Y	N	X	
109	Do system managers identify external product acceptance requirements?	Y	N	X	
110	Do system managers identify external product approval requirements?	Y	N	X	
111	Do system managers identify external product release requirements?	Y	N	X	
112	Do system managers identify service requirements?	Y	N	X	
113	Do system managers identify external service acceptance requirements?	Y	N	X	
114	Do system managers identify external service approval requirements?	Y	N	X	
115	Do system managers identify external service release requirements?	Y	N	X	
116	Do system managers identify equipment requirements?	Y	N	X	
117	Do system managers identify external equipment approval requirements?	Y	N	X	
118	Do system managers identify “special requirements”?	Y	N	X	
119	Do system managers identify “critical items” and “key characteristics”?	Y	N	X	
120	Do system managers identify information requirements?	Y	N	X	
121	Do system managers identify technical data and information requirements?	Y	N	X	
122	Do system managers identify procedural requirements?	Y	N	X	
123	Do system managers identify any work practices that providers need to follow?	Y	N	X	

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124	Do system managers identify any work instructions that providers need to follow?	Y	N	X	
125	Do system managers identify methodological requirements?	Y	N	X	
126	Do system managers identify how external methods are approved?	Y	N	X	
127	Do system managers identify interaction requirements?	Y	N	X	
128	Do system managers identify how external providers interact with system?	Y	N	X	
129	Do system managers identify notification requirements?	Y	N	X	
130	Do system managers specify supply chain notification requirements?	Y	N	X	
131	Do system managers ask external providers to notify them when changes are planned?	Y	N	X	
132	Do system managers get approval whenever important changes are being considered?	Y	N	X	
133	Do system managers specify nonconformance notification requirements?	Y	N	X	
134	Do system managers specify nonconformance approval and disposition requirements?	Y	N	X	
135	Do system managers identify design and development requirements?	Y	N	X	
136	Do system managers specify design and development control requirements?	Y	N	X	
137	Do system managers identify verification and validation requirements?	Y	N	X	
138	Do system managers identify verification and validation activities to be done externally?	Y	N	X	
139	Do system managers identify production requirements?	Y	N	X	
140	Do system managers specify production verification requirements?	Y	N	X	
141	Do system managers identify test and inspection requirements?	Y	N	X	
142	Do system managers identify part and component requirements?	Y	N	X	
143	Do system managers identify outsourcing requirements?	Y	N	X	
144	Do system managers identify supply chain requirements?	Y	N	X	

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145	Do system managers identify external staff awareness requirements?	Y	N	X	
146	Do system managers identify external competence requirements?	Y	N	X	
147	Do system managers identify monitoring and control requirements?	Y	N	X	
148	Do system managers identify quality management requirements?	Y	N	X	
149	Do system managers identify documentation requirements?	Y	N	X	

1.2.6 ASSESS HOW WELL SYSTEM MANAGERS SUPERVISE AND CONTROL SYSTEM ACTIVITIES

150	Do system managers verify that resources can produce required results?	Y	N	X	
151	Do system managers validate resources that will be used to operate system?	Y	N	X	
152	Do system managers validate tools before they are used to operate system?	Y	N	X	
153	Do system managers validate equipment before it is used to operate system?	Y	N	X	
154	Do system managers validate software before it is used to operate system?	Y	N	X	
155	Do system managers validate resources that will be used to automate system?	Y	N	X	
156	Do system managers validate tools before they are used to automate system?	Y	N	X	
157	Do system managers validate equipment before it is used to automate system?	Y	N	X	
158	Do system managers validate software before it is used to automate system?	Y	N	X	
159	Do system managers validate resources that will be used to control system?	Y	N	X	
160	Do system managers validate tools before they are used to control system?	Y	N	X	
161	Do system managers validate equipment before it is used to control system?	Y	N	X	
162	Do system managers validate software before it is used to control system?	Y	N	X	
163	Do system managers validate resources that will be used to monitor system?	Y	N	X	
164	Do system managers validate tools before they are used to monitor system?	Y	N	X	

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165	Do system managers validate equipment before it is used to monitor system?	Y	N	X	
166	Do system managers validate software before it is used to monitor system?	Y	N	X	
167	Do system managers validate resources that will be used to measure system?	Y	N	X	
168	Do system managers validate tools before they are used to measure system?	Y	N	X	
169	Do system managers validate equipment before it is used to measure system?	Y	N	X	
170	Do system managers validate software before it is used to measure system?	Y	N	X	
171	Do system managers supervise and control all quality system personnel?	Y	N	X	
172	Do system managers plan and control all relevant work transfer activities?	Y	N	X	
173	Do system managers ensure that risks are managed and requirements continue to be met?	Y	N	X	
174	Do system managers plan how they're going to manage and control the transfer of work?	Y	N	X	
175	Do system managers control system documents and record keeping?	Y	N	X	
176	Do system managers ensure that documents and records are properly reviewed and approved?	Y	N	X	

1.2.7 ASSESS HOW WELL SYSTEM MANAGERS MEASURE CONFORMANCE AND PERFORMANCE

177	Do system managers measure system performance and conformance?	Y	N	X	
178	Do system managers measure output performance and conformance?	Y	N	X	
179	Do system managers measure output delivery performance and conformance?	Y	N	X	
180	Do system managers measure post-delivery performance and conformance?	Y	N	X	

1.2.8 ASSESS HOW WELL SYSTEM MANAGERS MEET EXPECTATIONS AND REQUIREMENTS

181	Do system managers ensure that legal expectations and requirements are being met?	Y	N	X	
182	Do system managers ensure that safety expectations and requirements are being met?	Y	N	X	
183	Do system managers ensure that privacy expectations and requirements are being met?	Y	N	X	
184	Do system managers ensure that quality expectations and requirements are being met?	Y	N	X	

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185	Do system managers ensure that security expectations and requirements are being met?	Y	N	X	
186	Do system managers ensure that business expectations and requirements are being met?	Y	N	X	
187	Do system managers ensure that customer expectations and requirements are being met?	Y	N	X	

1.2.9 ASSESS HOW WELL SYSTEM MANAGERS UNDERSTAND THEIR RESPONSIBILITIES

188	Do system managers ensure that system produces intended outputs?	Y	N	X	
189	Do system managers preserve outputs during system operations?	Y	N	X	
190	Do system managers figure out how to preserve outputs during system operations?	Y	N	X	
191	Do system managers consider using suitable identification methods to preserve outputs?	Y	N	X	
192	Do system managers consider using suitable packaging methods to preserve outputs?	Y	N	X	
193	Do system managers consider using suitable handling methods to preserve outputs?	Y	N	X	
194	Do system managers consider using suitable storage methods to preserve outputs?	Y	N	X	
195	Do system managers consider using suitable transmission methods to preserve outputs?	Y	N	X	
196	Do system managers consider using suitable transportation methods to preserve outputs?	Y	N	X	
197	Do system managers preserve outputs in accordance with official requirements?	Y	N	X	
198	Do system managers preserve outputs by establishing cleaning and sanitization practices?	Y	N	X	
199	Do system managers preserve outputs by establishing arrangements to control foreign objects?	Y	N	X	
200	Do system managers preserve outputs by establishing handling methods and storage facilities?	Y	N	X	
201	Do system managers preserve outputs by establishing marking methods and labeling practices?	Y	N	X	
202	Do system managers preserve outputs by establishing shelf life controls and by rotating stock?	Y	N	X	
203	Do system managers establish controlled conditions for output delivery?	Y	N	X	
204	Do system managers use documented information to control output delivery activities?	Y	N	X	
205	Do system managers use suitable monitoring and measurement resources to control delivery?	Y	N	X	

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206	Do system managers use a suitable system environment to control output delivery system?	Y	N	X	
207	Do system managers use competent qualified personnel to control output delivery activities?	Y	N	X	
208	Do system managers address post-delivery requirements for outputs?	Y	N	X	
209	Do system managers develop controlled conditions for post-delivery?	Y	N	X	
210	Do system managers consider post-delivery requirements and commitments?	Y	N	X	
211	Do system managers consider the need to provide, update, and control output documents?	Y	N	X	
212	Do system managers consider the external work that must be done to support outputs?	Y	N	X	
213	Do system managers consider the actions that must be taken after outputs are delivered?	Y	N	X	
214	Do system managers implement controlled conditions for post-delivery of outputs?	Y	N	X	
215	Do system managers implement controlled conditions for post-delivery of system outputs?	Y	N	X	
216	Do system managers use suitable monitoring and measurement resources to control post-delivery?	Y	N	X	
217	Do system managers use a suitable system environment to control post-delivery activities?	Y	N	X	
218	Do system managers use competent qualified personnel to control post-delivery activities?	Y	N	X	
219	Do system managers identify and control nonconforming outputs?	Y	N	X	
220	Do system managers analyze and evaluate nonconforming outputs?	Y	N	X	
221	Do managers consider the nature of nonconforming outputs and do they evaluate their effects?	Y	N	X	
222	Do system managers take specific actions to manage and control nonconforming outputs?	Y	N	X	
223	Do system managers prevent the unintended use or delivery of nonconforming outputs?	Y	N	X	
224	Do system managers document and record all nonconforming system outputs?	Y	N	X	
225	Do system managers document the actions and decisions taken to prevent unintended use or delivery of nonconforming outputs?	Y	N	X	
226	Do system managers submit system performance reports?	Y	N	X	

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1. ASSESS QMS OPERATIONS MANAGEMENT PROCESS

1.3 ASSESS HOW WELL OPERATIONAL ACTIVITIES ARE BEING CARRIED OUT

1.3.1 ASSESS HOW WELL PERSONNEL FOCUS ON SYSTEM CUSTOMERS

227	Do system personnel identify customer needs and expectations?	Y	N	X	
228	Do system personnel identify customer assumptions and perceptions?	Y	N	X	
229	Do system personnel understand customer needs and expectations?	Y	N	X	
230	Do system personnel understand customer assumptions and perceptions?	Y	N	X	
231	Do system personnel meet relevant customer needs and expectations?	Y	N	X	
232	Do system personnel focus on enhancing customer satisfaction?	Y	N	X	

1.3.2 ASSESS HOW WELL PERSONNEL HANDLE RISKS AND OPPORTUNITIES

233	Do system personnel identify their risks and opportunities?	Y	N	X	
234	Do personnel identify risks and opportunities related to outputs?	Y	N	X	
235	Do system managers identify the risks that could negatively influence their ability to provide compliant outputs to system customers?	Y	N	X	
236	Do system managers identify the opportunities that could possibly enhance their ability to provide compliant outputs to system customers?	Y	N	X	
237	Do personnel identify risks and opportunities related to customer satisfaction?	Y	N	X	
238	Do system managers identify risks that could influence their ability to satisfy customers?	Y	N	X	
239	Do system managers identify opportunities that could enhance their ability to satisfy customers?	Y	N	X	
240	Do system personnel address their risks and opportunities?	Y	N	X	
241	Do personnel address risks and opportunities related to outputs?	Y	N	X	
242	Do system managers address the risks that could negatively influence their ability to provide compliant outputs to system customers?	Y	N	X	

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1. ASSESS QMS OPERATIONS MANAGEMENT PROCESS

243	Do system managers address the opportunities that could enhance their ability to provide compliant outputs to system customers?	Y	N	X	
244	Do system managers address risks and opportunities related to customer satisfaction?	Y	N	X	
245	Do system managers address risks that could influence their ability to satisfy customers?	Y	N	X	
246	Do system managers address opportunities that could enhance their ability to satisfy customers?	Y	N	X	

1.3.3 ASSESS HOW WELL PERSONNEL IMPLEMENT POLICIES AND PROCEDURES

247	Do quality system personnel follow system policies?	Y	N	X	
248	Do system personnel implement and follow safety policies?	Y	N	X	
249	Do system personnel implement and follow quality policies?	Y	N	X	
250	Do system personnel implement and follow security policies?	Y	N	X	
251	Do system personnel implement and follow privacy policies?	Y	N	X	
252	Do system personnel implement and follow business policies?	Y	N	X	
253	Do system personnel implement and follow continuity policies?	Y	N	X	
254	Do system personnel follow system procedures?	Y	N	X	
255	Do system personnel implement and follow safety procedures?	Y	N	X	
256	Do system personnel implement and follow quality procedures?	Y	N	X	
257	Do system personnel implement and follow privacy procedures?	Y	N	X	
258	Do system personnel implement and follow security procedures?	Y	N	X	
259	Do system personnel implement and follow business procedures?	Y	N	X	
260	Do system personnel implement and follow continuity procedures?	Y	N	X	

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1. ASSESS QMS OPERATIONS MANAGEMENT PROCESS

1.3.4 ASSESS HOW WELL PERSONNEL COMPLY WITH ALL RELEVANT REQUIREMENTS

261	Do system personnel determine relevant requirements?	Y	N	X	
262	Do system personnel identify customer requirements?	Y	N	X	
263	Do system personnel identify legal requirements?	Y	N	X	
264	Do system personnel meet all relevant requirements?	Y	N	X	
265	Do system personnel meet all relevant customer requirements?	Y	N	X	
266	Do system personnel provide products that meet customer requirements?	Y	N	X	
267	Do system personnel deliver services that meet customer requirements?	Y	N	X	
268	Do system personnel meet all relevant legal requirements?	Y	N	X	
269	Do system personnel provide products that meet legal requirements?	Y	N	X	
270	Do system personnel deliver services that meet legal requirements?	Y	N	X	

1.3.5 ASSESS HOW WELL PERSONNEL TAKE APPROPRIATE ACTION WHEN NECESSARY

271	Do system personnel take action when planned results aren't being achieved?	Y	N	X	
272	Do system personnel take action when planned results won't be achieved?	Y	N	X	
273	Do system personnel take action when planned results can't be achieved?	Y	N	X	

1.3.6 ASSESS HOW WELL PERSONNEL CONTROL SYSTEM DOCUMENTS AND RECORDS

274	Do system personnel retain and control system documents?	Y	N	X	
275	Do system personnel maintain and control system 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 system. 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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2. ASSESS QMS MAINTENANCE MANAGEMENT PROCESS

2.1 ASSESS HOW WELL RESOURCES ARE USED TO MAINTAIN SYSTEM

2.1.1 ASSESS THE EXPERTISE USED TO MAINTAIN YOUR SYSTEM

1	Do you provide the managers needed to maintain your quality system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
2	Do you acquire the knowledge that managers need in order to support system maintenance and achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
3	Do you share the knowledge that managers need so that they can support system maintenance and achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
4	Do you deliver suitable awareness programmes to the people who manage system maintenance activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
5	Do you deliver suitable training programmes to the people who manage system maintenance activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
6	Do you provide people needed to maintain your quality system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
7	Do you acquire the knowledge that your personnel need in order to maintain system and achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
8	Do you share the knowledge that personnel need in order to maintain system and achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
9	Do you deliver suitable awareness programmes for your system maintenance personnel?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
10	Do you deliver suitable training programmes for your system maintenance personnel?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

2.1.2 ASSESS THE TECHNOLOGY USED TO MAINTAIN YOUR SYSTEM

11	Do you provide the software needed to maintain quality system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
12	Do you provide the software needed to support system maintenance and achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
13	Do you provide the hardware needed to maintain quality system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
14	Do you provide the hardware needed to support system maintenance and achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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2. ASSESS QMS MAINTENANCE MANAGEMENT PROCESS

2.2 ASSESS HOW WELL MANAGEMENT SYSTEM IS BEING MAINTAINED

2.2.1 ASSESS THE METHODS USED TO MAINTAIN YOUR DOCUMENTS

15	Do you maintain documents that describe how work should be carried out?	Y	N	X	
16	Do you maintain documents that describe how system operations should be carried out?	Y	N	X	
17	Do you maintain documents that describe how system maintenance should be carried out?	Y	N	X	
18	Do you maintain documents that describe how system monitoring should be carried out?	Y	N	X	
19	Do you maintain documents that describe how system measurement should be carried out?	Y	N	X	
20	Do you maintain documents that describe how system control should be carried out?	Y	N	X	
21	Do you maintain documents that describe how system evaluation should be carried out?	Y	N	X	
22	Do you maintain documents that describe how system audits should be carried out?	Y	N	X	
23	Do you maintain documents that describe how system reviews should be carried out?	Y	N	X	
24	Do you maintain documents that describe how systemic change should be carried out?	Y	N	X	
25	Do you maintain documents that describe how system correction should be carried out?	Y	N	X	
26	Do you maintain documents that describe how system improvements should be carried out?	Y	N	X	

2.2.2 ASSESS THE METHODS USED TO MAINTAIN YOUR RECORDS

27	Do you maintain records that describe the scope of your quality management system?	Y	N	X	
28	Do you maintain records of quality management system responsibilities and authorities?	Y	N	X	
29	Do you maintain records of quality management system performance and competence?	Y	N	X	
30	Do you retain your documentation and use it as evidence to show that your quality management system personnel are in fact competent?	Y	N	X	
31	Do you maintain records showing that quality management system is performing as planned?	Y	N	X	

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2. ASSESS QMS MAINTENANCE MANAGEMENT PROCESS

32	Do you maintain records that show that system operations are being carried out as planned?	Y	N	X	
33	Do you maintain records that show that system maintenance is being carried out as planned?	Y	N	X	
34	Do you maintain records that show that system monitoring is being carried out as planned?	Y	N	X	
35	Do you maintain records that show that system measurement is being carried out as planned?	Y	N	X	
36	Do you maintain records that show that system control is being carried out as planned?	Y	N	X	
37	Do you maintain records that show that system evaluation is being carried out as planned?	Y	N	X	
38	Do you maintain records that show that system audits are being carried out as planned?	Y	N	X	
39	Do you maintain records that show that system reviews are being carried out as planned?	Y	N	X	
40	Do you maintain records that show that system changes are being carried out as planned?	Y	N	X	
41	Do you maintain records that show that system corrections are being carried out as planned?	Y	N	X	
42	Do you maintain records that show that system improvements are being carried out as planned?	Y	N	X	

2.2.3 ASSESS THE METHODS USED TO MAINTAIN YOUR PROPERTY

43	Do you maintain system property owned by your customers and suppliers that is needed to achieve conformity of outputs?	Y	N	X	
44	Do you identify property belonging to customers and external providers?	Y	N	X	
45	Do you verify property belonging to customers and external providers?	Y	N	X	
46	Do you protect property belonging to customers and external providers?	Y	N	X	
47	Do you report property belonging to your customers and external providers?	Y	N	X	
48	Do you report lost or damaged property to customers and external providers?	Y	N	X	
49	Do you report unsuitable property to customers and external providers?	Y	N	X	

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2. ASSESS QMS MAINTENANCE MANAGEMENT PROCESS

50	Do you document property belonging to your customers and external providers?	Y	N	X	
51	Do you maintain property owned by your quality management system that is needed to achieve conformity of system outputs?	Y	N	X	
52	Do you maintain equipment that your system needs in order to achieve conformity of outputs?	Y	N	X	
53	Do you maintain software that your system needs in order to achieve conformity of outputs?	Y	N	X	
54	Do you maintain tools that your system needs in order to achieve conformity of outputs?	Y	N	X	

2.2.4 ASSESS THE METHODS USED TO MAINTAIN YOUR PROCEDURES

55	Do you use authorized methods to maintain system management procedures?	Y	N	X	
56	Do you use authorized methods to maintain system control procedures?	Y	N	X	
57	Do you use authorized methods to maintain system operational procedures?	Y	N	X	
58	Do you use authorized methods to maintain system maintenance procedures?	Y	N	X	
59	Do you use authorized methods to maintain system monitoring procedures?	Y	N	X	
60	Do you use authorized methods to maintain system feedback procedures?	Y	N	X	
61	Do you use authorized methods to maintain system measurement procedures?	Y	N	X	
62	Do you use authorized methods to maintain equipment calibration procedures?	Y	N	X	
63	Do you use authorized methods to maintain system evaluation procedures?	Y	N	X	
64	Do you use authorized methods to maintain system audit procedures?	Y	N	X	
65	Do you use authorized methods to maintain system review procedures?	Y	N	X	
66	Do you use authorized methods to maintain system change procedures?	Y	N	X	
67	Do you use authorized methods to maintain system correction procedures?	Y	N	X	
68	Do you use authorized methods to maintain system improvement procedures?	Y	N	X	

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2. ASSESS QMS MAINTENANCE MANAGEMENT PROCESS

2.2.5 ASSESS THE METHODS USED TO MAINTAIN YOUR COMPETENCE

69	Do you share information and knowledge with management system personnel?	Y	N	X	
70	Do you ensure that they are aware of management system plans?	Y	N	X	
71	Do you ensure that they are aware of management system policies?	Y	N	X	
72	Do you ensure that they are aware of management system objectives?	Y	N	X	
73	Do you ensure that they are aware of management system procedures?	Y	N	X	
74	Do you ensure that they are aware of management system documents and records?	Y	N	X	
75	Do you ensure that personnel stay abreast of changes in knowledge and information?	Y	N	X	
76	Do you ensure that they are aware of the important contribution they make?	Y	N	X	
77	Do you ensure that they understand how they affect system performance?	Y	N	X	
78	Do you ensure that they understand how they influence system outputs?	Y	N	X	
79	Do you ensure that they are aware of all relevant requirements?	Y	N	X	
80	Do you explain why compliance is important to your system?	Y	N	X	
81	Do you ensure that they are aware of how they can help?	Y	N	X	
82	Do you explain how they can help enhance system effectiveness?	Y	N	X	
83	Do you acquire competence whenever shortcomings are discovered?	Y	N	X	
84	Do you acquire the necessary competence whenever system personnel fail to meet system competence requirements?	Y	N	X	
85	Do you consider helping your personnel to improve?	Y	N	X	
86	Do you consider providing suitable training?	Y	N	X	
87	Do you consider offering mentoring services?	Y	N	X	

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2. ASSESS QMS MAINTENANCE MANAGEMENT PROCESS

88	Do you consider hiring competent people?	Y	N	X	
89	Do you consider hiring competent employees?	Y	N	X	
90	Do you consider hiring competent contractors?	Y	N	X	
91	Do you consider reassigning unsuitable personnel?	Y	N	X	
92	Do you maintain the system knowledge that has been acquired?	Y	N	X	
93	Do you consider the need to protect and preserve lessons learned?	Y	N	X	
94	Do you consider the need to protect and preserve intellectual property?	Y	N	X	

2.2.6 ASSESS THE METHODS USED TO MAINTAIN YOUR TECHNOLOGIES

95	Do you maintain technology used to perform management system operations?	Y	N	X	
96	Do you maintain tools used to perform management system operations?	Y	N	X	
97	Do you define storage requirements for tools used for system operations?	Y	N	X	
98	Do you define how and when to check the status of tools used for system operations?	Y	N	X	
99	Do you maintain equipment used to perform management system operations?	Y	N	X	
100	Do you define storage requirements for equipment used for system operations?	Y	N	X	
101	Do you define how and when to check the status of equipment used for system operations?	Y	N	X	
102	Do you maintain software used to perform management system operations?	Y	N	X	
103	Do you define how and when to check the status of software used for system operations?	Y	N	X	
104	Do you maintain technology used to automate management system operations?	Y	N	X	
105	Do you maintain tools used to automate management system operations?	Y	N	X	
106	Do you define storage requirements for tools used to automate system operations?	Y	N	X	

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2. ASSESS QMS MAINTENANCE MANAGEMENT PROCESS

107	Do you maintain equipment used to automate management system operations?	Y	N	X	
108	Do you define storage requirements for equipment used to automate system operations?	Y	N	X	
109	Do you maintain software used to automate management system operations?	Y	N	X	
110	Do you define how and when to check the status of software used for automation?	Y	N	X	
111	Do you maintain technology used to control management system operations?	Y	N	X	
112	Do you maintain tools used to control management system operations?	Y	N	X	
113	Do you maintain equipment used to control management system operations?	Y	N	X	
114	Do you maintain software used to control management system operations?	Y	N	X	
115	Do you maintain technology used to monitor management system operations?	Y	N	X	
116	Do you maintain tools used to monitor management system operations?	Y	N	X	
117	Do you maintain equipment used to monitor management system operations?	Y	N	X	
118	Do you maintain software used to monitor management system operations?	Y	N	X	
119	Do you maintain technology used to measure management system operations?	Y	N	X	
120	Do you maintain software used to measure management system operations?	Y	N	X	
121	Do you maintain tools used to measure management system operations?	Y	N	X	
122	Do you maintain equipment used to measure management system operations?	Y	N	X	
123	Do you define storage requirements for equipment used to measure operations?	Y	N	X	
124	Do you establish identification systems for measurement equipment?	Y	N	X	
125	Do you verify or calibrate your system measurement equipment?	Y	N	X	
126	Do you safeguard your system measurement equipment?	Y	N	X	

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2. ASSESS QMS MAINTENANCE MANAGEMENT PROCESS

2.2.7 ASSESS THE METHODS USED TO MAINTAIN YOUR INFRASTRUCTURE

127	Do you maintain the infrastructure that your system needs in order to achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
128	Do you maintain the facilities that your system needs in order to achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
129	Do you maintain the utilities that your system needs in order to achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
130	Do you maintain the services that your system needs in order to achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
131	Do you maintain the technologies that your system needs in order to achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
132	Do you maintain the hardware that your system needs in order to achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
133	Do you maintain the software that your system needs in order to achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

2.2.8 ASSESS THE METHODS USED TO MAINTAIN YOUR COMMUNICATIONS

134	Do you maintain the internal communications that system needs to achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
135	Do you maintain the external communications that system needs to achieve conformity of outputs?	<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 system. 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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3. ASSESS QMS MEASUREMENT MANAGEMENT PROCESS

3.1 ASSESS HOW WELL MEASUREMENT ACTIVITIES ARE PLANNED

3.1.1 ASSESS HOW WELL MEASUREMENT RESOURCES ARE TARGETED

1	Do you figure out what kind of system activities need to be measured?	Y	N	X	
2	Do you figure out what kind of system 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	

3.1.2 ASSESS HOW WELL MEASUREMENT METHODS ARE DESIGNED

6	Do you plan how you're going to measure system elements?	Y	N	X	
7	Do you plan how you're going to measure your system 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 system 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	

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3. ASSESS QMS MEASUREMENT MANAGEMENT PROCESS

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

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

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3. ASSESS QMS MEASUREMENT MANAGEMENT PROCESS

61	Do you plan how to measure how well system control activities comply with requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
62	Do you plan how you're going to measure system evaluation activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
63	Do you plan how you're going to measure system audit activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
64	Do you plan how to measure how well system audit activities meet expectations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
65	Do you plan how to measure how well system audit activities apply policies?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
66	Do you plan how to measure how well system audit activities implement plans?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
67	Do you plan how to measure how well system audit activities follow procedures?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
68	Do you plan how to measure how well system audit activities achieve objectives?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
69	Do you plan how to measure how well system audit activities comply with requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
70	Do you plan how you're going to measure system review activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
71	Do you plan how to measure how well system review activities meet expectations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
72	Do you plan how to measure how well system review activities apply policies?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
73	Do you plan how to measure how well system review activities implement plans?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
74	Do you plan how to measure how well system review activities follow procedures?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
75	Do you plan how to measure how well system review activities achieve objectives?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
76	Do you plan how to measure how well system review activities comply with requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
77	Do you plan how you're going to measure system change activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
78	Do you plan how you're going to measure system correction activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
79	Do you plan how to measure how well system correction activities meet expectations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
80	Do you plan how to measure how well system correction activities apply policies?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
81	Do you plan how to measure how well system correction activities implement plans?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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3. ASSESS QMS MEASUREMENT MANAGEMENT PROCESS

82	Do you plan how to measure how well system correction activities follow procedures?	Y	N	X	
83	Do you plan how to measure how well system correction activities achieve objectives?	Y	N	X	
84	Do you plan how to measure how well system correction activities comply with requirements?	Y	N	X	
85	Do you plan how you're going to measure system improvement activities?	Y	N	X	
86	Do you plan how to measure how well system improvement activities meet expectations?	Y	N	X	
87	Do you plan how to measure how well system improvement activities apply policies?	Y	N	X	
88	Do you plan how to measure how well system improvement activities implement plans?	Y	N	X	
89	Do you plan how to measure how well system improvement activities follow procedures?	Y	N	X	
90	Do you plan how to measure how well system improvement activities achieve objectives?	Y	N	X	
91	Do you plan how to measure how well system improvement activities comply with requirements?	Y	N	X	
92	Do you plan how you're going to measure customer satisfaction?	Y	N	X	
93	Do you learn how management system customers feel about your 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	

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3. ASSESS QMS MEASUREMENT MANAGEMENT PROCESS

3.1.3 ASSESS HOW WELL MEASUREMENT DUTIES ARE DISTRIBUTED

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

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3. ASSESS QMS MEASUREMENT MANAGEMENT PROCESS

3.2 ASSESS HOW WELL MEASUREMENT METHODS ARE PERFORMING

3.2.1 ASSESS HOW EFFECTIVE MEASUREMENT METHODS ARE

122	Do you select measurement resources that are fit for purpose?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
123	Do you select measurement resources that will yield valid and reliable results?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
124	Do you select measurement resources that can handle your unique circumstances?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
125	Do you select measurement resources that will ensure that outputs meet requirements?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
126	Do you select measurement resources that are capable of providing the information you need?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	

3.2.2 ASSESS HOW ACCURATE MEASUREMENT METHODS ARE

127	Do you validate measurement resources before you use them?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
128	Do you validate resources that are used to measure management system?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
129	Do you validate software before it is used to measure management system?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
130	Do you validate tools before they are used to measure management system?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
131	Do you validate equipment before it is used to measure management system?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	

3.3 ASSESS HOW WELL RESOURCES ARE USED TO MEASURE SYSTEM

3.3.1 ASSESS THE EXPERTISE USED TO MEASURE YOUR SYSTEM

132	Do you provide the expertise needed to ensure that measuring methods will yield valid and reliable results?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
133	Do you provide the managers needed to measure your system?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
134	Do you acquire the knowledge that system managers need to support system measurement activities?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	

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3. ASSESS QMS MEASUREMENT MANAGEMENT PROCESS

135	Do you ensure that system managers get the knowledge they need to support measurement activities?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
136	Do you deliver suitable training and awareness programmes for managers of system measurement activities?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
137	Do you provide the personnel needed to measure your system?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
138	Do you acquire the knowledge that personnel need to measure your system?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
139	Do you consider internal sources of knowledge about system measurement?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
140	Do you consider external sources of knowledge about system measurement?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
141	Do you ensure that personnel get the knowledge they need to measure your system?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
142	Do you deliver suitable training and awareness programmes for system measuring personnel?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	

3.3.2 ASSESS THE TECHNOLOGY USED TO MEASURE YOUR SYSTEM

143	Do you provide the technology needed to ensure that measurement methods yield valid and reliable results?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
144	Do you provide the software needed to measure your system?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
145	Do you provide the software needed to support system measurement activities?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
146	Do you provide the hardware needed to measure your system?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
147	Do you provide the hardware needed to support system measurement activities?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
148	Do you provide the tools and equipment needed to measure your system?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	

3.3.3 ASSESS THE INFRASTRUCTURE USED TO MEASURE YOUR SYSTEM

149	Do you provide the infrastructure needed to ensure that measurement methods yield valid and reliable results?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
150	Do you provide the infrastructure needed to support system measurement and achieve conformity of outputs?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	

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3.4 ASSESS HOW WELL MANAGEMENT SYSTEM IS BEING MEASURED

3.4.1 ASSESS THE METHODS USED TO MEASURE SYSTEM ELEMENTS

151	Do you use authorized methods to measure system outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
152	Do you measure your outputs against expectations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
153	Do you measure how well outputs meet requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
154	Do you measure how well outputs achieve objectives?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
155	Do you measure how well outputs implement plans?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
156	Do you use authorized methods to measure system inputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
157	Do you measure your inputs against expectations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
158	Do you measure how well inputs meet requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
159	Do you measure how well inputs achieve objectives?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
160	Do you measure how well inputs implement plans?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
161	Do you use authorized methods to measure system activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
162	Do you use authorized methods to measure system operating activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
163	Do you measure how well system operating activities meet expectations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
164	Do you measure how well system operating activities apply policies?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
165	Do you measure how well system operating activities implement plans?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
166	Do you measure how well system operating activities follow procedures?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
167	Do you measure how well system operating activities achieve objectives?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
168	Do you measure how well system operating activities comply with requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
169	Do you use authorized methods to measure system maintenance activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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3. ASSESS QMS MEASUREMENT MANAGEMENT PROCESS

170	Do you measure how well system maintenance activities meet expectations?	Y	N	X	
171	Do you measure how well system maintenance activities apply policies?	Y	N	X	
172	Do you measure how well system maintenance activities implement plans?	Y	N	X	
173	Do you measure how well system maintenance activities follow procedures?	Y	N	X	
174	Do you measure how well system maintenance activities achieve objectives?	Y	N	X	
175	Do you measure how well system maintenance activities comply with requirements?	Y	N	X	
176	Do you use authorized methods to measure system measurement activities?	Y	N	X	
177	Do you measure how well system measurement activities meet expectations?	Y	N	X	
178	Do you measure how well system measurement activities apply policies?	Y	N	X	
179	Do you measure how well system measurement activities implement plans?	Y	N	X	
180	Do you measure how well system measurement activities follow procedures?	Y	N	X	
181	Do you measure how well system measurement activities achieve objectives?	Y	N	X	
182	Do you measure how well system measurement activities comply with requirements?	Y	N	X	
183	Do you use authorized methods to measure system monitoring activities?	Y	N	X	
184	Do you measure how well system monitoring activities meet expectations?	Y	N	X	
185	Do you measure how well system monitoring activities apply policies?	Y	N	X	
186	Do you measure how well system monitoring activities implement plans?	Y	N	X	
187	Do you measure how well system monitoring activities follow procedures?	Y	N	X	
188	Do you measure how well system monitoring activities achieve objectives?	Y	N	X	
189	Do you measure how well system monitoring activities comply with requirements?	Y	N	X	
190	Do you use authorized methods to measure system control activities?	Y	N	X	

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191	Do you measure how well system control activities meet expectations?	Y	N	X	
192	Do you measure how well system control activities apply policies?	Y	N	X	
193	Do you measure how well system control activities implement plans?	Y	N	X	
194	Do you measure how well system control activities follow procedures?	Y	N	X	
195	Do you measure how well system control activities achieve objectives?	Y	N	X	
196	Do you measure how well system control activities comply with requirements?	Y	N	X	
197	Do you use authorized methods to measure system evaluation activities?	Y	N	X	
198	Do you use authorized methods to measure system audit activities?	Y	N	X	
199	Do you measure how well system audit activities meet expectations?	Y	N	X	
200	Do you measure how well system audit activities apply policies?	Y	N	X	
201	Do you measure how well system audit activities implement plans?	Y	N	X	
202	Do you measure how well system audit activities follow procedures?	Y	N	X	
203	Do you measure how well system audit activities achieve objectives?	Y	N	X	
204	Do you measure how well system audit activities comply with requirements?	Y	N	X	
205	Do you use authorized methods to measure system review activities?	Y	N	X	
206	Do you measure how well system review activities meet expectations?	Y	N	X	
207	Do you measure how well system review activities apply policies?	Y	N	X	
208	Do you measure how well system review activities implement plans?	Y	N	X	
209	Do you measure how well system review activities follow procedures?	Y	N	X	
210	Do you measure how well system review activities achieve objectives?	Y	N	X	
211	Do you measure how well system review activities comply with requirements?	Y	N	X	
212	Do you use authorized methods to measure system change activities?	Y	N	X	

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3. ASSESS QMS MEASUREMENT MANAGEMENT PROCESS

213	Do you use authorized methods to measure system correction activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
214	Do you measure how well system correction activities meet expectations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
215	Do you measure how well system correction activities apply policies?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
216	Do you measure how well system correction activities implement plans?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
217	Do you measure how well system correction activities follow procedures?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
218	Do you measure how well system correction activities achieve objectives?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
219	Do you measure how well system correction activities comply with requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
220	Do you use authorized methods to measure system improvement activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
221	Do you measure how well system improvement activities meet expectations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
222	Do you measure how well system improvement activities apply policies?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
223	Do you measure how well system improvement activities implement plans?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
224	Do you measure how well system improvement activities follow procedures?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
225	Do you measure how well system improvement activities achieve objectives?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
226	Do you measure how well system improvement activities comply with requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

3.4.2 ASSESS THE METHODS USED TO MEASURE SYSTEM PERFORMANCE

227	Do you use authorized methods to measure the performance of system personnel?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
228	Do you measure the competence and effectiveness of your system personnel?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
229	Do you measure the system knowledge and skill that has been acquired?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
230	Do you measure how well system personnel meet system expectations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
231	Do you measure how well system personnel apply system policies?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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232	Do you measure how well system personnel implement system plans?	Y	N	X	
233	Do you measure how well system personnel follow system procedures?	Y	N	X	
234	Do you measure how well system personnel meet system requirements?	Y	N	X	
235	Do you measure how well system personnel achieve system objectives?	Y	N	X	
236	Do you measure how well system personnel achieve safety objectives?	Y	N	X	
237	Do you measure how well system personnel achieve quality objectives?	Y	N	X	
238	Do you measure how well system personnel achieve privacy objectives?	Y	N	X	
239	Do you measure how well system personnel achieve security objectives?	Y	N	X	
240	Do you measure how well system personnel achieve business objectives?	Y	N	X	
241	Do you measure how well system personnel achieve technical objectives?	Y	N	X	
242	Do you measure how well system personnel achieve continuity objectives?	Y	N	X	
243	Do you use authorized methods to measure the performance of system management?	Y	N	X	
244	Do you use authorized methods to measure system management activities?	Y	N	X	
245	Do you measure how well system management activities meet expectations?	Y	N	X	
246	Do you measure how well system management activities apply policies?	Y	N	X	
247	Do you measure how well system management activities implement plans?	Y	N	X	
248	Do you measure how well system management activities follow procedures?	Y	N	X	
249	Do you measure how well system management activities meet requirements?	Y	N	X	
250	Do you measure how well system management activities achieve objectives?	Y	N	X	
251	Do you measure how well system managers achieve safety objectives?	Y	N	X	

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3. ASSESS QMS MEASUREMENT MANAGEMENT PROCESS

252	Do you measure how well system managers achieve quality objectives?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
253	Do you measure how well system managers achieve privacy objectives?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
254	Do you measure how well system managers achieve security objectives?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
255	Do you measure how well system managers achieve business objectives?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
256	Do you measure how well system managers achieve technical objectives?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
257	Do you measure how well system managers achieve continuity objectives?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
258	Do you use authorized methods to measure external product and service providers?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
259	Do you use authorized criteria to measure the performance of external providers?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
260	Do you measure the performance of external system, product, and service providers?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
261	Do you use data and criteria to measure the performance of your external providers?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
262	Do you document performance measuring activities and retain these documents?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
263	Do you control documents that describe your performance measuring activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
264	Do you measure external system, product, and service verification activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
265	Do you measure verifications whenever they are delegated to external providers?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
266	Do you use authorized methods to measure internal product and service providers?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
267	Do you use authorized criteria to measure the performance of internal providers?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

3.5 ASSESS HOW WELL MEASUREMENT RESOURCES ARE BEING CONTROLLED

3.5.1 ASSESS HOW WELL MEASUREMENT DOCUMENTS ARE BEING CONTROLLED

268	Do you control the procedures needed to measure your system and its outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
269	Do you control the instructions needed to measure your system and its outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
270	Do you control the manuals needed to measure your system and its outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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3.5.2 ASSESS HOW WELL MEASUREMENT TECHNOLOGIES ARE BEING CONTROLLED

271	Do you control the software needed to measure your system and its outputs?	Y	N	X	
272	Do you control the hardware needed to measure your system and its outputs?	Y	N	X	
273	Do you control the tools needed to measure your system and its outputs?	Y	N	X	
274	Do you control the equipment needed to measure your system and its outputs?	Y	N	X	

3.5.3 ASSESS HOW WELL MEASUREMENT RECORDS ARE BEING CONTROLLED

275	Do you control the records needed to measure system activities and resources?	Y	N	X	
276	Do you use records to control your system measuring activities and resources?	Y	N	X	
277	Do you establish registers of system measurement activities and resources?	Y	N	X	
278	Do you use this register to record the identity of measurement resources?	Y	N	X	
279	Do you use your register to describe the type or kind of resources being used?	Y	N	X	
280	Do you use your register to specify a unique identifier for each piece of equipment?	Y	N	X	
281	Do you use register to specify the location of your measurement tools and equipment?	Y	N	X	
282	Do you use register to control the calibration of your measurement tools and equipment?	Y	N	X	
283	Do you maintain a register of your system measurement activities and resources?	Y	N	X	
284	Do you use records to keep track of measurement activities and resources?	Y	N	X	
285	Do you establish suitable measurement traceability methods?	Y	N	X	
286	Do you maintain suitable measurement traceability resources?	Y	N	X	
287	Do you establish recall methods for your measurement equipment?	Y	N	X	
288	Do you implement recall methods for your measurement equipment?	Y	N	X	
289	Do you recall measurement equipment that must be verified or calibrated?	Y	N	X	
290	Do you maintain recall records for your system measurement equipment?	Y	N	X	

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4. ASSESS QMS MONITORING MANAGEMENT PROCESS

4.1 ASSESS HOW WELL MONITORING ACTIVITIES ARE PLANNED

4.1.1 ASSESS HOW WELL MONITORING RESOURCES ARE TARGETED

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 system participants need to be monitored?	Y	N	X	
8	Do you figure out what kind of system managers need to be monitored?	Y	N	X	
9	Do you figure out what kind of system personnel need to be monitored?	Y	N	X	
10	Do you figure out what kind of system providers need to be monitored?	Y	N	X	
11	Do you figure out what kind of internal system providers need to be monitored?	Y	N	X	
12	Do you figure out what kind of external system providers need to be monitored?	Y	N	X	
13	Do you figure out what kind of system 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 system 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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4. ASSESS QMS MONITORING MANAGEMENT PROCESS

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	

4.1.2 ASSESS HOW WELL MONITORING METHODS ARE DESIGNED

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 system 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 system performance?	Y	N	X	
27	Do you plan how you're going to monitor system 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 system activities?	Y	N	X	
32	Do you plan how you're going to monitor system management activities?	Y	N	X	
33	Do you plan how to monitor how well system management activities meet expectations?	Y	N	X	
34	Do you plan how to monitor how well system management activities apply policies?	Y	N	X	
35	Do you plan how to monitor how well system management activities implement plans?	Y	N	X	
36	Do you plan how to monitor how well system management activities follow procedures?	Y	N	X	
37	Do you plan how to monitor how well system management activities achieve objectives?	Y	N	X	
38	Do you plan how to monitor how well system management activities comply with requirements?	Y	N	X	
39	Do you plan how you're going to monitor system operating activities?	Y	N	X	

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4. ASSESS QMS MONITORING MANAGEMENT PROCESS

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

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4. ASSESS QMS MONITORING MANAGEMENT PROCESS

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

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4. ASSESS QMS MONITORING MANAGEMENT PROCESS

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

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4. ASSESS QMS MONITORING MANAGEMENT PROCESS

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

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4. ASSESS QMS MONITORING MANAGEMENT PROCESS

124	Do you plan how you're going to monitor external system inputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
125	Do you plan how you're going to monitor system technologies?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
126	Do you plan how you're going to monitor system tools and equipment?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
127	Do you plan how you're going to monitor system monitoring devices?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
128	Do you plan how you're going to recall monitoring tools and equipment that must be recalibrated or reverified?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
129	Do you plan how you're going to monitor system measurement devices?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
130	Do you plan how you're going to recall measurement tools and equipment that must be recalibrated or reverified?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
131	Do you plan how you're going to monitor system environment?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
132	Do you plan how you're going to monitor your system's external context?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
133	Do you figure out how you're going to monitor the external issues and factors that could affect your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
134	Do you figure out how you're going to monitor the external interested parties that could affect your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
135	Do you plan how you're going to monitor your system's internal context?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
136	Do you figure out how you're going to monitor the internal issues and factors that could affect your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
137	Do you figure out how you're going to monitor the internal interested parties that could affect your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

4.1.3 ASSESS HOW WELL MONITORING DUTIES ARE DISTRIBUTED

138	Do you allocate responsibility and authority for monitoring system plans?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
139	Do you allocate responsibility and authority for monitoring system policies?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
140	Do you allocate responsibility and authority for monitoring system outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
141	Do you allocate responsibility and authority for monitoring system supplies?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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4. ASSESS QMS MONITORING MANAGEMENT PROCESS

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

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4. ASSESS QMS MONITORING MANAGEMENT PROCESS

4.2 ASSESS HOW WELL MONITORING METHODS ARE PERFORMING

4.2.1 ASSESS HOW EFFECTIVE MONITORING METHODS ARE

163	Do you select monitoring resources that are fit for purpose?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
164	Do you select monitoring resources that will yield valid and reliable results?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
165	Do you select monitoring resources that can handle your unique circumstances?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
166	Do you select monitoring resources that will ensure that outputs meet requirements?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
167	Do you select monitoring resources that are capable of providing the information you need?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	

4.2.2 ASSESS HOW ACCURATE MONITORING METHODS ARE

168	Do you validate monitoring resources before you use them?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
169	Do you validate tools before they are used to monitor management system?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
170	Do you validate equipment before it is used to monitor management system?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
171	Do you validate software before it is used to monitor management system?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	

4.3 ASSESS HOW WELL RESOURCES ARE USED TO MONITOR SYSTEM

4.3.1 ASSESS THE EXPERTISE USED TO MONITOR YOUR SYSTEM

172	Do you provide the expertise needed to ensure that monitoring methods will consistently yield valid and reliable results?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
173	Do you provide the managers needed to monitor your system?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
174	Do you acquire the knowledge that managers need to support system monitoring and achieve conformity of outputs?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
175	Do you share the knowledge that managers need so that they can support system monitoring and achieve conformity of outputs?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	

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4. ASSESS QMS MONITORING MANAGEMENT PROCESS

176	Do you deliver training and awareness programmes for managers of system monitoring activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
177	Do you provide the personnel needed to monitor your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
178	Do you acquire the knowledge that personnel need to monitor your system and achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
179	Do you consider internal sources of knowledge about system monitoring?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
180	Do you consider external sources of knowledge about system monitoring?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
181	Do you share the knowledge that personnel need to monitor system and achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
182	Do you deliver suitable training and awareness programmes for system monitoring personnel?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

4.3.2 ASSESS THE TECHNOLOGY USED TO MONITOR YOUR SYSTEM

183	Do you provide the technology needed to ensure that your monitoring methods will yield valid and reliable results?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
184	Do you provide the software needed to monitor your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
185	Do you provide the software needed to support system monitoring and achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
186	Do you provide the hardware needed to monitor your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
187	Do you provide the hardware needed to support system monitoring and achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

4.3.3 ASSESS THE INFRASTRUCTURE USED TO MONITOR YOUR SYSTEM

188	Do you provide the infrastructure needed to ensure that your monitoring methods will yield valid and reliable results?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
189	Do you provide the infrastructure needed to support your system monitoring and achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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4. ASSESS QMS MONITORING MANAGEMENT PROCESS

4.4 ASSESS HOW WELL MANAGEMENT SYSTEM IS BEING MONITORED

4.4.1 ASSESS THE METHODS USED TO MONITOR SYSTEM ACTIVITIES

190	Do you use authorized methods to monitor system management activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
191	Do you monitor how well system management activities meet expectations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
192	Do you monitor how well system management activities apply policies?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
193	Do you monitor how well system management activities implement plans?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
194	Do you monitor how well system management activities follow procedures?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
195	Do you monitor how well system management activities achieve objectives?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
196	Do you monitor how well system management activities comply with requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
197	Do you use authorized methods to monitor system operating activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
198	Do you monitor how well system operating activities meet expectations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
199	Do you monitor how well system operating activities apply policies?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
200	Do you monitor how well system operating activities implement plans?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
201	Do you monitor how well system operating activities follow procedures?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
202	Do you monitor how well system operating activities achieve objectives?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
203	Do you monitor how well system operating activities comply with requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
204	Do you use authorized methods to monitor system maintenance activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
205	Do you monitor how well system maintenance activities meet expectations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
206	Do you monitor how well system maintenance activities apply policies?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
207	Do you monitor how well system maintenance activities implement plans?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
208	Do you monitor how well system maintenance activities follow procedures?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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4. ASSESS QMS MONITORING MANAGEMENT PROCESS

209	Do you monitor how well system maintenance activities achieve objectives?	Y	N	X	
210	Do you monitor how well system maintenance activities comply with requirements?	Y	N	X	
211	Do you use authorized methods to monitor system measurement activities?	Y	N	X	
212	Do you monitor how well system measurement activities meet expectations?	Y	N	X	
213	Do you monitor how well system measurement activities apply policies?	Y	N	X	
214	Do you monitor how well system measurement activities implement plans?	Y	N	X	
215	Do you monitor how well system measurement activities follow procedures?	Y	N	X	
216	Do you monitor how well system measurement activities achieve objectives?	Y	N	X	
217	Do you monitor how well system measurement activities comply with requirements?	Y	N	X	
218	Do you use authorized methods to monitor system monitoring activities?	Y	N	X	
219	Do you monitor how well system monitoring activities meet expectations?	Y	N	X	
220	Do you monitor how well system monitoring activities apply policies?	Y	N	X	
221	Do you monitor how well system monitoring activities implement plans?	Y	N	X	
222	Do you monitor how well system monitoring activities follow procedures?	Y	N	X	
223	Do you monitor how well system monitoring activities achieve objectives?	Y	N	X	
224	Do you monitor how well system monitoring activities comply with requirements?	Y	N	X	
225	Do you use authorized methods to monitor system control activities?	Y	N	X	
226	Do you monitor how well system control activities meet expectations?	Y	N	X	
227	Do you monitor how well system control activities apply policies?	Y	N	X	
228	Do you monitor how well system control activities implement plans?	Y	N	X	
229	Do you monitor how well system control activities follow procedures?	Y	N	X	

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230	Do you monitor how well system control activities achieve objectives?	Y	N	X	
231	Do you monitor how well system control activities comply with requirements?	Y	N	X	
232	Do you use authorized methods to monitor system evaluation activities?	Y	N	X	
233	Do you use authorized methods to monitor system audit activities?	Y	N	X	
234	Do you monitor how well system audit activities meet expectations?	Y	N	X	
235	Do you monitor how well system audit activities apply policies?	Y	N	X	
236	Do you monitor how well system audit activities implement plans?	Y	N	X	
237	Do you monitor how well system audit activities follow procedures?	Y	N	X	
238	Do you monitor how well system audit activities achieve objectives?	Y	N	X	
239	Do you monitor how well system audit activities comply with requirements?	Y	N	X	
240	Do you use authorized methods to monitor system review activities?	Y	N	X	
241	Do you monitor how well system review activities meet expectations?	Y	N	X	
242	Do you monitor how well system review activities apply policies?	Y	N	X	
243	Do you monitor how well system review activities implement plans?	Y	N	X	
244	Do you monitor how well system review activities follow procedures?	Y	N	X	
245	Do you monitor how well system review activities achieve objectives?	Y	N	X	
246	Do you monitor how well system review activities comply with requirements?	Y	N	X	
247	Do you use authorized methods to monitor system change activities?	Y	N	X	
248	Do you use authorized methods to monitor system correction activities?	Y	N	X	
249	Do you monitor how well system correction activities meet expectations?	Y	N	X	
250	Do you monitor how well system correction activities apply policies?	Y	N	X	

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4. ASSESS QMS MONITORING MANAGEMENT PROCESS

251	Do you monitor how well system correction activities implement plans?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
252	Do you monitor how well system correction activities follow procedures?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
253	Do you monitor how well system correction activities achieve objectives?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
254	Do you monitor how well system correction activities comply with requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
255	Do you use authorized methods to monitor system improvement activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
256	Do you monitor how well system improvement activities meet expectations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
257	Do you monitor how well system improvement activities apply policies?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
258	Do you monitor how well system improvement activities implement plans?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
259	Do you monitor how well system improvement activities follow procedures?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
260	Do you monitor how well system improvement activities achieve objectives?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
261	Do you monitor how well system improvement activities comply with requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

4.4.2 ASSESS THE METHODS USED TO MONITOR SYSTEM OUTPUTS

262	Do you use authorized methods to monitor how well system outputs meet expectations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
263	Do you use authorized methods to monitor how well system outputs apply policies?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
264	Do you use authorized methods to monitor how well system outputs implement plans?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
265	Do you use authorized methods to monitor how well system outputs follow procedures?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
266	Do you use authorized methods to monitor how well system outputs achieve objectives?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
267	Do you use authorized methods to monitor how well system outputs comply with requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
268	Do you use authorized methods to monitor how well outputs meet customer requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
269	Do you use authorized methods to monitor how well outputs meet regulatory requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
270	Do you use authorized methods to monitor how well outputs meet corporate requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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4. ASSESS QMS MONITORING MANAGEMENT PROCESS

4.4.3 ASSESS THE METHODS USED TO MONITOR SYSTEM INPUTS

271	Do you use authorized methods to monitor supplies that have a major impact on outputs?	Y	N	X	
272	Do you use authorized methods to monitor services that have a major impact on outputs?	Y	N	X	
273	Do you use authorized methods to monitor materials that have a major impact on outputs?	Y	N	X	
274	Do you use authorized methods to monitor products that have a major impact on outputs?	Y	N	X	
275	Do you use authorized methods to monitor components that have a major impact on outputs?	Y	N	X	
276	Do you use authorized methods to monitor your “critical items” and “key characteristics”?	Y	N	X	

4.4.4 ASSESS THE METHODS USED TO MONITOR SYSTEM DOCUMENTS

277	Do you use authorized methods to monitor documents that specify how system is operated?	Y	N	X	
278	Do you use authorized methods to monitor documents that specify how system is maintained?	Y	N	X	
279	Do you use authorized methods to monitor documents that specify how system is monitored?	Y	N	X	
280	Do you use authorized methods to monitor documents that specify how system is measured?	Y	N	X	
281	Do you use authorized methods to monitor documents that specify how system is controlled?	Y	N	X	
282	Do you use authorized methods to monitor documents that specify how system is audited?	Y	N	X	
283	Do you use authorized methods to monitor documents that specify how system is reviewed?	Y	N	X	
284	Do you use authorized methods to monitor documents that specify how system is corrected?	Y	N	X	
285	Do you use authorized methods to monitor documents that specify how system is improved?	Y	N	X	

4.4.5 ASSESS THE METHODS USED TO MONITOR SYSTEM RECORDS

286	Do you use authorized methods to monitor records of personnel performance and competence?	Y	N	X	
287	Do you retain and maintain records of personnel performance and competence?	Y	N	X	
288	Do you use records to show that personnel know how to perform system tasks?	Y	N	X	

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289	Do you use authorized methods to monitor records that track the performance of your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
290	Do you use authorized methods to monitor records that keep track of system operations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
291	Do you use authorized methods to monitor records that keep track of system outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
292	Do you use authorized methods to monitor records that keep track of system activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
293	Do you use authorized methods to monitor records that keep track of system inputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
294	Do you use authorized methods to monitor records that keep track of system maintenance?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
295	Do you use authorized methods to monitor records that keep track of system measurement?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
296	Do you use authorized methods to monitor records that keep track of system monitoring?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
297	Do you use authorized methods to monitor records that keep track of system control?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
298	Do you use authorized methods to monitor records that keep track of system audits?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
299	Do you use authorized methods to monitor records that keep track of system reviews?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
300	Do you use authorized methods to monitor records that keep track of system corrections?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
301	Do you use authorized methods to monitor records that keep track of system improvements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

4.4.6 ASSESS THE METHODS USED TO MONITOR SYSTEM PROPERTY

302	Do you use authorized methods to monitor system property owned by your customers and suppliers that is needed to achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
303	Do you report problematic property to your customers and external providers?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
304	Do you report unsuitable property to customers and external providers?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
305	Do you report lost or damaged property to customers and external providers?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
306	Do you use authorized methods to monitor system property owned by your organization that is needed to achieve conformity of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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4. ASSESS QMS MONITORING MANAGEMENT PROCESS

4.4.7 ASSESS THE METHODS USED TO MONITOR SYSTEM PARTICIPANTS

307	Do you use authorized methods to monitor system personnel?	Y	N	X	
308	Do you use authorized methods to monitor objectives that system personnel must achieve?	Y	N	X	
309	Do you use authorized methods to monitor safety objectives that personnel must achieve?	Y	N	X	
310	Do you use authorized methods to monitor quality objectives that personnel must achieve?	Y	N	X	
311	Do you use authorized methods to monitor privacy objectives that personnel must achieve?	Y	N	X	
312	Do you use authorized methods to monitor security objectives that personnel must achieve?	Y	N	X	
313	Do you use authorized methods to monitor business objectives that personnel must achieve?	Y	N	X	
314	Do you use authorized methods to monitor technical objectives that personnel must achieve?	Y	N	X	
315	Do you use authorized methods to monitor continuity objectives that personnel must achieve?	Y	N	X	
316	Do you use authorized methods to monitor competence and performance of system personnel?	Y	N	X	
317	Do you use authorized methods to monitor system knowledge and skill that has been acquired?	Y	N	X	
318	Do you consider the need to protect and preserve system lessons learned?	Y	N	X	
319	Do you consider the need to protect and preserve your intellectual property?	Y	N	X	
320	Do you use authorized methods to monitor changes and trends in knowledge and information?	Y	N	X	
321	Do you use authorized methods to monitor system management?	Y	N	X	
322	Do you use authorized methods to monitor system management personnel?	Y	N	X	
323	Do you use authorized methods to monitor external providers?	Y	N	X	
324	Do you use authorized criteria to monitor the performance of external providers?	Y	N	X	
325	Do you use authorized criteria to monitor verification activities delegated to external providers?	Y	N	X	

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326	Do you use authorized methods to monitor interested parties?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
327	Do you use authorized methods to monitor external parties that could influence system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
328	Do you monitor the performance of external system, product, and service providers?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
329	Do system managers use data and criteria to monitor the performance of their external providers?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
330	Do system managers document performance monitoring activities and retain these documents?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
331	Do system managers control documents that describe their performance monitoring activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
332	Do you monitor external system, product, and service verification activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
333	Do you monitor verifications whenever they are delegated to external providers?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
334	Do you use authorized methods to monitor internal parties that could influence system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

4.4.8 ASSESS THE METHODS USED TO MONITOR SYSTEM TECHNOLOGIES

335	Do you use authorized methods to monitor technology used to perform system operations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
336	Do you use authorized methods to monitor software used to perform system operations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
337	Do you use authorized methods to monitor hardware used to perform system operations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
338	Do you use authorized methods to monitor technology used to automate system operations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
339	Do you use authorized methods to monitor software used to automate system operations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
340	Do you use authorized methods to monitor hardware used to automate system operations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
341	Do you use authorized methods to monitor technology used to maintain system operations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
342	Do you use authorized methods to monitor software used to maintain system operations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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343	Do you use authorized methods to monitor hardware used to maintain system operations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
344	Do you use authorized methods to monitor technology used to monitor system operations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
345	Do you use authorized methods to monitor software used to monitor system operations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
346	Do you use authorized methods to monitor hardware used to monitor system operations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
347	Do you use authorized methods to monitor technology used to measure system operations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
348	Do you use authorized methods to monitor software used to measure system operations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
349	Do you use authorized methods to monitor hardware used to measure system operations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
350	Do you use authorized methods to monitor technology used to control system operations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
351	Do you use authorized methods to monitor software used to control system operations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
352	Do you use authorized methods to monitor hardware used to control system operations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

4.4.9 ASSESS THE METHODS USED TO MONITOR SYSTEM ENVIRONMENT

353	Do you use authorized methods to monitor your system's external environment?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
354	Do you use authorized methods to monitor external interested parties and their requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
355	Do you use authorized methods to monitor your system's internal environment?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
356	Do you use authorized methods to monitor internal interested parties and their requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

4.4.10 ASSESS THE METHODS USED TO MONITOR SYSTEM INFRASTRUCTURE

357	Do you use authorized methods to monitor system networks and communications?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
358	Do you use authorized methods to monitor internal system networks and communications?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
359	Do you use authorized methods to monitor external system networks and communications?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
360	Do you use authorized methods to monitor system utilities and support services?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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4. ASSESS QMS MONITORING MANAGEMENT PROCESS

4.5 ASSESS HOW WELL MONITORING RESOURCES ARE BEING CONTROLLED

4.5.1 ASSESS HOW WELL MONITORING TECHNOLOGIES ARE BEING CONTROLLED

361	Do you control the technology needed to monitor your system?	Y	N	X	
362	Do you control the tools needed to monitor your system?	Y	N	X	
363	Do you control the software needed to monitor your system?	Y	N	X	
364	Do you control the equipment needed to monitor your system?	Y	N	X	

4.5.2 ASSESS HOW WELL MONITORING RECORDS ARE BEING CONTROLLED

365	Do you control the records needed to monitor your system?	Y	N	X	
366	Do you establish a register of your system monitoring resources?	Y	N	X	
367	Do you ensure that your monitoring resources continue to be fit for purpose?	Y	N	X	
368	Do you ensure that register describes the type of monitoring tools and equipment in use?	Y	N	X	
369	Do you ensure that register specifies the location of your monitoring tools and equipment?	Y	N	X	
370	Do you ensure that register tracks the calibration of your monitoring tools and equipment?	Y	N	X	
371	Do you ensure that your register records equipment calibration or verification methods?	Y	N	X	
372	Do you ensure that your register records calibration or verification acceptance criteria?	Y	N	X	
373	Do you ensure that register specifies equipment calibration or verification frequency?	Y	N	X	
374	Do you maintain a register of your system monitoring resources?	Y	N	X	
375	Do you maintain records that show that monitoring resources are still fit for purpose?	Y	N	X	
376	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 system. 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 QMS CONTROL MANAGEMENT PROCESS

5.1 ASSESS HOW WELL CONTROL ACTIVITIES ARE BEING PLANNED

5.1.1 ASSESS THE STEPS TAKEN TO PLAN HOW OUTPUTS ARE CONTROLLED

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

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5. ASSESS QMS CONTROL MANAGEMENT PROCESS

20	Do you consider security requirements as you develop output controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
21	Do you consider handling requirements as you develop output controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
22	Do you consider packaging requirements as you develop output controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
23	Do you consider availability requirements as you develop output controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
24	Do you consider preservation requirements as you develop output controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
25	Do you consider obsolescence requirements as you develop output controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
26	Do you consider recycling requirements as you develop output controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
27	Do you consider disposal requirements as you develop output controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
28	Do you consider final disposal requirements as you develop output controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
29	Do you consider production requirements as you develop output controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
30	Do you consider producibility requirements as you develop output controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
31	Do you consider measurement requirements as you develop output controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
32	Do you consider monitoring requirements as you develop output controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
33	Do you consider inspectability requirements as you develop output controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

5.1.2 ASSESS THE STEPS TAKEN TO PLAN HOW INPUTS ARE CONTROLLED

34	Do you figure out how you're going to control your system inputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
35	Do you consider system input requirements as you develop input controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
36	Do you consider input privacy requirements as you develop input controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
37	Do you consider input safety requirements as you develop input controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
38	Do you consider input security requirements as you develop input controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
39	Do you consider input quality requirements as you develop input controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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40	Do you consider input reliability requirements as you develop input controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
41	Do you consider input purity requirements as you develop input controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
42	Do you consider the need to control foreign objects that could compromise inputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
43	Do you consider the need to detect foreign objects that could compromise inputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
44	Do you consider the need to remove foreign objects that could compromise inputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
45	Do you consider the need to prevent foreign objects that could compromise inputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
46	Do you consider input availability requirements as you develop input controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
47	Do you consider input suitability requirements as you develop input controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
48	Do you consider suitability requirements for parts and materials to be used by system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
49	Do you consider suitability requirements for software programmes to be used by system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
50	Do you consider input storage requirements as you develop input controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
51	Do you consider input handling requirements as you develop input controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
52	Do you consider input monitoring requirements as you develop input controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
53	Do you consider input maintenance requirements as you develop input controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
54	Do you consider input measurement requirements as you develop input controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
55	Do you consider input preservation requirements as you develop input controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

5.1.3 ASSESS THE STEPS TAKEN TO PLAN HOW ACTIVITIES ARE CONTROLLED

56	Do you figure out how you're going to control your system activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
57	Do you consider system safety requirements as you develop system controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
58	Do you consider system privacy requirements as you develop system controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
59	Do you consider system quality requirements as you develop system controls?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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60	Do you consider system security requirements as you develop system controls?	Y	N	X	
61	Do you consider system reliability requirements as you develop system controls?	Y	N	X	
62	Do you consider system monitoring requirements as you develop system controls?	Y	N	X	
63	Do you consider system measurement requirements as you develop system controls?	Y	N	X	
64	Do you consider system improvement requirements as you develop system controls?	Y	N	X	
65	Do you consider system maintenance requirements as you develop system controls?	Y	N	X	
66	Do you consider system evaluation requirements as you develop system controls?	Y	N	X	
67	Do you consider system correction requirements as you develop system controls?	Y	N	X	
68	Do you consider system reporting requirements as you develop system controls?	Y	N	X	
69	Do you consider system review requirements as you develop system controls?	Y	N	X	
70	Do you consider system audit requirements as you develop system controls?	Y	N	X	

5.1.4 ASSESS THE STEPS TAKEN TO PLAN HOW PROVIDERS ARE CONTROLLED

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

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5. ASSESS QMS CONTROL MANAGEMENT PROCESS

5.2 ASSESS HOW WELL CONTROLS ARE DESIGNED AND DEVELOPED

5.2.1 ASSESS THE STEPS TAKEN TO DEVELOP WAYS OF CONTROLLING ELEMENTS

79	Do you develop controlled conditions for system outputs?	Y	N	X	
80	Do you develop ways of controlling your system outputs?	Y	N	X	
81	Do you develop ways of controlling the quality of system outputs?	Y	N	X	
82	Do you develop ways of controlling the reliability of system outputs?	Y	N	X	
83	Do you develop ways of controlling the suitability of system outputs?	Y	N	X	
84	Do you develop ways of controlling the suitability of parts and materials to be used in outputs?	Y	N	X	
85	Do you develop ways of controlling the suitability of software to be embedded into outputs?	Y	N	X	
86	Do you develop ways of controlling the suitability of software that you plan to purchase?	Y	N	X	
87	Do you develop ways of controlling the suitability of software that you plan to develop?	Y	N	X	
88	Do you develop ways of controlling the purity of system outputs?	Y	N	X	
89	Do you develop ways of controlling foreign objects that could affect your outputs?	Y	N	X	
90	Do you develop ways of detecting foreign objects that could compromise quality of outputs?	Y	N	X	
91	Do you develop ways of removing foreign objects that could compromise quality of outputs?	Y	N	X	
92	Do you develop ways of preventing foreign objects that could compromise quality of outputs?	Y	N	X	
93	Do you develop ways of controlling the safety of outputs?	Y	N	X	
94	Do you develop ways of ensuring that outputs can be safely produced?	Y	N	X	
95	Do you develop ways of ensuring that outputs can be safely packaged?	Y	N	X	
96	Do you develop ways of ensuring that outputs can be safely delivered?	Y	N	X	
97	Do you develop ways of ensuring that outputs can be safely handled?	Y	N	X	
98	Do you develop ways of ensuring that outputs can be safely stored?	Y	N	X	

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99	Do you develop ways of ensuring that outputs can be safely used?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
100	Do you develop ways of ensuring that outputs can be safely repaired?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
101	Do you develop ways of ensuring that outputs can be safely maintained?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
102	Do you develop ways of ensuring that outputs can be safely preserved?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
103	Do you develop ways of ensuring that outputs can be safely destroyed?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
104	Do you develop ways of ensuring that outputs can be safely recycled?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
105	Do you develop ways of controlling the security of outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
106	Do you develop ways of ensuring that outputs can be securely produced?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
107	Do you develop ways of ensuring that outputs can be securely packaged?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
108	Do you develop ways of ensuring that outputs can be securely delivered?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
109	Do you develop ways of ensuring that outputs can be securely handled?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
110	Do you develop ways of ensuring that outputs can be securely stored?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
111	Do you develop ways of ensuring that outputs can be securely used?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
112	Do you develop ways of ensuring that outputs can be securely repaired?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
113	Do you develop ways of ensuring that outputs can be securely maintained?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
114	Do you develop ways of ensuring that outputs can be securely preserved?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
115	Do you develop ways of ensuring that outputs can be securely destroyed?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
116	Do you develop controlled conditions for system inputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
117	Do you develop ways of controlling your system inputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
118	Do you develop ways of controlling the quality of system inputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
119	Do you develop ways of controlling the purity of system inputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
120	Do you develop ways of controlling foreign objects that compromise the quality of inputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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5. ASSESS QMS CONTROL MANAGEMENT PROCESS

121	Do you develop ways of detecting foreign objects that compromise the quality of inputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
122	Do you develop ways of removing foreign objects that compromise the quality of inputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
123	Do you develop ways of preventing foreign objects that compromise the quality of inputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
124	Do you develop ways of controlling the suitability of system inputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
125	Do you develop ways of controlling the suitability of parts and materials to be used as inputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
126	Do you develop ways of controlling the suitability of software that is embedded in inputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
127	Do you develop ways of controlling the acceptability of system inputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
128	Do you develop acceptance criteria for your system inputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
129	Do you develop methods and procedures for testing system inputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
130	Do you develop methods and procedures for inspecting system inputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
131	Do you develop methods and procedures for monitoring system inputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
132	Do you develop methods and procedures for measuring system inputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
133	Do you develop methods and procedures for evaluating system inputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
134	Do you develop ways of controlling the security of system inputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
135	Do you develop ways of controlling the safety of system inputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
136	Do you develop ways of controlling the privacy of system inputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
137	Do you develop controlled conditions for system activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
138	Do you develop ways of controlling your system activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
139	Do you develop ways of controlling system testing activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
140	Do you develop ways of controlling system control activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
141	Do you develop ways of controlling system inspection activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
142	Do you develop ways of controlling system management activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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5. ASSESS QMS CONTROL MANAGEMENT PROCESS

143	Do you develop ways of controlling system measurement activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
144	Do you develop ways of controlling system maintenance activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
145	Do you develop ways of controlling system production activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
146	Do you develop ways of controlling system monitoring activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
147	Do you develop ways of controlling system evaluation activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
148	Do you develop ways of controlling system audit activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
149	Do you develop ways of controlling system review activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
150	Do you develop ways of controlling system change activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
151	Do you develop ways of controlling system correction activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
152	Do you develop ways of controlling system improvement activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

5.2.2 ASSESS THE STEPS TAKEN TO DEVELOP WAYS OF CONTROLLING PROVIDERS

153	Do you develop ways of controlling external providers?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
154	Do you plan how to control external processes, products, and services?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
155	Do you consider the potential impact that externally provided processes, products, and services could have on your ability to consistently meet external requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
156	Do you consider the potential impact on your ability to meet customer requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
157	Do you consider the potential impact on statutory and regulatory requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
158	Do you create controls for external processes, products, and services?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
159	Do you develop controls for processes that your organization is outsourcing?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
160	Do you ensure that outsourced processes remain within your organization's control?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
161	Do you figure out how you're going to control external process providers?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
162	Do you consider the potential impact that external process providers could have on your ability to consistently meet customer and legal requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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163	Do you consider the controls that external process providers have implemented and do you think about how effective their controls really are in practice?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
164	Do you develop controls for products that your organization is outsourcing?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
165	Do you ensure that outsourced products remain within your organization's control?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
166	Do you figure out how you're going to control external product providers?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
167	Do you consider the potential impact that external product providers could have on your ability to consistently meet customer and legal requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
168	Do you consider the controls that external product providers have implemented and do you think about how effective their controls really are in practice?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
169	Do you develop controls for services that your organization is outsourcing?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
170	Do you ensure that outsourced services remain within your organization's control?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
171	Do you figure out how you're going to control external service providers?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
172	Do you consider the potential impact that external service providers could have on your ability to consistently meet customer and legal requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
173	Do you consider the controls that external service providers have implemented and do you think about how effective their controls really are in practice?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
174	Do you design external process, product, and service verification methods?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
175	Do you plan your external process, product, and service verification activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
176	Do you define the scope and extent of external verification and testing activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
177	Do you define requirements whenever verifications are delegated to external providers?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
178	Do you maintain a register of verification activities delegated to external providers?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
179	Do you consider risks when you carry out external verification and testing activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
180	Do you consider the risk of external process, product, and service nonconformities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
181	Do you consider the risk that counterfeit parts and components are being used?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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182	Do you consider the risk that raw materials might fail to meet requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
183	Do you use objective evidence to verify external processes, products, and services?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
184	Do you use documents and records to verify processes, products, and services?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
185	Do you examine related test documents and records?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
186	Do you examine related statistical documents and records?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
187	Do you examine related system control documents and records?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
188	Do you examine related conformance documents and records?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
189	Do you examine related production documents and records?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
190	Do you review production verification activities and results?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
191	Do you review data related to production part approval system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
192	Do you develop a process to evaluate the accuracy of test data and test reports?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
193	Do you validate test data when it is used to verify externally provided products?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
194	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 type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
195	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 type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
196	Do you develop ways of controlling internal providers?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
197	Do you plan how to control internal processes, products, and services?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
198	Do you consider the potential impact that internally provided processes, products, and services could have on your ability to consistently meet internal requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
199	Do you consider the potential impact on your ability to meet customer requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
200	Do you consider the potential impact on statutory and regulatory requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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201	Do you consider the controls that internal process, product, and service providers have implemented and think about how effective their controls actually are?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
202	Do you create controls for internal processes, products, and services?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
203	Do you design internal system, product, and service verification methods?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
204	Do you plan your internal process, product, and service verification activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
205	Do you define the scope and extent of internal verification and testing activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
206	Do you consider risks when you carry out internal verification and testing activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
207	Do you use objective evidence to verify internal processes, products, and services?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
208	Do you develop a process to evaluate the accuracy of test data and test reports?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

5.3 ASSESS HOW WELL RESOURCES ARE USED TO CONTROL SYSTEM

5.3.1 ASSESS THE HUMAN RESOURCES USED TO CONTROL SYSTEM

209	Do you provide the people that are needed in order to control your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
210	Do you provide the training that is needed in order to control your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
211	Do you provide the knowledge that is needed in order to control your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
212	Do you provide the expertise that is needed in order to control your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

5.3.2 ASSESS THE TECHNICAL RESOURCES USED TO CONTROL SYSTEM

213	Do you provide the policies that are needed in order to control your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
214	Do you provide the procedures that are needed in order to control your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
215	Do you provide the technologies that are needed in order to control your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
216	Do you provide the methodologies that are needed in order to control your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
217	Do you provide the infrastructure that is needed in order to control your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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5. ASSESS QMS CONTROL MANAGEMENT PROCESS

5.4 ASSESS HOW WELL MANAGEMENT SYSTEM IS CONTROLLED

5.4.1 ASSESS THE METHODS USED TO CONTROL SYSTEM INPUTS

218	Do you use authorized methods to control the identity of system inputs?	Y	N	X	
219	Do you establish suitable means for identifying your system inputs?	Y	N	X	
220	Do you specify the identity of inputs when conformity must be ensured?	Y	N	X	
221	Do you identify inputs whenever input conformity must be ensured?	Y	N	X	
222	Do you identify the monitoring and measurement status of inputs?	Y	N	X	
223	Do you record the identity of inputs when traceability is a requirement?	Y	N	X	
224	Do you clarify your organization's specific input traceability requirements?	Y	N	X	
225	Do you retain the documents and records that are needed to facilitate traceability?	Y	N	X	
226	Do you make arrangements to verify inputs at appropriate stages?	Y	N	X	
227	Do you verify that input requirements were met at all appropriate stages?	Y	N	X	
228	Do you retain evidence that shows that input acceptance criteria were met?	Y	N	X	
229	Do you retain evidence that shows that your input meets defined requirements?	Y	N	X	
230	Do you identify the people who may authorize the release of inputs for production?	Y	N	X	
231	Do you retain and control records to facilitate traceability of input releases?	Y	N	X	
232	Do you verify that your input acceptance criteria are being met?	Y	N	X	
233	Do you verify acceptance before inputs are officially released?	Y	N	X	
234	Do you establish a record of your input acceptance activities?	Y	N	X	
235	Do you document your criteria for input acceptance and rejection?	Y	N	X	
236	Do you document where in the sequence input verification is performed?	Y	N	X	

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237	Do you document and retain your input monitoring and measuring results?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
238	Do you maintain a record of input acceptance and rejection activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
239	Do you document how input monitoring and measuring must be carried out?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
240	Do you document all required input monitoring and measuring instructions?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
241	Do you document all required input monitoring and measuring equipment?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
242	Do you verify that critical input items are being controlled?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
243	Do you control critical input items in accordance with established methods?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
244	Do you verify that key input characteristics are being controlled?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
245	Do you control key input characteristics in accordance with established methods?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
246	Do you verify that inputs being used in the management system are being controlled?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
247	Do you identify and record purchased products (inputs) that are released for use in your system whenever verification activities have not yet been completed?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
248	Do you use your records to recall and replace purchased products (inputs) that have been used but do not actually meet requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
249	Do you verify that all input inspection and verification activities have been completed?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
250	Do you maintain a record of your input inspection and verification activities and results?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
251	Do you use records to show that all input inspections and verifications were completed?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

5.4.2 ASSESS THE METHODS USED TO CONTROL SYSTEM OUTPUTS

252	Do you use authorized methods to control output design and development activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
253	Do you control how output design and development results are defined?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
254	Do you control how output design and development reviews are carried out?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
255	Do you ask representatives from all relevant functions to participate in reviews?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
256	Do you include people concerned with the design and development stage under review?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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257	Do you evaluate how well design and development results meet requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
258	Do you control actions taken to address problems identified during reviews?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
259	Do you control how output design and development verifications are performed?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
260	Do you verify that design and development outputs meet input requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
261	Do you control actions taken to address problems identified during verifications?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
262	Do you control how output design and development validations are performed?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
263	Do you confirm that your outputs meet intended use requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
264	Do you verify that all intended use or application requirements are being met?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
265	Do you control actions taken to address problems identified during validations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
266	Do you reverify your outputs if changes occur that invalidate previous results?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
267	Do you control how output design and development progression is authorized?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
268	Do you control progression to the next stage of output design and development?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
269	Do you control how output design and development work is being documented?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
270	Do you control output design and development documents and records?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
271	Do you use authorized methods to control outputs while system is operating?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
272	Do you establish suitable means and methods for identifying system outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
273	Do you specify the identity of outputs whenever conformity must be ensured?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
274	Do you identify outputs whenever output conformity must be ensured?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
275	Do you establish the specific identity of your output configurations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
276	Do you specify the unique identity of all required output configurations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
277	Do you specify the unique identity of all actual output configurations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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278	Do you maintain the unique identity of your output configurations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
279	Do you determine differences between required and actual configurations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
280	Do you identify the monitoring and measurement status of system outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
281	Do you record the unique identity of outputs when traceability is a requirement?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
282	Do you clarify your organization's unique output traceability requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
283	Do you consider whether identities must be maintained throughout output life cycle?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
284	Do you consider whether or not you need to be able to trace outputs generated from the same inputs to the final destination?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
285	Do you consider whether or not you need to maintain a sequential production record for your outputs so that they can be retrieved?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
286	Do you consider whether or not you need to maintain a sequential assembly record?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
287	Do you consider whether or not you need to maintain a sequential inspection record?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
288	Do you consider whether or not you need to maintain a sequential verification record?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
289	Do you consider whether or not you need to maintain a sequential manufacturing record?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
290	Do you consider whether components need to be traceable to final assemblies?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
291	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?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
292	Do you retain the documents and records that are needed to facilitate traceability?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
293	Do you verify that input items, characteristics, and activities are being controlled?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
294	Do you verify that "critical items" and "key characteristics" are being controlled?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
295	Do you control identified "critical items" in accordance with established methods?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
296	Do you control "key characteristics" in accordance with established methods?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
297	Do you verify that inputs being used in the management system are being controlled?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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5. ASSESS QMS CONTROL MANAGEMENT PROCESS

298	Do you identify and record purchased products (inputs) that are released for use in your system whenever verification activities have not yet been completed?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
299	Do you use your records to recall and replace purchased products (inputs) that have been used but do not actually meet requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
300	Do you verify that all inspection and verification activities have been completed?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
301	Do you maintain a record of your inspection and verification activities and results?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
302	Do you use records to show that all inspections and verifications were completed?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
303	Do you use authorized methods to control how outputs are released?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
304	Do you verify acceptance before outputs are officially released?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
305	Do you implement arrangements to verify your system outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
306	Do you verify that output requirements are met at all appropriate stages?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
307	Do you retain evidence that shows that output acceptance criteria were met?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
308	Do you retain evidence that shows that your output meets defined requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
309	Do you identify the people who may authorize the release of outputs to system customers?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
310	Do you retain and control records to facilitate the traceability of output releases?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
311	Do you release outputs only if verifications are finished or if authorized to do so?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
312	Do you release output to system customers only if planned arrangements were completed or the customer or a relevant authority allows you to do so?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
313	Do you release outputs only if all the documents and records that should accompany output delivery are, in fact, present at delivery?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
314	Do you establish a record of your output acceptance activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
315	Do you document your criteria for output acceptance and rejection?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
316	Do you document where in the sequence output verification is performed?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
317	Do you document and retain your output monitoring and measuring results?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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318	Do you maintain a record of output acceptance and rejection activities?	Y	N	X	
319	Do you document how output monitoring and measuring must be carried out?	Y	N	X	
320	Do you document all required output monitoring and measuring instructions?	Y	N	X	
321	Do you document all required output monitoring and measuring equipment?	Y	N	X	

5.4.3 ASSESS THE METHODS USED TO CONTROL SYSTEM ACTIVITIES

322	Do you use authorized methods to control normal system activities?	Y	N	X	
323	Do you use authorized methods to control system control activities?	Y	N	X	
324	Do you use authorized methods to control system management activities?	Y	N	X	
325	Do you use authorized methods to control system maintenance activities?	Y	N	X	
326	Do you use authorized methods to control system measurement activities?	Y	N	X	
327	Do you use authorized methods to control system monitoring activities?	Y	N	X	
328	Do you use authorized methods to control system evaluation activities?	Y	N	X	
329	Do you use authorized methods to control system audit activities?	Y	N	X	
330	Do you use authorized methods to control system review activities?	Y	N	X	
331	Do you use authorized methods to control system change activities?	Y	N	X	
332	Do you use authorized methods to control system correction activities?	Y	N	X	
333	Do you use authorized methods to control system improvement activities?	Y	N	X	
334	Do you use authorized methods to control “special process” activities?	Y	N	X	
335	Do you establish methods for managing “special process” activities?	Y	N	X	
336	Do you validate “special process” activities and results?	Y	N	X	
337	Do you validate your ability to achieve planned results whenever outputs cannot be verified by subsequent monitoring or measurement?	Y	N	X	

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338	Do you identify in-process inspection and verification points whenever adequate verification of conformity cannot be performed at subsequent stages?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
339	Do you control "special process" activities and results?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
340	Do you make arrangements to control special process activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
341	Do you use criteria to control your special process activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
342	Do you use criteria to control how special activities are reviewed?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
343	Do you use criteria to control how all special activities are approved?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
344	Do you use approvals to control your special process activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
345	Do you approve equipment before it is used by special process activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
346	Do you approve facilities before they are used by special process activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
347	Do you approve personnel before they are assigned to special process activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
348	Do you approve their qualifications before assigning them to special process activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
349	Do you use procedures to control your special process activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
350	Do you follow specific procedures when implementing special process activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
351	Do you follow specific procedures when maintaining special process activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
352	Do you follow specific procedures when monitoring special process activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
353	Do you follow specific procedures when measuring special process activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
354	Do you follow specific procedures when controlling special process activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
355	Do you use methods to control your special process activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
356	Do you follow specific methods when implementing special process activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
357	Do you follow specific methods when maintaining special process activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
358	Do you follow specific methods when monitoring special process activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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359	Do you follow specific methods when measuring special process activities?	Y	N	X	
360	Do you follow specific methods when controlling special process activities?	Y	N	X	
361	Do you use documents to control your special process activities?	Y	N	X	
362	Do you specify retention requirements for these documents?	Y	N	X	
363	Do you use records to control your special process activities?	Y	N	X	
364	Do you specify retention requirements for these records?	Y	N	X	

5.4.4 ASSESS THE METHODS USED TO CONTROL SYSTEM TECHNOLOGY

365	Do you use authorized methods to control system equipment, tools, and software?	Y	N	X	
366	Do you validate technology prior to final release for system operations?	Y	N	X	
367	Do you validate technology that is used to perform system operations?	Y	N	X	
368	Do you validate tools before they are used to perform system operations?	Y	N	X	
369	Do you validate equipment before it is used to perform system operations?	Y	N	X	
370	Do you validate software before it is used to perform system operations?	Y	N	X	
371	Do you validate technology that is used to automate system operations?	Y	N	X	
372	Do you validate tools before they are used to automate system operations?	Y	N	X	
373	Do you validate equipment before it is used to automate system operations?	Y	N	X	
374	Do you validate software before it is used to automate system operations?	Y	N	X	
375	Do you validate technology that is used to maintain system operations?	Y	N	X	
376	Do you validate tools before they are used to maintain system operations?	Y	N	X	
377	Do you validate equipment before it is used to maintain system operations?	Y	N	X	
378	Do you validate software before it is used to maintain system operations?	Y	N	X	
379	Do you validate technology that is used to monitor system operations?	Y	N	X	

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5. ASSESS QMS CONTROL MANAGEMENT PROCESS

380	Do you validate tools before they are used to monitor system operations?	Y	N	X	
381	Do you validate equipment before it is used to monitor system operations?	Y	N	X	
382	Do you validate software before it is used to monitor system operations?	Y	N	X	
383	Do you validate technology that is used to measure system operations?	Y	N	X	
384	Do you validate tools before they are used to measure system operations?	Y	N	X	
385	Do you validate equipment before it is used to measure system operations?	Y	N	X	
386	Do you validate software before it is used to measure system operations?	Y	N	X	
387	Do you validate technology that is used to control system operations?	Y	N	X	
388	Do you validate tools before they are used to control system operations?	Y	N	X	
389	Do you validate equipment before it is used to control system operations?	Y	N	X	
390	Do you validate software before it is used to control system operations?	Y	N	X	

5.4.5 ASSESS THE METHODS USED TO CONTROL SYSTEM PERFORMANCE

391	Do you use authorized methods to control internal personnel?	Y	N	X	
392	Do you identify the people who can affect system performance?	Y	N	X	
393	Do you qualify the people who can affect system performance?	Y	N	X	
394	Do you ensure that they have the competence they need?	Y	N	X	
395	Do you ensure that they have the appropriate training?	Y	N	X	
396	Do you ensure that they have the appropriate education?	Y	N	X	
397	Do you ensure that they have the appropriate experience?	Y	N	X	
398	Do you supervise the people who can affect system performance?	Y	N	X	
399	Do you use authorized methods to control external providers?	Y	N	X	

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5. ASSESS QMS CONTROL MANAGEMENT PROCESS

400	Do you establish control of all externally provided processes, products, and services?	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> X	
401	Do you ensure that external processes, products, and services meet requirements?	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> X	
402	Do you ensure that externally provided products and services meet requirements if they are incorporated into your system outputs?	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
403	Do you ensure that externally provided products and services meet requirements if external providers deliver them directly to your system customers?	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
404	Do you ensure that externally provided processes and functions meet requirements?	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
405	Do you ensure that outsourced parts of processes and functions meet requirements?	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
406	Do you control the use of externally provided processes, products, and services?	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
407	Do you use customer-designated or customer-approved external providers if required?	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
408	Do you use customer-designated or customer-approved external system sources?	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
409	Do you use customer-designated or customer-approved "special processes"?	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
410	Do you manage risks associated with the selection and use of external providers?	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
411	Do you manage risks related to externally provided processes, products, and services?	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
412	Do you tell external providers to control their direct and sub-tier external providers?	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
413	Do you tell your providers to ensure that their own providers meet requirements?	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
414	Do you perform external process, product, and service verification activities?	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
415	Do you carry out product inspections and service verifications upon receipt?	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
416	Do you carry out periodic inspections and audits at external provider's premises?	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
417	Do you accept external processes, products, and services only if they meet requirements?	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
418	Do you complete verifications before processes, products, and services are accepted?	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
419	Do you complete all verifications before accepting products for use in production?	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
420	Do you identify externally provided products that were released for use in production?	<input checked="" type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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421		Do you record externally provided products that have been released for use in production pending completion of required verification activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
422		Do you recall and replace product if it subsequently fails to meet requirements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

5.4.6 ASSESS THE METHODS USED TO CONTROL SYSTEM DOCUMENTATION

423	Do you use authorized methods to control how documented information is controlled?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
424	Do you control how management system documents and records are created?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
425	Do you ensure that system documents and records are suitable for use?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
426	Do you ensure that documents and records are properly identified?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
427	Do you ensure that they have the right names and descriptive titles?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
428	Do you ensure that they have the right dates and reference numbers?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
429	Do you ensure that documents and records are properly formatted?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
430	Do you ensure that system documents and records use the appropriate media?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
431	Do you ensure that system documents and records use the appropriate graphics?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
432	Do you ensure that system documents and records use the appropriate language?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
433	Do you ensure that system documents and records use the appropriate software?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
434	Do you control how system documents and records are identified and described?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
435	Do you control how internal documents and records are identified and described?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
436	Do you control how external documents and records are identified and described?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
437	Do you control how system documents and records are distributed?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
438	Do you control how system documents and records are stored?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
439	Do you control how system documents and records are retrieved?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
440	Do you control how system documents and records are accessed?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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441	Do you prevent unauthorized access to system documents and records?	Y	N	X	
442	Do you ensure that documents and records are available for use where needed?	Y	N	X	
443	Do you ensure that documents and records are available for use when needed?	Y	N	X	
444	Do you control how system documents and records are used?	Y	N	X	
445	Do you control how active system documents and records are used?	Y	N	X	
446	Do you control how documents and records are used to plan your system?	Y	N	X	
447	Do you control how internal documents and records are used to plan your system?	Y	N	X	
448	Do you control how external documents and records are used to plan your system?	Y	N	X	
449	Do you control how documents and records are used to operate your system?	Y	N	X	
450	Do you control how internal documents and records are used to operate system?	Y	N	X	
451	Do you control how external documents and records are used to operate system?	Y	N	X	
452	Do you control how documents and records are used to implement your system?	Y	N	X	
453	Do you control how internal documents and records are used to implement system?	Y	N	X	
454	Do you control how external documents and records are used to implement system?	Y	N	X	
455	Do you control how documents and records are used to maintain your system?	Y	N	X	
456	Do you control how internal documents and records are used to maintain system?	Y	N	X	
457	Do you control how external documents and records are used to maintain system?	Y	N	X	
458	Do you control how documents and records are used to monitor your system?	Y	N	X	
459	Do you control how internal documents and records are used to monitor system?	Y	N	X	
460	Do you control how external documents and records are used to monitor system?	Y	N	X	
461	Do you control how documents and records are used to measure your system?	Y	N	X	
462	Do you control how internal documents and records are used to measure system?	Y	N	X	

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463	Do you control how external documents and records are used to measure system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
464	Do you control how documents and records are used to control your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
465	Do you control how internal documents and records are used to control system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
466	Do you control how external documents and records are used to control system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
467	Do you control how documents and records are used to evaluate your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
468	Do you control how documents and records are used to audit your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
469	Do you control how internal documents and records are used to audit system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
470	Do you control how external documents and records are used to audit system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
471	Do you control how documents and records are used to review your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
472	Do you control how internal documents and records are used to review system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
473	Do you control how external documents and records are used to review system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
474	Do you control how documents and records are used to change your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
475	Do you control how documents and records are used to correct your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
476	Do you control how internal documents and records are used to correct system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
477	Do you control how external documents and records are used to correct system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
478	Do you control how documents and records are used to improve your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
479	Do you control how internal documents and records are used to improve system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
480	Do you control how external documents and records are used to improve system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
481	Do you control how inactive system documents and records are used?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
482	Do you control how obsolete system documents and records are used?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
483	Do you prevent the unintended use of obsolete documents and records?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
484	Do you identify obsolete management system documents and records?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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5. ASSESS QMS CONTROL MANAGEMENT PROCESS

485	Do you control obsolete management system documents and records?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
486	Do you remove obsolete management system documents and records?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
487	Do you control how system documents and records are protected?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
488	Do you control how paper documents and records are protected?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
489	Do you ensure that paper documents and records are protected?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
490	Do you protect the integrity of your paper documents and records?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
491	Do you prevent unauthorized use of paper documents and records?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
492	Do you protect the confidentiality of paper documents and records?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
493	Do you protect the legibility of paper documents and records?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
494	Do you control how electronic documents and records are protected?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
495	Do you ensure that electronic documents and records are protected?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
496	Do you define and develop suitable data protection methods?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
497	Do you protect system documents and records from loss?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
498	Do you protect system documents and records from corruption?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
499	Do you protect system documents and records from physical damage?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
500	Do you protect system documents and records from unauthorized access?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
501	Do you protect system documents and records from unintended alteration?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
502	Do you protect system documents and records from inappropriate changes?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
503	Do you control how system documents and records are changed?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
504	Do you control how paper documents and records are changed?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
505	Do you control how electronic documents and records are changed?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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5. ASSESS QMS CONTROL MANAGEMENT PROCESS

506	Do you control how system documents and records are preserved?	Y	N	X	
507	Do you control the retention of documents and records?	Y	N	X	
508	Do you control the disposal of documents and records?	Y	N	X	
509	Do you use authorized methods to control system documents and records?	Y	N	X	
510	Do you control all the internal documents and records that your system needs?	Y	N	X	
511	Do you control information that your system needs in order to be effective?	Y	N	X	
512	Do you control all the documents and records needed to operate your system?	Y	N	X	
513	Do you control all the documents and records used to facilitate system operations?	Y	N	X	
514	Do you control all the documents and records used to facilitate output compliance?	Y	N	X	
515	Do you control all the documents and records needed to maintain your system?	Y	N	X	
516	Do you control all the documents and records used to maintain system operations?	Y	N	X	
517	Do you control all the documents and records used to maintain output compliance?	Y	N	X	
518	Do you control all the documents and records needed to monitor your system?	Y	N	X	
519	Do you control all the documents and records used to monitor system operations?	Y	N	X	
520	Do you control all the documents and records used to monitor output compliance?	Y	N	X	
521	Do you control all the documents and records needed to measure your system?	Y	N	X	
522	Do you control all the documents and records used to measure system operations?	Y	N	X	
523	Do you control all the documents and records used to measure output compliance?	Y	N	X	
524	Do you control all the documents and records needed to control your system?	Y	N	X	
525	Do you control all the documents and records used to control system operations?	Y	N	X	
526	Do you control all the documents and records used to control output compliance?	Y	N	X	

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527	Do you control all the documents and records needed to evaluate your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
528	Do you control all the documents and records needed to audit your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
529	Do you control all the documents and records used to audit system operations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
530	Do you control all the documents and records used to audit output compliance?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
531	Do you control all the documents and records needed to review your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
532	Do you control all the documents and records used to review system operations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
533	Do you control all the documents and records used to review output compliance?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
534	Do you control all the documents and records needed to modify your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
535	Do you control all the documents and records needed to correct your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
536	Do you control all the documents and records used to correct system operations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
537	Do you control all the documents and records used to correct output compliance?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
538	Do you control all the documents and records needed to improve your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
539	Do you control all the documents and records used to improve system operations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
540	Do you control all the documents and records used to improve output compliance?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
541	Do you control all the external documents and records that your system needs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
542	Do you control all external documented information needed in order to plan system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
543	Do you control all external documented information needed in order to operate system?	<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 system. 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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6. ASSESS QMS EVALUATION MANAGEMENT PROCESS

6.1 ASSESS HOW WELL EVALUTION ACTIVITIES ARE BEING PLANNED

6.1.1 ASSESS HOW WELL AUDIT ACTIVITIES ARE BEING PLANNED

1	Did you develop an internal audit programme?	Y	N	X	
2	Do you develop a programme that can find out if your system meets requirements?	Y	N	X	
3	Do you ensure it can determine how well your system meets corporate expectations?	Y	N	X	
4	Do you ensure it can determine how well your system meets international standards?	Y	N	X	
5	Do you develop a programme that can determine if your system is actually effective?	Y	N	X	
6	Do you ensure 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 auditors demonstrate that they are free from bias?	Y	N	X	
12	Do auditors show that they can ignore external influences?	Y	N	X	
13	Do you specify internal audit planning requirements?	Y	N	X	
14	Do auditors consider the results of previous audits?	Y	N	X	
15	Do auditors consider the impact proposed changes could have?	Y	N	X	
16	Do auditors consider the importance of the processes being audited?	Y	N	X	
17	Do you define internal audit reporting requirements?	Y	N	X	
18	Do auditors report results to management?	Y	N	X	
19	Do you formulate internal audit schedules?	Y	N	X	
20	Do you ensure that audits are done at planned intervals?	Y	N	X	

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6. ASSESS QMS EVALUATION MANAGEMENT PROCESS

6.1.2 ASSESS HOW WELL ANALYTICAL ACTIVITIES ARE BEING PLANNED

21	Do you plan how you're going to analyze the opinions and satisfaction of system 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 system 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 system planning?	Y	N	X	
28	Do you plan how you're going to determine if plans were 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 you're going to analyze the effectiveness of actions taken to address risks?	Y	N	X	
31	Do you plan how you're going 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 system?	Y	N	X	
33	Do you plan how you're going to use your analytical results to evaluate conformance?	Y	N	X	
34	Do you plan how you're going to analyze the conformity of management system outputs?	Y	N	X	
35	Do you plan how you're going to analyze your management system output problems?	Y	N	X	
36	Do you plan how you're going to analyze output problems reported by external sources?	Y	N	X	
37	Do you plan how you're going to analyze output problems reported using advisories?	Y	N	X	
38	Do you plan how you're going to analyze output problems reported by means of alerts?	Y	N	X	
39	Do you plan how you're going to analyze problems reported by means of industry alerts?	Y	N	X	
40	Do you plan how you're going to analyze problems reported by means of government alerts?	Y	N	X	

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6. ASSESS QMS EVALUATION MANAGEMENT PROCESS

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

6.1.3 ASSESS HOW WELL REVIEW ACTIVITIES ARE BEING PLANNED

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

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6. ASSESS QMS EVALUATION MANAGEMENT PROCESS

6.2 ASSESS HOW WELL RESOURCES ARE USED TO EVALUATE SYSTEM

6.2.1 ASSESS THE PERSONNEL USED TO EVALUATE YOUR SYSTEM

61	Do you provide the people that you need in order to audit your system?	Y	N	X	
62	Do you provide the people that you need in order to analyze your system?	Y	N	X	
63	Do you provide the people that you need in order to review your system?	Y	N	X	

6.2.2 ASSESS THE KNOWLEDGE USED TO EVALUATE YOUR SYSTEM

64	Do you provide the knowledge that you need in order to audit your system?	Y	N	X	
65	Do you provide the knowledge that you need in order to analyze your system?	Y	N	X	
66	Do you provide the knowledge that you need in order to review your system?	Y	N	X	

6.2.3 ASSESS THE TECHNOLOGY USED TO EVALUATE YOUR SYSTEM

67	Do you provide the technology that you need in order to audit your system?	Y	N	X	
68	Do you provide the technology that you need in order to analyze your system?	Y	N	X	
69	Do you provide the technology that you need in order to review your system?	Y	N	X	

6.2.4 ASSESS THE INFRASTRUCTURE USED TO EVALUATE YOUR SYSTEM

70	Do you provide the infrastructure that you need in order to audit your system?	Y	N	X	
71	Do you provide the infrastructure that you need in order to analyze your system?	Y	N	X	
72	Do you provide the infrastructure that you need in order to review your system?	Y	N	X	

6.3 ASSESS HOW WELL MANAGEMENT SYSTEM IS BEING EVALUATED

6.3.1 ASSESS THE METHODS USED TO AUDIT YOUR SYSTEM

73	Do you use authorized methods to plan your internal audit activities?	Y	N	X	
74	Do you define the scope for each internal management system audit?	Y	N	X	
75	Do you specify audit criteria for each internal management system audit?	Y	N	X	

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

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

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6. ASSESS QMS EVALUATION MANAGEMENT PROCESS

118	Do you retain your internal audit results and control these results?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
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6.3.2 ASSESS THE METHODS USED TO ANALYZE YOUR SYSTEM

119	Do you use authorized methods to analyze the opinions of customers?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
120	Do you use your analytical results to evaluate customer satisfaction?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
121	Do you evaluate the degree of customer satisfaction?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
122	Do you use authorized methods to analyze system performance?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
123	Do you use your results to analyze conformance?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
124	Do you analyze the conformity of system outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
125	Do you analyze management system output problems?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
126	Do you analyze output problems reported by external sources?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
127	Do you analyze output problems reported using advisories?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
128	Do you analyze output problems reported by means of alerts?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
129	Do you analyze problems reported by means of industry alerts?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
130	Do you analyze problems reported by means of government alerts?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
131	Do you analyze output problems revealed by internal sources?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
132	Do you use your results to analyze effectiveness?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
133	Do you analyze the effectiveness of management system operations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
134	Do you determine if you need to improve its system effectiveness?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
135	Do you use authorized methods to analyze the effectiveness of your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
136	Do you use your results to analyze management system effectiveness?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
137	Do you analyze the effectiveness of management system operations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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138	Do you determine if you need to improve management system operations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
139	Do you analyze the effectiveness of management system maintenance?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
140	Do you determine if you need to improve management system maintenance?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
141	Do you analyze the effectiveness of management system monitoring?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
142	Do you determine if you need to improve management system monitoring?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
143	Do you analyze the effectiveness of management system measurement?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
144	Do you determine if you need to improve management system measurement?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
145	Do you analyze the effectiveness of management system evaluations?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
146	Do you analyze the effectiveness of management system audits?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
147	Do you determine if you need to improve management system audits?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
148	Do you analyze the effectiveness of management system reviews?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
149	Do you determine if you need to improve management system reviews?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
150	Do you analyze the effectiveness of management system changes?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
151	Do you analyze the effectiveness of management system corrections?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
152	Do you determine if you need to improve system correction activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
153	Do you analyze the effectiveness of management system improvements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
154	Do you determine if you need to improve system improvement activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
155	Do you use your results to analyze management system management?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
156	Do you analyze the effectiveness of actions taken by managers?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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157	Do you analyze the effectiveness of actions taken to address system risks?	Y	N	X	
158	Do you analyze the effectiveness of actions taken to address system opportunities?	Y	N	X	
159	Do you analyze the effectiveness of actions taken to address system nonconformities?	Y	N	X	
160	Do you analyze the effectiveness of actions taken to address system performance problems?	Y	N	X	
161	Do you use authorized methods to analyze the competence of system participants?	Y	N	X	
162	Do you analyze the competence and performance of system 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 system, 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	

6.3.3 ASSESS THE METHODS USED TO REVIEW YOUR SYSTEM

169	Do you use authorized methods to review the performance of your system?	Y	N	X	
170	Do you review your management system nonconformities?	Y	N	X	
171	Do you review management system 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	

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176	Do you use customer complaints to review customer satisfaction?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
177	Do you review the performance of management system personnel?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
178	Do you review how well objectives are being met?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
179	Do you review the competence of system personnel?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
180	Do you review system management activities and results?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
181	Do you review system control methods and results?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
182	Do you review system operations methods and results?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
183	Do you review system monitoring methods and results?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
184	Do you review system measurement methods and results?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
185	Do you review system maintenance methods and results?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
186	Do you review system evaluation methods and results?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
187	Do you review system audit activities and results?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
188	Do you review system analysis activities and results?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
189	Do you review system modification methods and results?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
190	Do you review actual management system modifications?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
191	Do you review actions taken to modify management system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
192	Do you review the effectiveness of actions taken to improve system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
193	Do you review the effectiveness of corrective and preventive actions?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
194	Do you review corrective actions taken to address system nonconformities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
195	Do you review preventive actions taken to address system nonconformities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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196	Do you review potential management system changes?	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 management system 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 management system 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	
205	Do you review verifications whenever they are delegated to external providers?	Y	N	X	
206	Do you review the issues that could influence management system 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 management system resources?	Y	N	X	
210	Do you generate suitable management system review outputs?	Y	N	X	

6.4 ASSESS HOW WELL EVALUATION ACTIVITIES ARE BEING RECORDED

6.4.1 ASSESS HOW WELL SYSTEM AUDITS ARE BEING RECORDED

211	Do you record your management system audit activities and results?	Y	N	X	
212	Do you maintain your quality management system audit records?	Y	N	X	
213	Do you control your quality management system audit records?	Y	N	X	

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6. ASSESS QMS EVALUATION MANAGEMENT PROCESS

6.4.2 ASSESS HOW WELL SYSTEM ANALYSES ARE BEING RECORDED

214	Do you record your management system analysis activities and results?	Y	N	X	
215	Do you maintain your quality management system analysis records?	Y	N	X	
216	Do you control your quality management system analysis records?	Y	N	X	

6.4.3 ASSESS HOW WELL SYSTEM REVIEWS ARE BEING RECORDED

217	Do you record your management system review activities and results?	Y	N	X	
218	Do you maintain your quality management system review records?	Y	N	X	
219	Do you control your quality management system 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 system. 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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7. ASSESS QMS CHANGE MANAGEMENT PROCESS

7.1 ASSESS HOW WELL SYSTEMIC CHANGE IS BEING MANAGED

7.1.1 ASSESS THE METHODS USED TO MANAGE SYSTEMIC CORRECTIONS

1	Do you establish appropriate corrective action methods and procedures?	Y	N	X	
2	Do you document your system's 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 and procedures?	Y	N	X	
5	Do you figure out how you're going to record the actions taken to correct system and outputs?	Y	N	X	
6	Do you figure out how you're going to record the system and output corrections that are made?	Y	N	X	

7.1.2 ASSESS THE METHODS USED TO MANAGE SYSTEMIC IMPROVEMENTS

7	Do you establish appropriate system and output improvement methods and procedures?	Y	N	X	
8	Do you document your system and output improvement methods and procedures?	Y	N	X	
9	Do you maintain documents describing system and output improvement methods and procedures?	Y	N	X	
10	Do you establish appropriate system and output improvement record keeping methods?	Y	N	X	
11	Do you figure out how you're going to record the actions taken to improve system and outputs?	Y	N	X	
12	Do you figure out how you're going to record the system and output improvements that are made?	Y	N	X	

7.2 ASSESS HOW WELL CHANGE OPPORTUNITIES ARE IDENTIFIED

7.2.1 ASSESS THE METHODS USED TO DISCOVER OPPORTUNITIES TO CHANGE SYSTEM

13	Do you discover opportunities to correct your management system and 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	

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7. ASSESS QMS CHANGE MANAGEMENT PROCESS

17	Do you discover opportunities to make corrections by examining lessons learned?	Y	N	X	
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 management system and outputs?	Y	N	X	
21	Do you discover systemic improvement opportunities by examining audit reports?	Y	N	X	
22	Do you discover systemic improvement opportunities by examining review results?	Y	N	X	
23	Do you discover systemic improvement opportunities by examining best practices?	Y	N	X	
24	Do you discover systemic improvement opportunities by examining lessons learned?	Y	N	X	
25	Do you discover systemic improvement opportunities by examining nonconformities?	Y	N	X	
26	Do you discover systemic improvement opportunities by examining customer feedback?	Y	N	X	

7.2.2 ASSESS THE METHODS USED TO CONFIRM THAT CHANGES ARE ACTUALLY NEEDED

27	Do you confirm that proposed management system modifications are necessary?	Y	N	X	
28	Do you confirm that proposed management system modifications would be feasible?	Y	N	X	
29	Do you confirm that proposed management system modifications would be appropriate?	Y	N	X	
30	Do you confirm that proposed management system modifications would be effective?	Y	N	X	
31	Do you confirm that proposed management system modifications would be cost-effective?	Y	N	X	
32	Do you confirm that proposed management system output modifications would be necessary?	Y	N	X	
33	Do you confirm that proposed management system output modifications would be feasible?	Y	N	X	
34	Do you confirm that proposed management system output modifications would be appropriate?	Y	N	X	
35	Do you confirm that proposed management system output modifications would be effective?	Y	N	X	
36	Do you confirm that proposed management system output modifications would be cost-effective?	Y	N	X	

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7. ASSESS QMS CHANGE MANAGEMENT PROCESS

7.2.3 ASSESS THE METHODS USED TO APPROVE OPPORTUNITIES TO CHANGE SYSTEM

37	Do you authorize proposed management system corrections and improvements?	Y	N	X	
38	Do you authorize proposed management output corrections and improvements?	Y	N	X	

7.3 ASSESS HOW WELL SYSTEMATIC CHANGES ARE BEING PLANNED

7.3.1 ASSESS THE METHODS USED TO PLAN SYSTEMIC CORRECTIONS

39	Do you plan how you're going to apply your corrective action methods and procedures?	Y	N	X	
40	Do you plan how you're going to react to your system and output nonconformities?	Y	N	X	
41	Do you plan how you're going to control and correct system and output nonconformities?	Y	N	X	
42	Do you plan how you're going to deal with all relevant effects and consequences?	Y	N	X	
43	Do you plan how you're going to document your corrective action activities and results?	Y	N	X	
44	Do you plan how you're going to document the actions taken and the results achieved?	Y	N	X	
45	Do you plan how you're going to retain and control your record of actions and results?	Y	N	X	
46	Do you plan how you're going to evaluate the need to eliminate causes?	Y	N	X	
47	Do you plan how you're going to review and analyze the nonconformity?	Y	N	X	
48	Do you plan how you're going to determine the causes of the nonconformity?	Y	N	X	
49	Do you plan how to determine if human factors are responsible for the nonconformity?	Y	N	X	
50	Do you plan how to determine if external providers are responsible for the nonconformity?	Y	N	X	
51	Do you plan how to flow down corrective action requirements to your external providers?	Y	N	X	
52	Do you plan how you're going to decide if corrective action should be taken?	Y	N	X	
53	Do you plan how you're going to develop corrective actions to address causes?	Y	N	X	
54	Do you plan how you're going to make sure that your actions are feasible?	Y	N	X	

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7. ASSESS QMS CHANGE MANAGEMENT PROCESS

55	Do you plan how you're going to make sure that your actions are appropriate?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
56	Do you plan how you're going to make sure that actions consider consequences?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
57	Do you plan how you're going to make sure that your actions are effective?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
58	Do you plan how you're going to make sure that your actions are cost-effective?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
59	Do you plan how you're going to get managers to authorize corrective action?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
60	Do you plan how you're going to submit corrective action requests?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
61	Do you plan how you're going to take corrective actions to deal with causes?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
62	Do you plan how you're going to correct your system and its outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
63	Do you plan how you're going to review the effectiveness of corrective actions?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
64	Do you plan how you're going to respond when correction actions aren't taken?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
65	Do you plan how you're going to update your list of system and output risks?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

7.3.2 ASSESS THE METHODS USED TO PLAN SYSTEMIC IMPROVEMENTS

66	Do you plan improvements and other changes to your management system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
67	Do you identify people authorized to approve changes in your system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
68	Do you use your system purpose and scope to guide system improvements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
69	Do you use system policy statements to guide system improvements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
70	Do you use your quality policy to guide your system improvements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
71	Do you use your quality objectives to guide system improvements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
72	Do you use your privacy policy to guide your system improvements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
73	Do you use your privacy objectives to guide system improvements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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7. ASSESS QMS CHANGE MANAGEMENT PROCESS

74	Do you use your safety policy to guide your system improvements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
75	Do you use your safety objectives to guide system improvements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
76	Do you use your security policy to guide your system improvements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
77	Do you use your security objectives to guide system improvements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
78	Do you use your business continuity policy to guide your system improvements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
79	Do you use your business continuity objectives to guide system improvements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
80	Do you consider improvements and other changes to your management system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
81	Do you consider the purpose and effects of the changes you intend to make?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
82	Do you consider responsibilities and authorities whenever you make changes?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
83	Do you consider allocating or reallocating responsibilities and authorities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
84	Do you consider the consequences that changes could potentially produce?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
85	Do you consider the availability of resources whenever you make changes?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
86	Do you consider the integrity of your system whenever you make changes?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
87	Do you figure out how you're going to control changes in your management system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
88	Do you ensure that system continues to meet requirements even though changes are being made?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
89	Do you plan improvements and other changes to management system outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
90	Do you identify people authorized to approve changes in system outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
91	Do you use your system purpose and scope to guide output improvements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
92	Do you use system policy statements to guide system improvements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
93	Do you use your quality policy to guide your output improvements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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7. ASSESS QMS CHANGE MANAGEMENT PROCESS

94	Do you use your quality objectives to guide output improvements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
95	Do you use your privacy policy to guide your output improvements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
96	Do you use your privacy objectives to guide output improvements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
97	Do you use your safety policy to guide your output improvements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
98	Do you use your safety objectives to guide output improvements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
99	Do you use your security policy to guide your output improvements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
100	Do you use your security objectives to guide output improvements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
101	Do you use your business continuity policy to guide your output improvements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
102	Do you use your business continuity objectives to guide output improvements?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
103	Do you consider improvements and other changes to management system outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
104	Do you consider the purpose and effects of the output changes you intend to make?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
105	Do you consider responsibilities and authorities whenever you make output changes?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
106	Do you consider the consequences that output changes could potentially produce?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
107	Do you consider the availability of resources whenever you make output changes?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
108	Do you consider the integrity of your outputs whenever you make changes?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
109	Do you figure out how you're going to control changes in your system's outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
110	Do you ensure that outputs continue to meet requirements even though changes are being made?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

7.4 ASSESS HOW WELL MANAGEMENT SYSTEM IS BEING CHANGED

7.4.1 ASSESS THE METHODS USED TO CORRECT MANAGEMENT SYSTEM

111	Do you apply your corrective action methods and procedures?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
112	Do you evaluate the need to eliminate causes of nonconformity?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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7. ASSESS QMS CHANGE MANAGEMENT PROCESS

113	Do you review and analyze your system and output nonconformities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
114	Do you determine the causes of system and output nonconformities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
115	Do you determine if human factors are responsible for the nonconformity?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
116	Do you determine if external providers are responsible for the nonconformity?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
117	Do you flow down corrective action requirements to your external providers?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
118	Do you decide if the causes of system or output nonconformity must be addressed?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
119	Do you develop corrective actions to address causes of nonconformity?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
120	Do you ensure that your corrective actions are feasible?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
121	Do you ensure that your corrective actions are appropriate?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
122	Do you ensure that actions also consider effects?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
123	Do you ensure that your corrective actions are effective?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
124	Do you ensure that your corrective actions are cost-effective?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
125	Do you take corrective action to address the causes of nonconformity?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
126	Do you provide the resources needed to correct system and outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
127	Do you provide suitable resources needed to correct system outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
128	Do you provide suitable resources needed to correct system activities?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
129	Do you control your corrective action activities and results?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
130	Do you monitor your corrective action activities and results?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
131	Do you record your corrective action activities and results?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
132	Do you document the actions taken and the results achieved?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
133	Do you retain and control your record of corrective actions taken?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

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7. ASSESS QMS CHANGE MANAGEMENT PROCESS

7.4.2 ASSESS THE METHODS USED TO IMPROVE MANAGEMENT SYSTEM

134	Do you apply system and output improvement methods and procedures?	Y	N	X	
135	Do you evaluate the need to make system and output improvements?	Y	N	X	
136	Do you provide the resources needed to make system and output improvements?	Y	N	X	
137	Do you provide suitable resources needed to improve your system outputs?	Y	N	X	
138	Do you provide suitable resources needed to improve your system activities?	Y	N	X	
139	Do you develop improvements to your system and system outputs?	Y	N	X	
140	Do you ensure that your system and output improvements are feasible?	Y	N	X	
141	Do you ensure that your system and output improvements are appropriate?	Y	N	X	
142	Do you ensure that system and output improvements also consider effects?	Y	N	X	
143	Do you ensure that your system and output improvements are effective?	Y	N	X	
144	Do you ensure that your system and output improvements are cost-effective?	Y	N	X	
145	Do you implement improvements to your management system and system outputs?	Y	N	X	
146	Do you improve the suitability, adequacy, and effectiveness of your management system?	Y	N	X	
147	Do you improve the quality, safety, privacy, and security of management system outputs?	Y	N	X	
148	Do you control improvements to your management system and system outputs?	Y	N	X	
149	Do you control improvements and other changes affecting system software?	Y	N	X	
150	Do you control improvements and other changes affecting system operations?	Y	N	X	
151	Do you control improvements and other changes affecting system equipment?	Y	N	X	
152	Do you control improvements and other changes affecting system tools?	Y	N	X	
153	Do you monitor improvements to your management system and system outputs?	Y	N	X	
154	Do you monitor the implementation of system and output improvement activities?	Y	N	X	

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7. ASSESS QMS CHANGE MANAGEMENT PROCESS

155	Do you record improvements to your management system and system outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
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7.5 ASSESS HOW WELL CHANGES ARE REVIEWED AND EVALUATED

7.5.1 ASSESS THE METHODS USED TO REVIEW AND EVALUATE CORRECTIONS

156	Do you review and evaluate actions taken to correct your management system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
157	Do you document your system correction reviews and the actions that are taken?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
158	Do you establish a record of system correction reviews and actions taken?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
159	Do you review and evaluate actions taken to correct system outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
160	Do you document your output correction reviews and the actions that are taken?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
161	Do you establish a record of output correction reviews and actions taken?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	

7.5.2 ASSESS THE METHODS USED TO REVIEW AND EVALUATE IMPROVEMENTS

162	Do you review and evaluate improvements and changes to management system?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
163	Do you document management system improvement reviews and the actions that are taken?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
164	Do you establish a record of management system improvement reviews and the actions taken?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
165	Do you review and evaluate improvements and changes to management system outputs?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
166	Do you document your output improvement reviews and the actions that are taken?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input checked="" type="checkbox"/> X	
167	Do you establish a record of output improvement reviews and the actions taken?	<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 system. 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:	YOUR LOCATION:
COMPLETED BY:	DATE COMPLETED:
REVIEWED BY:	DATE REVIEWED:
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