

Quality Management System Development Plan

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PLAIN ENGLISH QUALITY MANAGEMENT SYSTEM DEVELOPMENT PLAN

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PLAIN ENGLISH QUALITY MANAGEMENT SYSTEM DEVELOPMENT PLAN

I. INTRODUCTION TO QUALITY MANAGEMENT SYSTEMS

INTRODUCTION TO QUALITY MANAGEMENT SYSTEMS

Almost all quality management standards expect organizations to establish quality management systems. These include at least the following:

- ISO 9001 Quality Management Standard
- ISO 13485 Quality Management Standard for Medical Devices
- IATF 16949 Quality Management Standard for Automotive Sector
- AS9100 Quality Management Standard for Aerospace and Defense

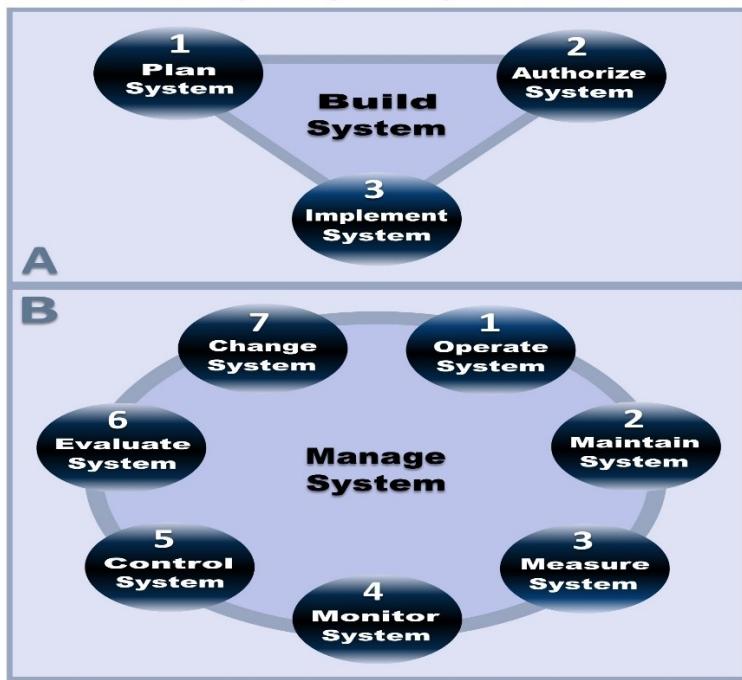
A *Quality Management System (QMS)* is a network of interrelated and interacting elements that organizations use to carry out activities and continuously improve. Management systems facilitate improvement because they are iterative: they repeat themselves. Improvement is possible because all aspects of the system are continuously measured, monitored, audited, analyzed, and reviewed. That's how organizations improve and that's why management systems are both popular and powerful.

QMS *elements* include policies, procedures, programs, processes, practices, projects, plans, objectives, rules, roles, responsibilities, relationships, contracts, agreements, documents, records, methods, techniques, technologies, tools, equipment, as well as all the resources that support these elements.

This means that even if your first QMS is imperfect and incomplete, it will inevitably improve over time.

When you look at the *elements* that make up a *QMS*, you'll notice many familiar items. That's because most mature organization's already have most of these elements. This should make developing your *QMS* a bit easier than you might have assumed.

Overview of Quality Management System Development Plan



We identified the basic elements that make up a *Quality Management System (QMS)* by looking for all of the activities and outcomes that are common to all existing quality management system standards. That's how we created our *Quality Management System Development Plan*.

However, it soon became obvious that such a Plan should have two different components: a temporary construction phase (Part A) and a permanent management phase (Part B). Once you've built the basic structure of your system the construction phase is done. You can then focus on managing it.

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II. OVERVIEW OF QMS DEVELOPMENT PLAN

A. BUILD QUALITY MANAGEMENT SYSTEM

A1. PLAN SYSTEM	<ul style="list-style-type: none">A1.1 Study the context of your system<ul style="list-style-type: none">A1.1.1 Consider system participantsA1.1.2 Consider system environmentA1.1.3 Consider system risks and threatsA1.2 Clarify the purpose of your system<ul style="list-style-type: none">A1.2.1 Define system scope and boundariesA1.2.2 Establish your system objectivesA1.3 Consider your system requirements<ul style="list-style-type: none">A1.3.1 Clarify system output requirementsA1.3.2 Clarify system knowledge requirementsA1.3.3 Clarify system competence requirementsA1.3.4 Clarify system management requirementsA1.3.5 Clarify system communication requirementsA1.3.6 Clarify system infrastructure requirementsA1.3.7 Clarify system environment requirementsA1.3.8 Clarify system resource requirementsA1.4 Define output and input requirements<ul style="list-style-type: none">A1.4.1 Define system's output requirementsA1.4.2 Define system's input requirementsA1.5 Identify system documents and records<ul style="list-style-type: none">A1.5.1 Evaluate documentation requirementsA1.5.2 Establish system documents and recordsA1.6 Establish system roles and responsibilities<ul style="list-style-type: none">A1.6.1 Assign system responsibilities and authoritiesA1.6.2 Document system responsibilities and authorities
A2. AUTHORIZE SYSTEM	<ul style="list-style-type: none">A2.1 Confirm that system has what it needs<ul style="list-style-type: none">A2.1.1 Confirm that responsibilities have been assignedA2.1.2 Confirm that documents have been providedA2.1.3 Confirm that resources have been allocatedA2.2 Verify that your system can do the job<ul style="list-style-type: none">A2.2.1 Verify that system can achieve objectivesA2.2.2 Verify that system can meet requirementsA2.3 Approve the implementation of system<ul style="list-style-type: none">A2.3.1 Grant approval if system has what it needsA2.3.2 Grant approval if system can do the job
A3. IMPLEMENT SYSTEM	<ul style="list-style-type: none">A3.1 Provide resources needed to implement systemA3.2 Create the environment that your system needsA3.3 Establish plans to achieve your system objectivesA3.4 Explain system policies, procedures, and objectivesA3.5 Communicate system management expectationsA3.6 Expect all system managers to be accountable

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II. OVERVIEW OF QMS DEVELOPMENT PLAN

B. MANAGE QUALITY MANAGEMENT SYSTEM

B1. OPERATE SYSTEM	<p>B1.1 Provide resources to facilitate system operations</p> <p>B1.1.1 Provide the expertise needed to operate your system</p> <p>B1.1.2 Provide the technology needed to operate your system</p> <p>B1.1.3 Provide the infrastructure needed to operate your system</p> <p>B1.2 Ask system owners to manage system operations</p> <p>B1.2.1 Expect system managers to address risks and opportunities</p> <p>B1.2.2 Expect system managers to implement policies and procedures</p> <p>B1.2.3 Expect system managers to specify output requirements and capabilities</p> <p>B1.2.4 Expect system managers to communicate with their system customers</p> <p>B1.2.5 Expect system managers to evaluate and select their external providers</p> <p>B1.2.6 Expect system managers to supervise and control all system activities</p> <p>B1.2.7 Expect system managers to measure conformance and performance</p> <p>B1.2.8 Expect system managers to meet expectations and requirements</p> <p>B1.2.9 Expect system managers to be accountable for their system</p> <p>B1.3 Expect personnel to carry out system operations</p> <p>B1.3.1 Expect personnel to focus on system customers</p> <p>B1.3.2 Expect personnel to handle risks and opportunities</p> <p>B1.3.3 Expect personnel to implement policies and procedures</p> <p>B1.3.4 Expect personnel to comply with all relevant requirements</p> <p>B1.3.5 Expect personnel to take appropriate action when necessary</p> <p>B1.3.6 Expect personnel to control system documents and records</p>
B2. MAINTAIN SYSTEM	<p>B2.1 Provide the resources needed to maintain system</p> <p>B2.1.1 Provide the expertise needed to maintain your system</p> <p>B2.1.2 Provide the technology needed to maintain your system</p> <p>B2.2 Use authorized methods to maintain your system</p> <p>B2.2.1 Use authorized methods to maintain your documents</p> <p>B2.2.2 Use authorized methods to maintain your records</p> <p>B2.2.3 Use authorized methods to maintain your property</p> <p>B2.2.4 Use authorized methods to maintain your procedures</p> <p>B2.2.5 Use authorized methods to maintain your competence</p> <p>B2.2.6 Use authorized methods to maintain your technologies</p> <p>B2.2.7 Use authorized methods to maintain your infrastructure</p> <p>B2.2.8 Use authorized methods to maintain your communications</p>

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B3. MEASURE SYSTEM	B3.1 Plan how you're going to measure your system B3.1.1 Figure out what needs to be measured B3.1.2 Figure out how measurements will be done B3.1.3 Figure out who will perform measurement tasks B3.2 Qualify the resources needed to measure system B3.2.1 Make sure that resources can measure your system B3.2.2 Make sure that resources are validated before use B3.3 Provide the resources needed to measure system B3.3.1 Provide the expertise needed to measure your system B3.3.2 Provide the technology needed to measure your system B3.3.3 Provide the infrastructure needed to measure your system B3.4 Use authorized methods to measure your system B3.4.1 Use authorized methods to measure system elements B3.4.2 Use authorized methods to measure system participants B3.5 Control the resources needed to measure system B3.5.1 Control the documents needed to measure your system B3.5.2 Control the technology needed to measure your system B3.5.3 Control the records needed to measure your system
B4. MONITOR SYSTEM	B4.1 Plan how you're going to monitor your system B4.1.1 Figure out what needs to be monitored B4.1.2 Figure out how monitoring will be done B4.1.3 Figure out who will perform monitoring tasks B4.2 Qualify the resources needed to monitor system B4.2.1 Make sure that resources can monitor your system B4.2.2 Make sure that resources are validated before use B4.3 Provide the resources needed to monitor system B4.3.1 Provide the expertise needed to monitor your system B4.3.2 Provide the technology needed to monitor your system B4.3.3 Provide the infrastructure needed to monitor your system B4.4 Use authorized methods to monitor your system B4.4.1 Use authorized methods to monitor system activities B4.4.2 Use authorized methods to monitor system outputs B4.4.3 Use authorized methods to monitor system inputs B4.4.4 Use authorized methods to monitor system documents B4.4.5 Use authorized methods to monitor system records B4.4.6 Use authorized methods to monitor system property B4.4.7 Use authorized methods to monitor system participants B4.4.8 Use authorized methods to monitor system technologies B4.4.9 Use authorized methods to monitor system environment B4.4.10 Use authorized methods to monitor system infrastructure B4.5 Control the resources needed to monitor system B4.5.1 Control the technologies needed to monitor system B4.5.2 Control the records needed to monitor system

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B5. CONTROL SYSTEM	<p>B5.1 Plan how you're going to control system</p> <p>B5.1.1 Consider how to control your system outputs</p> <p>B5.1.2 Consider how to control your system inputs</p> <p>B5.1.3 Consider how to control your system activities</p> <p>B5.1.4 Consider how to control your system providers</p> <p>B5.2 Develop ways of controlling your system</p> <p>B5.2.1 Develop ways of controlling system elements</p> <p>B5.2.2 Develop ways of controlling system providers</p> <p>B5.3 Provide resources needed to control system</p> <p>B5.3.1 Provide human resources needed to control system</p> <p>B5.3.2 Provide technical resources needed to control system</p> <p>B5.4 Use authorized methods to control system</p> <p>B5.4.1 Use authorized methods to control system inputs</p> <p>B5.4.2 Use authorized methods to control system outputs</p> <p>B5.4.3 Use authorized methods to control system activities</p> <p>B5.4.4 Use authorized methods to control system technology</p> <p>B5.4.5 Use authorized methods to control system performance</p> <p>B5.4.6 Use authorized methods to control system documentation</p>
B6. EVALUATE SYSTEM	<p>B6.1 Plan how you're going to evaluate system</p> <p>B6.1.1 Plan how you're going to audit your system</p> <p>B6.1.2 Plan how you're going to analyze your system</p> <p>B6.1.3 Plan how you're going to review your system</p> <p>B6.2 Provide resources needed to evaluate system</p> <p>B6.2.1 Provide the people that you need to evaluate your system</p> <p>B6.2.2 Provide the knowledge that you need to evaluate your system</p> <p>B6.2.3 Provide the technology that you need to evaluate your system</p> <p>B6.2.4 Provide the infrastructure that you need to evaluate your system</p> <p>B6.3 Use authorized methods to evaluate system</p> <p>B6.3.1 Use authorized methods to audit your system</p> <p>B6.3.2 Use authorized methods to analyze your system</p> <p>B6.3.3 Use authorized methods to review your system</p> <p>B6.4 Record the results of system evaluations</p> <p>B6.4.1 Record the results of management system audits</p> <p>B6.4.2 Record the results of management system analyses</p> <p>B6.4.3 Record the results of management system reviews</p>

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II. OVERVIEW OF QMS DEVELOPMENT PLAN

B7. CHANGE SYSTEM	<p>B7.1 Establish change management methods</p> <p>B7.1.1 Establish methods for correcting system and outputs</p> <p>B7.1.2 Establish methods for improving system and outputs</p> <p>B7.2 Generate opportunities to change system</p> <p>B7.2.1 Discover opportunities to change system and outputs</p> <p>B7.2.2 Confirm that system and output changes are needed</p> <p>B7.2.3 Approve opportunities to change system and outputs</p> <p>B7.3 Plan changes to your management system</p> <p>B7.3.1 Plan how you're going to correct system and outputs</p> <p>B7.3.2 Plan how you're going to improve system and outputs</p> <p>B7.4 Use approved methods to change system</p> <p>B7.4.1 Use approved methods to correct system and outputs</p> <p>B7.4.2 Use approved methods to improve system and outputs</p> <p>B7.5 Review and evaluate changes to system</p> <p>B7.5.1 Review and evaluate system and output corrections</p> <p>B7.5.2 Review and evaluate system and output improvements</p>
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A1. PLAN QUALITY MANAGEMENT SYSTEM

A1.1 STUDY THE CONTEXT OF YOUR SYSTEM

A1.1.1 CONSIDER SYSTEM PARTICIPANTS

1	Identify the parties that have an interest in your system.	DO	DN	NA	
2	Identify the internal parties that have an interest in your system.	DO	DN	NA	
3	Identify the internal parties that could influence your system.	DO	DN	NA	
4	Clarify the needs and expectations of interested internal parties.	DO	DN	NA	
5	Clarify the issues and concerns that interested internal parties have.	DO	DN	NA	
6	Identify the external parties that have an interest in your system.	DO	DN	NA	
7	Identify the external parties that could influence your system.	DO	DN	NA	
8	Clarify the needs and expectations of interested external parties.	DO	DN	NA	
9	Clarify the issues and concerns that interested external parties have.	DO	DN	NA	

A1.1.2 CONSIDER SYSTEM ENVIRONMENT

10	Consider your internal system environment.	DO	DN	NA	
11	Consider the impact it could have on system performance.	DO	DN	NA	
12	Consider the impact your organization's culture could have.	DO	DN	NA	
13	Consider the impact your organization's expertise could have.	DO	DN	NA	
14	Consider the impact your organization's technology could have.	DO	DN	NA	
15	Consider the impact your organization's infrastructure could have.	DO	DN	NA	
16	Consider your external system environment.	DO	DN	NA	
17	Consider the impact it could have on system performance.	DO	DN	NA	
18	Consider the impact your legal environment could have.	DO	DN	NA	

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A1. PLAN QUALITY MANAGEMENT SYSTEM

19	Identify statutory system output requirements.	DO	DN	NA	
20	Identify regulatory system output requirements.	DO	DN	NA	
21	Consider the impact your social environment could have.	DO	DN	NA	
22	Consider the impact your market environment could have.	DO	DN	NA	
23	Identify your customers' system output requirements.	DO	DN	NA	
24	Consider the impact your economic environment could have.	DO	DN	NA	
25	Consider the impact your competitive environment could have.	DO	DN	NA	
26	Consider the impact your technological environment could have.	DO	DN	NA	

A1.1.3 CONSIDER SYSTEM RISKS AND THREATS

27	Consider how your context could weaken system performance.	DO	DN	NA	
28	Consider how interested parties could threaten system performance or disrupt operations.	DO	DN	NA	
29	Consider how interested parties could weaken your ability to provide outputs that meet customer requirements.	DO	DN	NA	
30	Consider how interested parties could weaken your ability to provide outputs that meet legal requirements.	DO	DN	NA	
31	Consider how potential problems could threaten system performance or disrupt operations.	DO	DN	NA	
32	Consider how internal problems could weaken your ability to achieve system objectives.	DO	DN	NA	
33	Consider how your values could weaken your ability to achieve system objectives.	DO	DN	NA	
34	Consider how your culture could weaken your ability to achieve system objectives.	DO	DN	NA	
35	Consider how your knowledge could weaken your ability to achieve system objectives.	DO	DN	NA	
36	Consider how your infrastructure could weaken your ability to achieve system objectives.	DO	DN	NA	
37	Consider how your performance could weaken your ability to achieve system objectives.	DO	DN	NA	

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A1. PLAN QUALITY MANAGEMENT SYSTEM

38	Consider how external problems could weaken your ability to achieve system objectives.	DO	DN	NA	
39	Consider how legal problems could weaken your ability to achieve objectives.	DO	DN	NA	
40	Consider how social problems could weaken your ability to achieve objectives.	DO	DN	NA	
41	Consider how cultural problems could weaken your ability to achieve objectives.	DO	DN	NA	
42	Consider how market problems could weaken your ability to achieve objectives.	DO	DN	NA	
43	Consider how economic problems could weaken your ability to achieve objectives.	DO	DN	NA	
44	Consider how competitive problems could weaken your ability to achieve objectives.	DO	DN	NA	
45	Consider how technological problems could weaken your ability to achieve objectives.	DO	DN	NA	
46	Consider how to address the risks that could weaken system performance.	DO	DN	NA	
47	Figure out what you need to do to ensure that your system achieves its objectives.	DO	DN	NA	
48	Figure out how to prevent or reduce undesired affects that your system could cause.	DO	DN	NA	

A1.2 CLARIFY THE PURPOSE OF YOUR SYSTEM

A1.2.1 DEFINE SYSTEM SCOPE AND BOUNDARIES

49	Clarify the scope and boundaries of your system.	DO	DN	NA	
50	Consider how your context could influence your system.	DO	DN	NA	
51	Consider how internal issues could influence your system.	DO	DN	NA	
52	Consider the impact your organization's values could have.	DO	DN	NA	
53	Consider the impact your organization's culture could have.	DO	DN	NA	
54	Consider the impact your organization's services could have.	DO	DN	NA	
55	Consider the impact your organization's products could have.	DO	DN	NA	
56	Consider the impact your organization's knowledge could have.	DO	DN	NA	
57	Consider the impact your organization's infrastructure could have.	DO	DN	NA	

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A1. PLAN QUALITY MANAGEMENT SYSTEM

58	Consider the impact your organization's performance could have.	DO	DN	NA	
59	Consider how external issues could influence your system.	DO	DN	NA	
60	Consider the impact legal issues and factors could have.	DO	DN	NA	
61	Consider the impact social issues and factors could have.	DO	DN	NA	
62	Consider the impact cultural issues and factors could have.	DO	DN	NA	
63	Consider the impact market issues and factors could have.	DO	DN	NA	
64	Consider the impact economic issues and factors could have.	DO	DN	NA	
65	Consider the impact competitive issues and factors could have.	DO	DN	NA	
66	Consider the impact technological issues and factors could have.	DO	DN	NA	
67	Document the scope and boundaries of your system.	DO	DN	NA	
68	Retain the documents that describe the scope and boundaries of your system.	DO	DN	NA	
69	Control the documents that describe the scope and boundaries of your system.	DO	DN	NA	

A1.2.2 ESTABLISH YOUR SYSTEM OBJECTIVES

70	Establish business objectives for your system.	DO	DN	NA	
71	Establish quality objectives for your system.	DO	DN	NA	

A1.3 CONSIDER YOUR SYSTEM REQUIREMENTS

A1.3.1 CLARIFY SYSTEM OUTPUT REQUIREMENTS

72	Consider the quality requirements that system outputs must meet.	DO	DN	NA	
73	Consider the safety requirements that system outputs must meet.	DO	DN	NA	
74	Consider the privacy requirements that system outputs must meet.	DO	DN	NA	
75	Consider the security requirements that system outputs must meet.	DO	DN	NA	

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A1. PLAN QUALITY MANAGEMENT SYSTEM

A1.3.2 CLARIFY SYSTEM KNOWLEDGE REQUIREMENTS

76	Determine the knowledge that system personnel need to have.	DO	DN	NA	
77	Determine the knowledge that system personnel need in order to support system operations and achieve conformity of outputs.	DO	DN	NA	
78	Consider internal sources of system knowledge.	DO	DN	NA	
79	Consider the need to learn from failures and successes.	DO	DN	NA	
80	Consider the need to gather knowledge about processes.	DO	DN	NA	
81	Consider the need to capture undocumented knowledge.	DO	DN	NA	
82	Consider external sources of system knowledge.	DO	DN	NA	
83	Consider the knowledge that suppliers can provide.	DO	DN	NA	
84	Consider the knowledge that customers can share with you.	DO	DN	NA	
85	Consider the knowledge that can be gathered at conferences.	DO	DN	NA	
86	Consider the knowledge that can be acquired from academia.	DO	DN	NA	

A1.3.3 CLARIFY SYSTEM COMPETENCE REQUIREMENTS

87	Identify the people who can influence the performance of your system.	DO	DN	NA	
88	Establish competence requirements for your system.	DO	DN	NA	
89	Make sure that system personnel have the appropriate training.	DO	DN	NA	
90	Make sure that system personnel have the appropriate education.	DO	DN	NA	
91	Make sure that system personnel have the appropriate experience.	DO	DN	NA	
92	Make sure that system personnel have the appropriate knowledge.	DO	DN	NA	
93	Implement competence requirements for your system.	DO	DN	NA	

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A1. PLAN QUALITY MANAGEMENT SYSTEM

94	Define the knowledge and skill required to verify your system.	DO	DN	NA	
95	Define the knowledge and skill required to implement your system.	DO	DN	NA	
96	Define the knowledge and skill required to operate your system.	DO	DN	NA	
97	Define the knowledge and skill required to maintain your system.	DO	DN	NA	
98	Define the knowledge and skill required to measure your system.	DO	DN	NA	
99	Define the knowledge and skill required to monitor your system.	DO	DN	NA	
100	Define the knowledge and skill required to control your system.	DO	DN	NA	
101	Define the knowledge and skill required to evaluate your system.	DO	DN	NA	
102	Define the knowledge and skill required to audit your system.	DO	DN	NA	
103	Define the knowledge and skill required to review your system.	DO	DN	NA	
104	Define the knowledge and skill required to change your system.	DO	DN	NA	
105	Define the knowledge and skill required to correct your system.	DO	DN	NA	
106	Define the knowledge and skill required to improve your system.	DO	DN	NA	

A1.3.4 CLARIFY SYSTEM MANAGEMENT REQUIREMENTS

107	Specify legal management requirements for your system.	DO	DN	NA	
108	Specify legal management requirements for system outputs.	DO	DN	NA	
109	Specify statutory management requirements for system outputs.	DO	DN	NA	
110	Specify regulatory management requirements for system outputs.	DO	DN	NA	
111	Specify business management requirements for your system.	DO	DN	NA	
112	Specify technical management requirements for your system.	DO	DN	NA	
113	Specify quality management requirements for your system.	DO	DN	NA	

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A1. PLAN QUALITY MANAGEMENT SYSTEM

114	Derive quality requirements from your quality policy.	DO	DN	NA	
115	Derive quality requirements from customer expectations.	DO	DN	NA	
116	Specify safety management requirements for your system.	DO	DN	NA	
117	Specify privacy management requirements for your system.	DO	DN	NA	
118	Specify security management requirements for your system.	DO	DN	NA	
119	Specify business continuity management requirements for your system.	DO	DN	NA	

A1.3.5 CLARIFY SYSTEM COMMUNICATION REQUIREMENTS

120	Figure out how internal system communications will be handled.	DO	DN	NA	
121	Figure out what internal system communications need to say.	DO	DN	NA	
122	Figure out when internal system communications should be done.	DO	DN	NA	
123	Figure out who should carry out internal system communications.	DO	DN	NA	
124	Figure out who should receive internal system communications.	DO	DN	NA	
125	Figure out how external system communications will be handled.	DO	DN	NA	
126	Figure out what external system communications need to say.	DO	DN	NA	
127	Figure out when external system communications should be done.	DO	DN	NA	
128	Figure out who should carry out external system communications.	DO	DN	NA	

A1.3.6 CLARIFY SYSTEM INFRASTRUCTURE REQUIREMENTS

129	Identify the infrastructure that your system needs in order to support operations and achieve conformity of outputs.	DO	DN	NA	
130	Consider the buildings that your system needs.	DO	DN	NA	
131	Consider the utilities that your system needs.	DO	DN	NA	
132	Consider the equipment that your system needs.	DO	DN	NA	

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133	Consider the hardware that your system needs.	DO	DN	NA	
134	Consider the software that your system needs.	DO	DN	NA	
135	Consider the technology that your system needs.	DO	DN	NA	
136	Consider your information technology needs.	DO	DN	NA	
137	Consider your communication technology needs.	DO	DN	NA	
138	Consider your transportation technology needs.	DO	DN	NA	

A1.3.7 CLARIFY SYSTEM ENVIRONMENT REQUIREMENTS

139	Identify the environment that your system needs in order to achieve conformity of outputs.	DO	DN	NA	
140	Consider the social factors that could affect your system.	DO	DN	NA	
141	Consider whether privacy issues could affect your system.	DO	DN	NA	
142	Consider the cultural factors that could affect your system.	DO	DN	NA	
143	Consider the psychological factors that could affect your system.	DO	DN	NA	
144	Consider the ergonomic factors that could affect your system.	DO	DN	NA	
145	Consider the climatic factors that could affect your system.	DO	DN	NA	
146	Consider the physical factors that could affect your system.	DO	DN	NA	
147	Consider the sanitation factors that could affect your system.	DO	DN	NA	

A1.3.8 CLARIFY SYSTEM RESOURCE REQUIREMENTS

148	Consider internal capabilities and external sources.	DO	DN	NA	
149	Consider your internal capabilities and constraints.	DO	DN	NA	
150	Consider what needs to be obtained from external sources.	DO	DN	NA	
151	Determine the resources that your system needs.	DO	DN	NA	

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152	Identify the resources needed to authorize your system.	DO	DN	NA	
153	Identify the resources needed to implement your system.	DO	DN	NA	
154	Identify the resources needed to operate your system.	DO	DN	NA	
155	Identify the resources needed to measure your system.	DO	DN	NA	
156	Identify the resources needed to monitor your system.	DO	DN	NA	
157	Identify the resources needed to control your system.	DO	DN	NA	
158	Identify the resources needed to maintain your system.	DO	DN	NA	
159	Identify the resources needed to evaluate your system.	DO	DN	NA	
160	Identify the resources needed to audit your system.	DO	DN	NA	
161	Identify the resources needed to review your system.	DO	DN	NA	
162	Identify the resources needed to change your system.	DO	DN	NA	
163	Identify the resources needed to correct your system.	DO	DN	NA	
164	Identify the resources needed to improve your system.	DO	DN	NA	

A1.4 DEFINE OUTPUT AND INPUT REQUIREMENTS

A1.4.1 DEFINE SYSTEM'S OUTPUT REQUIREMENTS

165	Identify the outputs that your system must generate.	DO	DN	NA	
166	Identify the tangible outputs that system must be able to generate.	DO	DN	NA	
167	Identify the products that your system must be able to generate.	DO	DN	NA	
168	Identify the materials that your system must be able to generate.	DO	DN	NA	
169	Identify the components that your system must be able to generate.	DO	DN	NA	
170	Identify the intangible outputs that system must be able to generate.	DO	DN	NA	

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171	Identify the services that your system must be able to generate.	DO	DN	NA	
172	Identify the information that your system must be able to generate.	DO	DN	NA	
173	Develop criteria that system outputs must meet.	DO	DN	NA	
174	Establish acceptance criteria for system outputs.	DO	DN	NA	
175	Plan how system output requirements will be met.	DO	DN	NA	
176	Plan output design and development activities.	DO	DN	NA	
177	Consider your output needs and complexities.	DO	DN	NA	
178	Consider your ability to meet output requirements.	DO	DN	NA	
179	Consider how to ensure that outputs meet safety requirements.	DO	DN	NA	
180	Consider how to ensure that outputs meet quality requirements.	DO	DN	NA	
181	Consider how to ensure that outputs meet privacy requirements.	DO	DN	NA	
182	Consider how to ensure that outputs meet security requirements.	DO	DN	NA	
183	Consider how to ensure that outputs meet control requirements.	DO	DN	NA	
184	Consider how to ensure that outputs meet testing requirements.	DO	DN	NA	
185	Consider how to ensure that outputs meet production requirements.	DO	DN	NA	
186	Consider how to ensure that outputs meet suitability requirements.	DO	DN	NA	
187	Consider how to ensure that outputs meet reliability requirements.	DO	DN	NA	
188	Consider how to ensure that outputs meet monitoring requirements.	DO	DN	NA	
189	Consider how to ensure that outputs meet measurement requirements.	DO	DN	NA	
190	Consider how to ensure that outputs meet preservation requirements.	DO	DN	NA	
191	Consider how to ensure that outputs meet maintenance requirements.	DO	DN	NA	

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192	Consider how to ensure that outputs meet obsolescence requirements.	DO	DN	NA	
193	Consider how to ensure that outputs meet post-delivery requirements.	DO	DN	NA	
194	Consider how to ensure that outputs meet delivery requirements.	DO	DN	NA	
195	Consider output design and development complexities.	DO	DN	NA	
196	Consider your output design and development activities.	DO	DN	NA	
197	Consider output design and development requirements.	DO	DN	NA	
198	Consider your output evaluation requirements.	DO	DN	NA	
199	Consider output review requirements.	DO	DN	NA	
200	Consider output verification requirements.	DO	DN	NA	
201	Consider output validation requirements.	DO	DN	NA	
202	Consider design and development output requirements.	DO	DN	NA	
203	Consider output design and development expectations.	DO	DN	NA	
204	Consider your output control expectations.	DO	DN	NA	
205	Consider the level of control expected by your customers.	DO	DN	NA	
206	Consider the level of control expected by interested parties.	DO	DN	NA	
207	Consider output design and development relationships.	DO	DN	NA	
208	Consider the need to control interactions between people.	DO	DN	NA	
209	Consider the need to control interactions between groups.	DO	DN	NA	
210	Consider output design and development responsibilities.	DO	DN	NA	
211	Consider design and development authorities.	DO	DN	NA	
212	Consider output design and development documentation.	DO	DN	NA	

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213	Consider the need to control and maintain documentation.	DO	DN	NA	
214	Consider the need to confirm that requirements are being met.	DO	DN	NA	
215	Consider output design and development resources.	DO	DN	NA	
216	Consider internal design and development resource needs.	DO	DN	NA	
217	Consider external design and development resource needs.	DO	DN	NA	
218	Figure out how system outputs will be controlled.	DO	DN	NA	
219	Define your configuration management requirements.	DO	DN	NA	
220	Define how you intend to control nonconforming outputs.	DO	DN	NA	
221	Document your output nonconformity control methods.	DO	DN	NA	
222	Define responsibility and authority for handling nonconforming outputs.	DO	DN	NA	
223	Define responsibility and authority for review of nonconforming outputs.	DO	DN	NA	
224	Define responsibility and authority for disposition of nonconforming outputs.	DO	DN	NA	
225	Define how you plan to manage and control your nonconforming outputs.	DO	DN	NA	
226	Define how you're going to contain the impact of nonconformities.	DO	DN	NA	
227	Define how you intend to contain the effect on other processes.	DO	DN	NA	
228	Define how you intend to contain the effect on other outputs.	DO	DN	NA	
229	Define how you intend to contain the effect on other parties.	DO	DN	NA	
230	Define how you intend to contain the effect on customers.	DO	DN	NA	
231	Define how you intend to report your nonconforming outputs.	DO	DN	NA	
232	Define how nonconformities affecting products and services are reported.	DO	DN	NA	
233	Define how you intend to notify interested parties about nonconformities.	DO	DN	NA	
234	Define how internal parties will be notified about nonconformities.	DO	DN	NA	

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235	Define how you plan to notify internal organizations about nonconformities.	DO	DN	NA	
236	Define how external parties will be notified about nonconformities.	DO	DN	NA	
237	Define how you plan to notify customers about nonconformities.	DO	DN	NA	
238	Define how you plan to notify distributors about nonconformities.	DO	DN	NA	
239	Define how you plan to notify regulators about nonconformities.	DO	DN	NA	
240	Define how you plan to notify suppliers about nonconformities.	DO	DN	NA	
241	Define how appropriate corrective actions will be implemented.	DO	DN	NA	

A1.4.2 DEFINE SYSTEM'S INPUT REQUIREMENTS

242	Identify management system input requirements.	DO	DN	NA	
243	Identify the products that your system will need to have.	DO	DN	NA	
244	Identify the product providers that will be needed.	DO	DN	NA	
245	Identify the services that your system will need to have.	DO	DN	NA	
246	Identify the service providers that will be needed.	DO	DN	NA	
247	Identify the technologies that your system will need to have.	DO	DN	NA	
248	Identify the hardware that your system will need to have.	DO	DN	NA	
249	Identify the software that your system will need to have.	DO	DN	NA	
250	Identify the information that your system will need to have.	DO	DN	NA	
251	Identify the materials that your system will need to have.	DO	DN	NA	
252	Identify the supplies that your system will need to have.	DO	DN	NA	
253	Identify the parts that your system will need to have.	DO	DN	NA	
254	Document management system input requirements.	DO	DN	NA	

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A1. PLAN QUALITY MANAGEMENT SYSTEM

A1.5 IDENTIFY SYSTEM DOCUMENTS AND RECORDS

A1.5.1 EVALUATE DOCUMENTATION REQUIREMENTS

255	Figure out how extensive documented system information should be.	DO	DN	NA	
256	Consider system activities when you establish documents and records.	DO	DN	NA	
257	Consider your system outputs when you establish documents and records.	DO	DN	NA	
258	Consider system personnel when you establish documents and records.	DO	DN	NA	
259	Consider the competence and expertise of your system personnel.	DO	DN	NA	
260	Consider your system obligations when you establish documents and records.	DO	DN	NA	
261	Consider system property and information provided by your customers.	DO	DN	NA	
262	Consider system property and information provided by external providers.	DO	DN	NA	

A1.5.2 ESTABLISH SYSTEM DOCUMENTS AND RECORDS

263	Document quality management system participants.	DO	DN	NA	
264	Document the parties that have an interest in your system.	DO	DN	NA	
265	Document the scope of your quality management system.	DO	DN	NA	
266	Consider interested party requirements when you document the scope of your system.	DO	DN	NA	
267	Consider your system environment when you document the scope of your system.	DO	DN	NA	
268	Consider your system outputs when you document the scope of your system.	DO	DN	NA	
269	Document your quality management system outputs.	DO	DN	NA	
270	Document characteristics of outputs you plan to produce.	DO	DN	NA	
271	Develop and document your output definition data.	DO	DN	NA	
272	Document your quality management system activities.	DO	DN	NA	

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A1. PLAN QUALITY MANAGEMENT SYSTEM

273	Document characteristics of system activities to be performed.	DO	DN	NA	
274	Document performance criteria that your system should meet.	DO	DN	NA	
275	Document performance criteria that system outputs should meet.	DO	DN	NA	
276	Document the activities that should make up your system.	DO	DN	NA	
277	Document the activities needed to generate your outputs.	DO	DN	NA	
278	Document the activities needed to control your “critical items”.	DO	DN	NA	
279	Document the activities needed to prevent unintended deliveries.	DO	DN	NA	
280	Document system verification and validation methods.	DO	DN	NA	
281	Document the resources needed to support system.	DO	DN	NA	
282	Document the resources needed to manage system.	DO	DN	NA	
283	Document quality management system inputs.	DO	DN	NA	
284	Document the products that your system will need to have.	DO	DN	NA	
285	Document the product providers that will be needed.	DO	DN	NA	
286	Document the services that your system will need to have.	DO	DN	NA	
287	Document the service providers that will be needed.	DO	DN	NA	
288	Document the technologies that your system will need to have.	DO	DN	NA	
289	Document the hardware that your system will need to have.	DO	DN	NA	
290	Document the software that your system will need to have.	DO	DN	NA	
291	Document the information that your system will need to have.	DO	DN	NA	
292	Document the materials that your system will need to have.	DO	DN	NA	
293	Document the supplies that your system will need to have.	DO	DN	NA	
294	Document the parts that your system will need to have.	DO	DN	NA	

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A1. PLAN QUALITY MANAGEMENT SYSTEM

295	Document quality management system assignments.	DO	DN	NA	
296	Document quality management system authorities.	DO	DN	NA	
297	Document quality management system responsibilities.	DO	DN	NA	
298	Document the objectives that your system must achieve.	DO	DN	NA	
299	Document the policies that your system must implement.	DO	DN	NA	
300	Document the procedures that your system must follow.	DO	DN	NA	

A1.6 ESTABLISH SYSTEM ROLES AND RESPONSIBILITIES

A1.6.1 ASSIGN SYSTEM RESPONSIBILITIES AND AUTHORITIES

301	Assign responsibility and authority for managing quality management system.	DO	DN	NA	
302	Assign responsibility and authority for applying your quality policy and procedures.	DO	DN	NA	
303	Assign responsibility and authority for complying with regulations and standards.	DO	DN	NA	
304	Assign responsibility and authority for maintaining a focus on system customers.	DO	DN	NA	
305	Assign responsibility and authority for meeting customer requirements.	DO	DN	NA	
306	Assign responsibility and authority for enhancing customer satisfaction.	DO	DN	NA	
307	Assign responsibility and authority for interacting with your external parties.	DO	DN	NA	
308	Assign responsibility and authority for authorizing quality management system.	DO	DN	NA	
309	Assign responsibility and authority for operating quality management system.	DO	DN	NA	
310	Assign responsibility and authority for ensuring that system is efficient and effective.	DO	DN	NA	
311	Make managers accountable for ensuring that system produces intended outputs.	DO	DN	NA	
312	Assign responsibility and authority for maintaining quality management system.	DO	DN	NA	
313	Assign responsibility and authority for measuring quality management system.	DO	DN	NA	
314	Assign responsibility and authority for monitoring quality management system.	DO	DN	NA	

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A1. PLAN QUALITY MANAGEMENT SYSTEM

315	Assign responsibility and authority for controlling quality management system.	DO	DN	NA	
316	Assign responsibility and authority for controlling system modifications.	DO	DN	NA	
317	Make managers accountable for protecting system integrity when changes occur.	DO	DN	NA	
318	Assign responsibility and authority for evaluating quality management system.	DO	DN	NA	
319	Assign responsibility and authority for auditing quality management system.	DO	DN	NA	
320	Assign responsibility and authority for preparing internal audit reports.	DO	DN	NA	
321	Assign responsibility and authority for reviewing quality management system.	DO	DN	NA	
322	Assign responsibility and authority for preparing management review reports.	DO	DN	NA	
323	Assign responsibility and authority for submitting system performance reports.	DO	DN	NA	
324	Assign responsibility and authority for reporting system improvement opportunities.	DO	DN	NA	
325	Assign responsibility and authority for changing quality management system.	DO	DN	NA	
326	Assign responsibility and authority for correcting quality management system.	DO	DN	NA	
327	Assign responsibility and authority for improving quality management system.	DO	DN	NA	

A1.6.2 DOCUMENT SYSTEM RESPONSIBILITIES AND AUTHORITIES

328	Document responsibility and authority for managing quality management system.	DO	DN	NA	
329	Document responsibility and authority for validating quality management system.	DO	DN	NA	
330	Document responsibility and authority for approving quality management system.	DO	DN	NA	
331	Document responsibility and authority for operating quality management system.	DO	DN	NA	
332	Document responsibility and authority for maintaining quality management system.	DO	DN	NA	
333	Document responsibility and authority for monitoring quality management system.	DO	DN	NA	
334	Document responsibility and authority for measuring quality management system.	DO	DN	NA	
335	Document responsibility and authority for controlling quality management system.	DO	DN	NA	

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A1. PLAN QUALITY MANAGEMENT SYSTEM

Consider each task and select a response. If you haven't done it and it needs to be done, select DO. If you've already done it, select DN. If the task is not applicable in your situation and you can justify and explain why it should be ignored or excluded, select NA.

In the spaces below, please enter the name and location of your organization, who completed this page, who reviewed it, and the dates.

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A2. AUTHORIZE QUALITY MANAGEMENT SYSTEM

A2.1 CONFIRM THAT SYSTEM HAS WHAT IT NEEDS

A2.1.1 CONFIRM THAT RESPONSIBILITIES HAVE BEEN ASSIGNED

1	Confirm that responsibility and authority for managing system has been assigned.	DO	DN	NA	
2	Confirm that responsibility and authority for operating system has been assigned.	DO	DN	NA	
3	Confirm that responsibility and authority for measuring system has been assigned.	DO	DN	NA	
4	Confirm that responsibility and authority for authorizing system has been assigned.	DO	DN	NA	
5	Confirm that responsibility and authority for maintaining system has been assigned.	DO	DN	NA	
6	Confirm that responsibility and authority for monitoring system has been assigned.	DO	DN	NA	
7	Confirm that responsibility and authority for controlling system has been assigned.	DO	DN	NA	
8	Confirm that responsibility and authority for reviewing system has been assigned.	DO	DN	NA	
9	Confirm that responsibility and authority for changing system has been assigned.	DO	DN	NA	
10	Confirm that responsibility and authority for auditing system has been assigned.	DO	DN	NA	

A2.1.2 CONFIRM THAT DOCUMENTS HAVE BEEN PROVIDED

11	Confirm that quality management system scope is documented.	DO	DN	NA	
12	Confirm that quality management system plans are documented.	DO	DN	NA	
13	Confirm that quality management system inputs are documented.	DO	DN	NA	
14	Confirm that quality management system policies are documented.	DO	DN	NA	
15	Confirm that quality management system outputs are documented.	DO	DN	NA	
16	Confirm that quality management system objectives are documented.	DO	DN	NA	
17	Confirm that quality management system procedures are documented.	DO	DN	NA	
18	Confirm that quality management system participants are documented.	DO	DN	NA	
19	Confirm that quality management system responsibilities are documented.	DO	DN	NA	

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A2. AUTHORIZE QUALITY MANAGEMENT SYSTEM

A2.1.3 CONFIRM THAT RESOURCES HAVE BEEN ALLOCATED

20	Confirm that resources needed to design system have been allocated.	DO	DN	NA	
21	Confirm that resources needed to manage system have been allocated.	DO	DN	NA	
22	Confirm that resources needed to authorize system have been allocated.	DO	DN	NA	
23	Confirm that resources needed to implement system have been allocated.	DO	DN	NA	
24	Confirm that resources needed to maintain system have been allocated.	DO	DN	NA	
25	Confirm that resources needed to measure system have been allocated.	DO	DN	NA	
26	Confirm that resources needed to monitor system have been allocated.	DO	DN	NA	
27	Confirm that resources needed to operate system have been allocated.	DO	DN	NA	
28	Confirm that resources needed to control system have been allocated.	DO	DN	NA	
29	Confirm that resources needed to change system have been allocated.	DO	DN	NA	
30	Confirm that resources needed to review system have been allocated.	DO	DN	NA	
31	Confirm that resources needed to audit system have been allocated.	DO	DN	NA	

A2.2 VERIFY THAT YOUR SYSTEM CAN DO THE JOB

A2.2.1 VERIFY THAT SYSTEM CAN ACHIEVE OBJECTIVES

32	Verify that management system can achieve business objectives.	DO	DN	NA	
33	Verify that management system can achieve quality objectives.	DO	DN	NA	
34	Verify that management system can achieve safety objectives.	DO	DN	NA	
35	Verify that management system can achieve privacy objectives.	DO	DN	NA	
36	Verify that management system can achieve security objectives.	DO	DN	NA	
37	Verify that management system can achieve technical objectives.	DO	DN	NA	

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A2. AUTHORIZE QUALITY MANAGEMENT SYSTEM

38	Verify that management system can achieve continuity objectives.	DO	DN	NA	
----	--	----	----	----	--

A2.2.2 VERIFY THAT SYSTEM CAN MEET REQUIREMENTS

39	Verify that your management system can meet communication requirements.	DO	DN	NA	
40	Verify that management system can meet internal communication requirements.	DO	DN	NA	
41	Verify that management system can meet external communication requirements.	DO	DN	NA	
42	Verify that your management system can meet infrastructure requirements.	DO	DN	NA	
43	Verify that management system will have access to all the necessary facilities.	DO	DN	NA	
44	Verify that management system will have access to all the necessary equipment.	DO	DN	NA	
45	Verify that management system will have access to all the necessary technology.	DO	DN	NA	
46	Verify that management system will have access to all the necessary hardware.	DO	DN	NA	
47	Verify that management system will have access to all the necessary software.	DO	DN	NA	
48	Verify that management system will have access to all the necessary utilities.	DO	DN	NA	
49	Verify that management system will have access to all the necessary tools.	DO	DN	NA	
50	Verify that your management system can meet competence requirements.	DO	DN	NA	
51	Verify that management system personnel know how to implement the system.	DO	DN	NA	
52	Verify that management system personnel know how to operate the system.	DO	DN	NA	
53	Verify that management system personnel know how to maintain the system.	DO	DN	NA	
54	Verify that management system personnel know how to measure the system.	DO	DN	NA	
55	Verify that management system personnel know how to monitor the system.	DO	DN	NA	
56	Verify that management system personnel know how to control the system.	DO	DN	NA	
57	Verify that management system personnel know how to audit the system.	DO	DN	NA	

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A2. AUTHORIZE QUALITY MANAGEMENT SYSTEM

58	Verify that management system personnel know how to review the system.	DO	DN	NA	
59	Verify that management system personnel know how to analyze the system.	DO	DN	NA	
60	Verify that management system personnel know how to correct the system.	DO	DN	NA	
61	Verify that management system personnel know how to improve the system.	DO	DN	NA	
62	Verify that your management system can meet output requirements.	DO	DN	NA	
63	Verify that management system outputs can meet legal requirements.	DO	DN	NA	
64	Verify that management system outputs can meet safety requirements.	DO	DN	NA	
65	Verify that management system outputs can meet quality requirements.	DO	DN	NA	
66	Verify that management system outputs can meet privacy requirements.	DO	DN	NA	
67	Verify that management system outputs can meet security requirements.	DO	DN	NA	
68	Verify that management system outputs can meet technical requirements.	DO	DN	NA	
69	Verify that management system outputs can meet business continuity requirements.	DO	DN	NA	

A2.3 APPROVE THE IMPLEMENTATION OF SYSTEM

A2.3.1 GRANT APPROVAL IF SYSTEM HAS WHAT IT NEEDS

70	Approve implementation if system responsibilities have been assigned.	DO	DN	NA	
71	Approve implementation if suitable management responsibilities have been assigned.	DO	DN	NA	
72	Approve implementation if suitable measurement responsibilities have been assigned.	DO	DN	NA	
73	Approve implementation if suitable maintenance responsibilities have been assigned.	DO	DN	NA	
74	Approve implementation if suitable operational responsibilities have been assigned.	DO	DN	NA	
75	Approve implementation if suitable monitoring responsibilities have been assigned.	DO	DN	NA	

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A2. AUTHORIZE QUALITY MANAGEMENT SYSTEM

76	Approve implementation if suitable control responsibilities have been assigned.	DO	DN	NA	
77	Approve implementation if suitable review responsibilities have been assigned.	DO	DN	NA	
78	Approve implementation if suitable audit responsibilities have been assigned.	DO	DN	NA	
79	Approve implementation if system documents have been established.	DO	DN	NA	
80	Approve implementation if management system scope has been documented.	DO	DN	NA	
81	Approve implementation if management system plans have been documented.	DO	DN	NA	
82	Approve implementation if management system inputs have been documented.	DO	DN	NA	
83	Approve implementation if management system policies have been documented.	DO	DN	NA	
84	Approve implementation if management system outputs have been documented.	DO	DN	NA	
85	Approve implementation if management system activities have been documented.	DO	DN	NA	
86	Approve implementation if management system objectives have been documented.	DO	DN	NA	
87	Approve implementation if management system procedures have been documented.	DO	DN	NA	
88	Approve implementation if management system participants have been documented.	DO	DN	NA	
89	Approve implementation if management system responsibilities have been documented.	DO	DN	NA	
90	Approve implementation if system resources have been allocated.	DO	DN	NA	
91	Approve implementation if resources needed to design system have been allocated.	DO	DN	NA	
92	Approve implementation if resources needed to manage system have been allocated.	DO	DN	NA	
93	Approve implementation if resources needed to authorize system have been allocated.	DO	DN	NA	
94	Approve implementation if resources needed to implement system have been allocated.	DO	DN	NA	
95	Approve implementation if resources needed to maintain system have been allocated.	DO	DN	NA	

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A2. AUTHORIZE QUALITY MANAGEMENT SYSTEM

96	Approve implementation if resources needed to measure system have been allocated.	DO	DN	NA	
97	Approve implementation if resources needed to monitor system have been allocated.	DO	DN	NA	
98	Approve implementation if resources needed to operate system have been allocated.	DO	DN	NA	
99	Approve implementation if resources needed to control system have been allocated.	DO	DN	NA	
100	Approve implementation if resources needed to change system have been allocated.	DO	DN	NA	
101	Approve implementation if resources needed to review system have been allocated.	DO	DN	NA	
102	Approve implementation if resources needed to audit system have been allocated.	DO	DN	NA	

A2.3.2 GRANT APPROVAL IF SYSTEM CAN DO THE JOB

103	Approve implementation if proposed system can achieve objectives.	DO	DN	NA	
104	Approve implementation if proposed system can achieve technical objectives.	DO	DN	NA	
105	Approve implementation if proposed system can achieve business objectives.	DO	DN	NA	
106	Approve implementation if proposed system can achieve quality objectives.	DO	DN	NA	
107	Approve implementation if proposed system can achieve safety objectives.	DO	DN	NA	
108	Approve implementation if proposed system can achieve privacy objectives.	DO	DN	NA	
109	Approve implementation if proposed system can achieve security objectives.	DO	DN	NA	
110	Approve implementation if proposed system can achieve continuity objectives.	DO	DN	NA	
111	Approve implementation if proposed system can meet requirements.	DO	DN	NA	
112	Approve implementation if proposed system meets output requirements.	DO	DN	NA	
113	Approve implementation if system outputs meet legal requirements.	DO	DN	NA	
114	Approve implementation if system outputs meet safety requirements.	DO	DN	NA	

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A2. AUTHORIZE QUALITY MANAGEMENT SYSTEM

115	Approve implementation if system outputs meet quality requirements.	DO	DN	NA	
116	Approve implementation if system outputs meet privacy requirements.	DO	DN	NA	
117	Approve implementation if system outputs meet security requirements.	DO	DN	NA	
118	Approve implementation if system outputs meet technical requirements.	DO	DN	NA	
119	Approve implementation if proposed system meets competence requirements.	DO	DN	NA	
120	Approve implementation if personnel know how to implement system.	DO	DN	NA	
121	Approve implementation if personnel know how to maintain system.	DO	DN	NA	
122	Approve implementation if personnel know how to measure system.	DO	DN	NA	
123	Approve implementation if personnel know how to monitor system.	DO	DN	NA	
124	Approve implementation if personnel know how to operate system.	DO	DN	NA	
125	Approve implementation if personnel know how to control system.	DO	DN	NA	
126	Approve implementation if personnel know how to audit system.	DO	DN	NA	
127	Approve implementation if personnel know how to review system.	DO	DN	NA	
128	Approve implementation if personnel know how to change system.	DO	DN	NA	
129	Approve implementation if personnel know how to analyze system.	DO	DN	NA	
130	Approve implementation if proposed system meets infrastructure requirements.	DO	DN	NA	
131	Approve implementation if proposed system has all the necessary technology.	DO	DN	NA	
132	Approve implementation if proposed system has all the necessary hardware.	DO	DN	NA	
133	Approve implementation if proposed system has all the necessary software.	DO	DN	NA	
134	Approve implementation if proposed system has all the necessary facilities.	DO	DN	NA	
135	Approve implementation if proposed system has all the necessary tools.	DO	DN	NA	

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A2. AUTHORIZE QUALITY MANAGEMENT SYSTEM

136	Approve implementation if proposed system has all the necessary utilities.	DO	DN	NA	
137	Approve implementation if proposed system has all the necessary equipment.	DO	DN	NA	
138	Approve implementation if proposed system meets communication requirements.	DO	DN	NA	
139	Approve implementation if system meets internal communication requirements.	DO	DN	NA	
140	Approve implementation if system meets external communication requirements.	DO	DN	NA	

Consider each task and select a response. If you haven't done it and it needs to be done, select DO. If you've already done it, select DN. If the task is not applicable in your situation and you can justify and explain why it should be ignored or excluded, select NA.

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PLAIN ENGLISH QUALITY MANAGEMENT SYSTEM DEVELOPMENT PLAN

A3. IMPLEMENT QUALITY MANAGEMENT SYSTEM

A3.1 PROVIDE RESOURCES NEEDED TO IMPLEMENT SYSTEM

1	Provide the expertise needed to implement your system.	DO	DN	NA	
2	Acquire the knowledge needed to implement your system.	DO	DN	NA	
3	Consider internal sources of knowledge about system implementation.	DO	DN	NA	
4	Consider external sources of knowledge about system implementation.	DO	DN	NA	
5	Share the knowledge needed to implement your system.	DO	DN	NA	
6	Share implementation knowledge with managers.	DO	DN	NA	
7	Teach managers how to implement your system.	DO	DN	NA	
8	Share implementation knowledge with personnel.	DO	DN	NA	
9	Teach personnel how to implement your system.	DO	DN	NA	
10	Provide the technology needed to implement your system.	DO	DN	NA	
11	Provide the software needed to implement your system.	DO	DN	NA	
12	Provide the hardware needed to implement your system.	DO	DN	NA	
13	Provide the tools needed to implement your system.	DO	DN	NA	
14	Provide the equipment needed to implement your system.	DO	DN	NA	
15	Provide the infrastructure needed to implement your system.	DO	DN	NA	

A3.2 CREATE THE ENVIRONMENT THAT YOUR SYSTEM NEEDS

16	Establish the environment that your system needs in order to achieve conformity of outputs.	DO	DN	NA	
17	Create the culture that your system needs in order to achieve conformity of outputs.	DO	DN	NA	
18	Get the technology that your system needs in order to achieve conformity of outputs.	DO	DN	NA	
19	Acquire the knowledge that your system needs in order to achieve conformity of outputs.	DO	DN	NA	

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PLAIN ENGLISH QUALITY MANAGEMENT SYSTEM DEVELOPMENT PLAN

A3. IMPLEMENT QUALITY MANAGEMENT SYSTEM

20	Acquire the knowledge that system managers need to achieve conformity of outputs.	DO	DN	NA	
21	Acquire the knowledge that system personnel need to achieve conformity of outputs.	DO	DN	NA	
22	Develop the expertise that your system needs in order to achieve conformity of outputs.	DO	DN	NA	
23	Develop the management expertise that your system will need.	DO	DN	NA	
24	Deliver training and awareness programmes to managers.	DO	DN	NA	
25	Teach system managers how to operate your system.	DO	DN	NA	
26	Teach system managers how to maintain your system.	DO	DN	NA	
27	Teach system managers how to measure your system.	DO	DN	NA	
28	Teach system managers how to monitor your system.	DO	DN	NA	
29	Teach system managers how to control your system.	DO	DN	NA	
30	Develop the system expertise that system personnel will need.	DO	DN	NA	
31	Deliver training and awareness programmes to personnel.	DO	DN	NA	
32	Teach system personnel how to operate your system.	DO	DN	NA	
33	Teach system personnel how to maintain your system.	DO	DN	NA	
34	Teach system personnel how to measure your system.	DO	DN	NA	
35	Teach system personnel how to monitor your system.	DO	DN	NA	
36	Teach system personnel how to control your system.	DO	DN	NA	

A3.3 ESTABLISH PLANS TO ACHIEVE YOUR SYSTEM OBJECTIVES

37	Figure out what must be done to achieve system objectives.	DO	DN	NA	
38	Figure out what must be done to achieve business objectives.	DO	DN	NA	
39	Figure out what must be done to achieve technical objectives.	DO	DN	NA	
40	Figure out what must be done to achieve quality objectives.	DO	DN	NA	

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A3. IMPLEMENT QUALITY MANAGEMENT SYSTEM

41	Figure out what must be done to achieve safety objectives.	DO	DN	NA	
42	Figure out what must be done to achieve privacy objectives.	DO	DN	NA	
43	Figure out what must be done to achieve security objectives.	DO	DN	NA	
44	Figure out what must be done to achieve continuity objectives.	DO	DN	NA	
45	Figure out who will be responsible for achieving system objectives.	DO	DN	NA	
46	Figure out who will be responsible for achieving business objectives.	DO	DN	NA	
47	Figure out who will be responsible for achieving technical objectives.	DO	DN	NA	
48	Figure out who will be responsible for achieving quality objectives.	DO	DN	NA	
49	Figure out who will be responsible for achieving safety objectives.	DO	DN	NA	
50	Figure out who will be responsible for achieving privacy objectives.	DO	DN	NA	
51	Figure out who will be responsible for achieving security objectives.	DO	DN	NA	
52	Figure out who will be responsible for achieving continuity objectives.	DO	DN	NA	
53	Figure out what resources will be needed to achieve system objectives.	DO	DN	NA	
54	Figure out what resources will be needed to achieve business objectives.	DO	DN	NA	
55	Figure out what resources will be needed to achieve technical objectives.	DO	DN	NA	
56	Figure out what resources will be needed to achieve quality objectives.	DO	DN	NA	
57	Figure out what resources will be needed to achieve safety objectives.	DO	DN	NA	
58	Figure out what resources will be needed to achieve privacy objectives.	DO	DN	NA	
59	Figure out what resources will be needed to achieve security objectives.	DO	DN	NA	
60	Figure out what resources will be needed to achieve continuity objectives.	DO	DN	NA	

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A3. IMPLEMENT QUALITY MANAGEMENT SYSTEM

A3.4 EXPLAIN SYSTEM POLICIES, PROCEDURES, AND OBJECTIVES

61	Ensure that managers understand policies, procedures, and objectives.	DO	DN	NA	
62	Make sure that system managers understand your system policies.	DO	DN	NA	
63	Make sure that system managers know how to apply system policies.	DO	DN	NA	
64	Make sure that system managers understand your system procedures.	DO	DN	NA	
65	Make sure that system managers know how to follow system procedures.	DO	DN	NA	
66	Make sure that system managers understand their system objectives.	DO	DN	NA	
67	Make sure that system managers know how to achieve system objectives.	DO	DN	NA	
68	Make sure that managers know who is responsible for achieving objectives.	DO	DN	NA	
69	Ensure that personnel understand policies, procedures, and objectives.	DO	DN	NA	
70	Make sure that system personnel understand your system policies.	DO	DN	NA	
71	Make sure that system personnel know how to apply system policies.	DO	DN	NA	
72	Make sure that system personnel understand your system procedures.	DO	DN	NA	
73	Make sure that system personnel know how to follow system procedures.	DO	DN	NA	
74	Make sure that system personnel understand their system objectives.	DO	DN	NA	
75	Make sure that system personnel know how to achieve system objectives.	DO	DN	NA	
76	Make sure that personnel know who is responsible for achieving objectives.	DO	DN	NA	

A3.5 COMMUNICATE SYSTEM MANAGEMENT EXPECTATIONS

77	Explain why system policies must be applied.	DO	DN	NA	
78	Explain why system procedures must be followed.	DO	DN	NA	
79	Explain why system objectives must be achieved.	DO	DN	NA	
80	Explain why system requirements must be met.	DO	DN	NA	
81	Explain why output requirements must be met.	DO	DN	NA	

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A3. IMPLEMENT QUALITY MANAGEMENT SYSTEM

82	Explain why system methods must be used.	DO	DN	NA	
83	Explain why the systems approach is important.	DO	DN	NA	
84	Explain why safety management is important.	DO	DN	NA	
85	Explain why safety plans must be carried out.	DO	DN	NA	
86	Explain why safety policies must be implemented.	DO	DN	NA	
87	Explain why safety procedures must be followed.	DO	DN	NA	
88	Explain why safety objectives must be achieved.	DO	DN	NA	
89	Explain why safety requirements must be met.	DO	DN	NA	
90	Explain why quality management is important.	DO	DN	NA	
91	Explain why quality plans must be carried out.	DO	DN	NA	
92	Explain why quality policies must be implemented.	DO	DN	NA	
93	Explain why quality procedures must be followed.	DO	DN	NA	
94	Explain why quality objectives must be achieved.	DO	DN	NA	
95	Explain why quality requirements must be met.	DO	DN	NA	
96	Explain why continuity management is important.	DO	DN	NA	
97	Explain why business continuity plans must be carried out.	DO	DN	NA	
98	Explain why business continuity policies must be implemented.	DO	DN	NA	
99	Explain why business continuity procedures must be followed.	DO	DN	NA	
100	Explain why business continuity objectives must be achieved.	DO	DN	NA	
101	Explain why business continuity requirements must be met.	DO	DN	NA	
102	Explain why data privacy management is important.	DO	DN	NA	
103	Explain why personal privacy management is important.	DO	DN	NA	

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104	Explain why personal privacy plans must be carried out.	DO	DN	NA	
105	Explain why personal privacy policies must be implemented.	DO	DN	NA	
106	Explain why personal privacy procedures must be followed.	DO	DN	NA	
107	Explain why personal privacy objectives must be achieved.	DO	DN	NA	
108	Explain why personal privacy requirements must be met.	DO	DN	NA	
109	Explain why corporate security management is important.	DO	DN	NA	
110	Explain why information security management is important.	DO	DN	NA	
111	Explain why information security plans must be carried out.	DO	DN	NA	
112	Explain why information security policies must be implemented.	DO	DN	NA	
113	Explain why information security procedures must be followed.	DO	DN	NA	
114	Explain why information security objectives must be achieved.	DO	DN	NA	
115	Explain why information security requirements must be met.	DO	DN	NA	
116	Explain why component security management is important.	DO	DN	NA	
117	Explain why component security plans must be carried out.	DO	DN	NA	
118	Explain why component security policies must be implemented.	DO	DN	NA	
119	Explain why component security procedures must be followed.	DO	DN	NA	
120	Explain why component security objectives must be achieved.	DO	DN	NA	
121	Explain why component security requirements must be met.	DO	DN	NA	

A3.6 EXPECT ALL SYSTEM MANAGERS TO BE ACCOUNTABLE

122	Ask managers to accept responsibility for quality management system.	DO	DN	NA	
123	Ask managers to be accountable for ensuring that the system is effective.	DO	DN	NA	
124	Ask them to be accountable for ensuring that system produces intended outputs.	DO	DN	NA	

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A3. IMPLEMENT QUALITY MANAGEMENT SYSTEM

125	Ask managers to be accountable for ensuring that system meets requirements.	DO	DN	NA	
126	Ask them to be accountable for ensuring that system meets customer requirements.	DO	DN	NA	
127	Ask them to be accountable for ensuring that system meets technical requirements.	DO	DN	NA	
128	Ask them to be accountable for ensuring that system meets business requirements.	DO	DN	NA	
129	Ask them to be accountable for ensuring that system meets security requirements.	DO	DN	NA	
130	Ask them to be accountable for ensuring that system meets quality requirements.	DO	DN	NA	
131	Ask them to be accountable for ensuring that system meets privacy requirements.	DO	DN	NA	
132	Ask them to be accountable for ensuring that system meets safety requirements.	DO	DN	NA	
133	Ask them to be accountable for ensuring that system meets legal requirements.	DO	DN	NA	
134	Ask managers to be accountable for ensuring that system complies with standards.	DO	DN	NA	
135	Ask them to be accountable for ensuring that system complies with audit standards.	DO	DN	NA	
136	Ask them to be accountable for ensuring that system complies with safety standards.	DO	DN	NA	
137	Ask them to be accountable for ensuring that system complies with privacy standards.	DO	DN	NA	
138	Ask them to be accountable for ensuring that system complies with quality standards.	DO	DN	NA	
139	Ask them to be accountable for ensuring that system complies with service standards.	DO	DN	NA	
140	Ask them to be accountable for ensuring that system complies with product standards.	DO	DN	NA	
141	Ask them to be accountable for ensuring that system complies with security standards.	DO	DN	NA	
142	Ask managers to be accountable for ensuring that system implements policies.	DO	DN	NA	
143	Ask them to be accountable for ensuring that system implements audit policies.	DO	DN	NA	
144	Ask them to be accountable for ensuring that system implements safety policies.	DO	DN	NA	
145	Ask them to be accountable for ensuring that system implements privacy policies.	DO	DN	NA	
146	Ask them to be accountable for ensuring that system implements quality policies.	DO	DN	NA	

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A3. IMPLEMENT QUALITY MANAGEMENT SYSTEM

147	Ask them to be accountable for ensuring that system implements service policies.	DO	DN	NA	
148	Ask them to be accountable for ensuring that system implements product policies.	DO	DN	NA	
149	Ask them to be accountable for ensuring that system implements security policies.	DO	DN	NA	
150	Ask managers to be accountable for ensuring that system follows procedures.	DO	DN	NA	
151	Ask them to be accountable for ensuring that system follows safety procedures.	DO	DN	NA	
152	Ask them to be accountable for ensuring that system follows privacy procedures.	DO	DN	NA	
153	Ask them to be accountable for ensuring that system follows quality procedures.	DO	DN	NA	
154	Ask them to be accountable for ensuring that system follows service procedures.	DO	DN	NA	
155	Ask them to be accountable for ensuring that system follows product procedures.	DO	DN	NA	
156	Ask them to be accountable for ensuring that system follows security procedures.	DO	DN	NA	
157	Ask managers to be accountable for ensuring that system carries out plans.	DO	DN	NA	
158	Ask them to be accountable for ensuring that system carries out safety plans.	DO	DN	NA	
159	Ask them to be accountable for ensuring that system carries out privacy plans.	DO	DN	NA	
160	Ask them to be accountable for ensuring that system carries out quality plans.	DO	DN	NA	
161	Ask them to be accountable for ensuring that system carries out service plans.	DO	DN	NA	
162	Ask them to be accountable for ensuring that system carries out product plans.	DO	DN	NA	
163	Ask them to be accountable for ensuring that system carries out security plans.	DO	DN	NA	

Consider each task and select a response. If you haven't done it and it needs to be done, select DO. If you've already done it, select DN. If the task is not applicable in your situation and you can justify and explain why it should be ignored or excluded, select NA.

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B1. OPERATE QUALITY MANAGEMENT SYSTEM

B1.1 PROVIDE RESOURCES TO FACILITATE SYSTEM OPERATIONS

B1.1.1 PROVIDE THE EXPERTISE NEEDED TO OPERATE YOUR SYSTEM

1	Provide the personnel needed to manage system operations.	DO	DN	NA	
2	Acquire the knowledge that managers need to manage system operations and achieve conformity of outputs.	DO	DN	NA	
3	Consider internal sources of knowledge about managing systems.	DO	DN	NA	
4	Consider external sources of knowledge about managing systems.	DO	DN	NA	
5	Share the knowledge that managers need to manage system operations and achieve conformity of outputs.	DO	DN	NA	
6	Deliver suitable system management training and awareness programmes to system managers.	DO	DN	NA	
7	Provide the personnel needed to operate your system.	DO	DN	NA	
8	Acquire the knowledge that personnel need to operate your system and achieve conformity of outputs.	DO	DN	NA	
9	Consider internal sources of knowledge about system operations.	DO	DN	NA	
10	Consider external sources of knowledge about system operations.	DO	DN	NA	
11	Share the knowledge that personnel need to operate your system and achieve conformity of outputs.	DO	DN	NA	
12	Deliver suitable system training and awareness programmes to support system operations.	DO	DN	NA	

B1.1.2 PROVIDE THE TECHNOLOGY NEEDED TO OPERATE YOUR SYSTEM

13	Provide the software needed to operate your quality management system.	DO	DN	NA	
14	Provide software needed to support operations and achieve conformity of outputs.	DO	DN	NA	
15	Provide the hardware needed to operate your quality management system.	DO	DN	NA	
16	Provide hardware needed to support operations and achieve conformity of outputs.	DO	DN	NA	

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MANAGE QUALITY MANAGEMENT SYSTEM

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B1. OPERATE QUALITY MANAGEMENT SYSTEM

B1.1.3 PROVIDE THE INFRASTRUCTURE NEEDED TO OPERATE YOUR SYSTEM

17	Provide the infrastructure needed to support system operations and achieve conformity of outputs.	DO	DN	NA	
18	Provide the physical infrastructure needed to support system operations and achieve conformity of outputs.	DO	DN	NA	
19	Provide the electrical infrastructure needed to support system operations and achieve conformity of outputs.	DO	DN	NA	
20	Provide the transportation infrastructure needed to support system operations and achieve conformity of outputs.	DO	DN	NA	
21	Provide the communications infrastructure needed to support system operations and achieve conformity of outputs.	DO	DN	NA	

B1.2 ASK SYSTEM OWNERS TO MANAGE SYSTEM OPERATIONS

B1.2.1 EXPECT SYSTEM MANAGERS TO ADDRESS RISKS AND OPPORTUNITIES

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

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

B1.2.2 EXPECT SYSTEM MANAGERS TO IMPLEMENT POLICIES AND PROCEDURES

39	Expect system managers to implement system policies.	DO	DN	NA	
40	Expect managers to implement business policies.	DO	DN	NA	
41	Expect managers to implement quality policies.	DO	DN	NA	
42	Expect managers to implement safety policies.	DO	DN	NA	
43	Expect managers to implement privacy policies.	DO	DN	NA	
44	Expect managers to implement security policies.	DO	DN	NA	
45	Expect managers to implement continuity policies.	DO	DN	NA	
46	Expect system managers to implement system procedures.	DO	DN	NA	
47	Expect managers to implement business procedures.	DO	DN	NA	

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48	Expect managers to implement quality procedures.	DO	DN	NA	
49	Expect managers to implement safety procedures.	DO	DN	NA	
50	Expect managers to implement privacy procedures.	DO	DN	NA	
51	Expect managers to implement security procedures.	DO	DN	NA	
52	Expect managers to implement continuity procedures.	DO	DN	NA	
53	Expect system managers to implement system plans.	DO	DN	NA	
54	Expect managers to implement business plans.	DO	DN	NA	
55	Expect managers to implement quality plans.	DO	DN	NA	
56	Expect managers to implement safety plans.	DO	DN	NA	
57	Expect managers to implement privacy plans.	DO	DN	NA	
58	Expect managers to implement security plans.	DO	DN	NA	
59	Expect managers to implement continuity plans.	DO	DN	NA	

B1.2.3 EXPECT SYSTEM MANAGERS TO SPECIFY OUTPUT REQUIREMENTS AND CAPABILITIES

60	Expect system managers to determine requirements for outputs offered to customers.	DO	DN	NA	
61	Expect managers to determine statutory and regulatory requirements for outputs.	DO	DN	NA	
62	Expect managers to determine your organization's own requirements for outputs.	DO	DN	NA	
63	Expect managers to determine any additional "special requirements" for outputs.	DO	DN	NA	
64	Expect system managers to review output requirements before accepting orders.	DO	DN	NA	
65	Expect them to review requirements before agreeing to supply outputs to customers.	DO	DN	NA	
66	Expect managers to coordinate reviews with other functions within your organization.	DO	DN	NA	

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

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B1.2.4 EXPECT SYSTEM MANAGERS TO COMMUNICATE WITH THEIR SYSTEM CUSTOMERS

88	Expect quality management system managers to provide information to customers.	DO	DN	NA	
89	Expect quality management system managers to share information about outputs.	DO	DN	NA	
90	Expect quality management system managers to obtain information from customers.	DO	DN	NA	
91	Expect system managers to obtain information about customer orders and contracts.	DO	DN	NA	
92	Expect system managers to receive information about changes to orders and contracts.	DO	DN	NA	
93	Expect quality system managers to obtain information about system outputs.	DO	DN	NA	
94	Expect system managers to gather customer feedback about system outputs.	DO	DN	NA	
95	Expect quality system managers to gather complaints about system outputs.	DO	DN	NA	
96	Expect system managers to obtain information about property supplied by customers.	DO	DN	NA	
97	Expect system managers to manage and control property supplied by customers.	DO	DN	NA	

B1.2.5 EXPECT SYSTEM MANAGERS TO EVALUATE AND SELECT THEIR EXTERNAL PROVIDERS

98	Expect system managers to accept responsibility for externally provided processes, products, and services.	DO	DN	NA	
99	Expect them to accept responsibility for conformity of external processes, products, and services.	DO	DN	NA	
100	Expect system managers to identify risks related to the external provision of processes, products, and services.	DO	DN	NA	
101	Expect them to identify risks related to the selection and use of external providers and external sources.	DO	DN	NA	
102	Expect system managers to define data and criteria to manage external process, product, and service providers.	DO	DN	NA	
103	Expect them to use data and criteria to evaluate external process, product, and service providers.	DO	DN	NA	

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

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

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145	Expect system managers to identify external staff awareness requirements.	DO	DN	NA	
146	Expect system managers to identify external competence requirements.	DO	DN	NA	
147	Expect system managers to identify monitoring and control requirements.	DO	DN	NA	
148	Expect system managers to identify documentation requirements.	DO	DN	NA	

B1.2.6 EXPECT SYSTEM MANAGERS TO SUPERVISE AND CONTROL ALL SYSTEM ACTIVITIES

149	Expect system managers to verify that resources can produce required results.	DO	DN	NA	
150	Expect system managers to validate resources that will be used to operate system.	DO	DN	NA	
151	Expect system managers to validate tools before they are used to operate system.	DO	DN	NA	
152	Expect system managers to validate equipment before it is used to operate system.	DO	DN	NA	
153	Expect system managers to validate software before it is used to operate system.	DO	DN	NA	
154	Expect system managers to validate resources that will be used to automate system.	DO	DN	NA	
155	Expect system managers to validate tools before they are used to automate system.	DO	DN	NA	
156	Expect system managers to validate equipment before it is used to automate system.	DO	DN	NA	
157	Expect system managers to validate software before it is used to automate system.	DO	DN	NA	
158	Expect system managers to validate resources that will be used to control system.	DO	DN	NA	
159	Expect system managers to validate tools before they are used to control system.	DO	DN	NA	
160	Expect system managers to validate equipment before it is used to control system.	DO	DN	NA	
161	Expect system managers to validate software before it is used to control system.	DO	DN	NA	
162	Expect system managers to validate resources that will be used to monitor system.	DO	DN	NA	
163	Expect system managers to validate tools before they are used to monitor system.	DO	DN	NA	
164	Expect system managers to validate equipment before it is used to monitor system.	DO	DN	NA	

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

B1.2.7 EXPECT SYSTEM MANAGERS TO MEASURE CONFORMANCE AND PERFORMANCE

176	Expect system managers to measure system performance and conformance.	DO	DN	NA	
177	Expect system managers to measure output performance and conformance.	DO	DN	NA	
178	Expect system managers to measure output delivery performance and conformance.	DO	DN	NA	
179	Expect system managers to measure post-delivery performance and conformance.	DO	DN	NA	

B1.2.8 EXPECT SYSTEM MANAGERS TO MEET EXPECTATIONS AND REQUIREMENTS

180	Expect system managers to ensure that legal expectations and requirements are being met.	DO	DN	NA	
181	Expect system managers to ensure that safety expectations and requirements are being met.	DO	DN	NA	
182	Expect system managers to ensure that privacy expectations and requirements are being met.	DO	DN	NA	
183	Expect system managers to ensure that quality expectations and requirements are being met.	DO	DN	NA	
184	Expect system managers to ensure that security expectations and requirements are being met.	DO	DN	NA	

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185	Expect system managers to ensure that business expectations and requirements are being met.	DO	DN	NA	
186	Expect system managers to ensure that customer expectations and requirements are being met.	DO	DN	NA	

B1.2.9 EXPECT SYSTEM MANAGERS TO BE ACCOUNTABLE FOR THEIR SYSTEM

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

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205	Expect them to use a suitable system environment to control output delivery system.	DO	DN	NA	
206	Expect them to use competent qualified personnel to control output delivery activities.	DO	DN	NA	
207	Expect managers to address post-delivery requirements for outputs.	DO	DN	NA	
208	Expect managers to develop controlled conditions for post-delivery.	DO	DN	NA	
209	Expect them to consider post-delivery requirements and commitments.	DO	DN	NA	
210	Expect them to consider the need to provide, update, and control output documents.	DO	DN	NA	
211	Expect them to consider the external work that must be done to support outputs.	DO	DN	NA	
212	Expect them to consider the actions that must be taken after outputs are delivered.	DO	DN	NA	
213	Expect managers to implement controlled conditions for post-delivery of outputs.	DO	DN	NA	
214	Expect them to implement controlled conditions for post-delivery of system outputs.	DO	DN	NA	
215	Expect them to use suitable monitoring and measurement resources to control post-delivery.	DO	DN	NA	
216	Expect them to use a suitable system environment to control post-delivery activities.	DO	DN	NA	
217	Expect them to use competent qualified personnel to control post-delivery activities.	DO	DN	NA	
218	Expect managers to identify and control all nonconforming outputs.	DO	DN	NA	
219	Expect quality management system managers to evaluate nonconforming outputs.	DO	DN	NA	
220	Expect them to consider the nature of nonconforming outputs and to evaluate their effects.	DO	DN	NA	
221	Expect quality system managers to take action to control nonconforming outputs.	DO	DN	NA	
222	Expect them to prevent the unintended use or delivery of nonconforming outputs.	DO	DN	NA	
223	Expect quality system managers to document nonconforming system outputs.	DO	DN	NA	
224	Expect system managers to document the actions and decisions taken to prevent the unintended use or delivery of nonconforming outputs.	DO	DN	NA	
225	Expect managers to submit system performance reports.	DO	DN	NA	

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B1. OPERATE QUALITY MANAGEMENT SYSTEM

B1.3 EXPECT PERSONNEL TO CARRY OUT SYSTEM OPERATIONS

B1.3.1 EXPECT PERSONNEL TO FOCUS ON SYSTEM CUSTOMERS

226	Expect system personnel to identify customer needs and expectations.	DO	DN	NA	
227	Expect system personnel to identify customer assumptions and perceptions.	DO	DN	NA	
228	Expect system personnel to understand customer needs and expectations.	DO	DN	NA	
229	Expect system personnel to understand customer assumptions and perceptions.	DO	DN	NA	
230	Expect system personnel to meet relevant customer needs and expectations.	DO	DN	NA	
231	Expect system personnel to focus on enhancing customer satisfaction.	DO	DN	NA	

B1.3.2 EXPECT PERSONNEL TO HANDLE RISKS AND OPPORTUNITIES

232	Expect quality system personnel to identify their risks and opportunities.	DO	DN	NA	
233	Expect personnel to identify risks and opportunities related to outputs.	DO	DN	NA	
234	Expect them to identify the risks that could negatively influence their ability to provide compliant outputs to system customers.	DO	DN	NA	
235	Expect them to identify the opportunities that could possibly enhance their ability to provide compliant outputs to system customers.	DO	DN	NA	
236	Expect personnel to identify risks and opportunities related to customer satisfaction.	DO	DN	NA	
237	Expect them to identify risks that could influence their ability to satisfy customers.	DO	DN	NA	
238	Expect them to identify opportunities that could enhance their ability to satisfy customers.	DO	DN	NA	
239	Expect quality system personnel to address their risks and opportunities.	DO	DN	NA	
240	Expect personnel to address risks and opportunities related to outputs.	DO	DN	NA	
241	Expect them to address the risks that could negatively influence their ability to provide compliant outputs to system customers.	DO	DN	NA	

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242	Expect them to address the opportunities that could enhance their ability to provide compliant outputs to system customers.	DO	DN	NA	
243	Expect personnel to address risks and opportunities related to customer satisfaction.	DO	DN	NA	
244	Expect them to address risks that could influence their ability to satisfy customers.	DO	DN	NA	
245	Expect them to address opportunities that could enhance their ability to satisfy customers.	DO	DN	NA	

B1.3.3 EXPECT PERSONNEL TO IMPLEMENT POLICIES AND PROCEDURES

246	Expect quality system personnel to follow system policies.	DO	DN	NA	
247	Expect them to implement and follow safety policies.	DO	DN	NA	
248	Expect them to implement and follow quality policies.	DO	DN	NA	
249	Expect them to implement and follow security policies.	DO	DN	NA	
250	Expect them to implement and follow privacy policies.	DO	DN	NA	
251	Expect them to implement and follow business policies.	DO	DN	NA	
252	Expect them to implement and follow continuity policies.	DO	DN	NA	
253	Expect quality system personnel to follow system procedures.	DO	DN	NA	
254	Expect them to implement and follow safety procedures.	DO	DN	NA	
255	Expect them to implement and follow quality procedures.	DO	DN	NA	
256	Expect them to implement and follow privacy procedures.	DO	DN	NA	
257	Expect them to implement and follow security procedures.	DO	DN	NA	
258	Expect them to implement and follow business procedures.	DO	DN	NA	
259	Expect them to implement and follow continuity procedures.	DO	DN	NA	

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B1. OPERATE QUALITY MANAGEMENT SYSTEM

B1.3.4 EXPECT PERSONNEL TO COMPLY WITH ALL RELEVANT REQUIREMENTS

260	Expect system personnel to determine relevant requirements.	DO	DN	NA	
261	Expect them to identify customer requirements.	DO	DN	NA	
262	Expect them to identify legal requirements.	DO	DN	NA	
263	Expect system personnel to meet all relevant requirements.	DO	DN	NA	
264	Expect them to meet all relevant customer requirements.	DO	DN	NA	
265	Expect them to provide products that meet customer requirements.	DO	DN	NA	
266	Expect them to deliver services that meet customer requirements.	DO	DN	NA	
267	Expect them to meet all relevant legal requirements.	DO	DN	NA	
268	Expect them to provide products that meet legal requirements.	DO	DN	NA	
269	Expect them to deliver services that meet legal requirements.	DO	DN	NA	

B1.3.5 EXPECT PERSONNEL TO TAKE APPROPRIATE ACTION WHEN NECESSARY

270	Expect system personnel to take action when planned results aren't being achieved.	DO	DN	NA	
271	Expect system personnel to take action when planned results won't be achieved.	DO	DN	NA	
272	Expect system personnel to take action when planned results can't be achieved.	DO	DN	NA	

B1.3.6 EXPECT PERSONNEL TO CONTROL SYSTEM DOCUMENTS AND RECORDS

273	Expect system personnel to retain and control system documents.	DO	DN	NA	
274	Expect system personnel to maintain and control system records.	DO	DN	NA	

Consider each task and select a response. If you haven't done it and it needs to be done, select DO. If you've already done it, select DN. If the task is not applicable in your situation and you can justify and explain why it should be ignored or excluded, select NA.

In the spaces below, please enter the name and location of your organization, who completed this page, who reviewed it, and the dates.

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B2. MAINTAIN QUALITY MANAGEMENT SYSTEM

B2.1 PROVIDE THE RESOURCES NEEDED TO MAINTAIN SYSTEM

B2.1.1 PROVIDE THE EXPERTISE NEEDED TO MAINTAIN YOUR SYSTEM

1	Provide the managers needed to maintain your quality system.	DO	DN	NA	
2	Acquire the knowledge that managers need in order to support system maintenance and achieve conformity of outputs.	DO	DN	NA	
3	Share the knowledge that managers need so that they can support system maintenance and achieve conformity of outputs.	DO	DN	NA	
4	Deliver suitable awareness programmes to the people who manage system maintenance activities.	DO	DN	NA	
5	Deliver suitable training programmes to the people who manage system maintenance activities.	DO	DN	NA	
6	Provide people needed to maintain your quality system.	DO	DN	NA	
7	Acquire the knowledge that your personnel need in order to maintain system and achieve conformity of outputs.	DO	DN	NA	
8	Share the knowledge that personnel need in order to maintain system and achieve conformity of outputs.	DO	DN	NA	
9	Deliver suitable awareness programmes for your system maintenance personnel.	DO	DN	NA	
10	Deliver suitable training programmes for your system maintenance personnel.	DO	DN	NA	

B2.1.2 PROVIDE THE TECHNOLOGY NEEDED TO MAINTAIN YOUR SYSTEM

11	Provide the software needed to maintain quality system.	DO	DN	NA	
12	Provide the software needed to support system maintenance and achieve conformity of outputs.	DO	DN	NA	
13	Provide the hardware needed to maintain quality system.	DO	DN	NA	
14	Provide the hardware needed to support system maintenance and achieve conformity of outputs.	DO	DN	NA	

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B2. MAINTAIN QUALITY MANAGEMENT SYSTEM

B2.2 USE AUTHORIZED METHODS TO MAINTAIN YOUR SYSTEM

B2.2.1 USE AUTHORIZED METHODS TO MAINTAIN YOUR DOCUMENTS

15	Maintain documents that describe how work should be carried out.	DO	DN	NA	
16	Maintain documents that describe how system operations should be carried out.	DO	DN	NA	
17	Maintain documents that describe how system maintenance should be carried out.	DO	DN	NA	
18	Maintain documents that describe how system monitoring should be carried out.	DO	DN	NA	
19	Maintain documents that describe how system measurement should be carried out.	DO	DN	NA	
20	Maintain documents that describe how system control should be carried out.	DO	DN	NA	
21	Maintain documents that describe how system evaluation should be carried out.	DO	DN	NA	
22	Maintain documents that describe how system audits should be carried out.	DO	DN	NA	
23	Maintain documents that describe how system reviews should be carried out.	DO	DN	NA	
24	Maintain documents that describe how system changes should be carried out.	DO	DN	NA	
25	Maintain documents that describe how system correction should be carried out.	DO	DN	NA	
26	Maintain documents that describe how system improvements should be carried out.	DO	DN	NA	

B2.2.2 USE AUTHORIZED METHODS TO MAINTAIN YOUR RECORDS

27	Maintain records that describe the scope of your quality management system.	DO	DN	NA	
28	Maintain records of quality management system responsibilities and authorities.	DO	DN	NA	
29	Maintain records of quality management system performance and competence.	DO	DN	NA	
30	Retain your documentation and use it as evidence to show that your quality management system personnel are in fact competent.	DO	DN	NA	
31	Maintain records showing that quality management system is performing as planned.	DO	DN	NA	

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B2. MAINTAIN QUALITY MANAGEMENT SYSTEM

32	Maintain records that show that system operations are being carried out as planned.	DO	DN	NA	
33	Maintain records that show that system maintenance is being carried out as planned.	DO	DN	NA	
34	Maintain records that show that system monitoring is being carried out as planned.	DO	DN	NA	
35	Maintain records that show that system measurement is being carried out as planned.	DO	DN	NA	
36	Maintain records that show that system control is being carried out as planned.	DO	DN	NA	
37	Maintain records that show that system evaluation is being carried out as planned.	DO	DN	NA	
38	Maintain records that show that system audits are being carried out as planned.	DO	DN	NA	
39	Maintain records that show that system reviews are being carried out as planned.	DO	DN	NA	
40	Maintain records that show that system changes are being carried out as planned.	DO	DN	NA	
41	Maintain records that show that system corrections are being carried out as planned.	DO	DN	NA	
42	Maintain records that show that system improvements are being carried out as planned.	DO	DN	NA	

B2.2.3 USE AUTHORIZED METHODS TO MAINTAIN YOUR PROPERTY

43	Maintain system property owned by your customers and suppliers that is needed to achieve conformity of outputs.	DO	DN	NA	
44	Identify property belonging to customers and external providers.	DO	DN	NA	
45	Verify property belonging to customers and external providers.	DO	DN	NA	
46	Protect property belonging to customers and external providers.	DO	DN	NA	
47	Report property belonging to your customers and external providers.	DO	DN	NA	
48	Report lost or damaged property to customers and external providers.	DO	DN	NA	
49	Report unsuitable property to customers and external providers.	DO	DN	NA	

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B2. MAINTAIN QUALITY MANAGEMENT SYSTEM

50	Document property belonging to your customers and external providers.	DO	DN	NA	
51	Maintain property owned by your quality management system that is needed to achieve conformity of system outputs.	DO	DN	NA	
52	Maintain equipment that your system needs in order to achieve conformity of outputs.	DO	DN	NA	
53	Maintain software that your system needs in order to achieve conformity of outputs.	DO	DN	NA	
54	Maintain tools that your system needs in order to achieve conformity of outputs.	DO	DN	NA	

B2.2.4 USE AUTHORIZED METHODS TO MAINTAIN YOUR PROCEDURES

55	Use authorized methods to maintain system management procedures.	DO	DN	NA	
56	Use authorized methods to maintain system control procedures.	DO	DN	NA	
57	Use authorized methods to maintain system operational procedures.	DO	DN	NA	
58	Use authorized methods to maintain system maintenance procedures.	DO	DN	NA	
59	Use authorized methods to maintain system monitoring procedures.	DO	DN	NA	
60	Use authorized methods to maintain system feedback procedures.	DO	DN	NA	
61	Use authorized methods to maintain system measurement procedures.	DO	DN	NA	
62	Use authorized methods to maintain equipment calibration procedures.	DO	DN	NA	
63	Use authorized methods to maintain system evaluation procedures.	DO	DN	NA	
64	Use authorized methods to maintain system audit procedures.	DO	DN	NA	
65	Use authorized methods to maintain system review procedures.	DO	DN	NA	
66	Use authorized methods to maintain system change procedures.	DO	DN	NA	
67	Use authorized methods to maintain system correction procedures.	DO	DN	NA	
68	Use authorized methods to maintain system improvement procedures.	DO	DN	NA	

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B2. MAINTAIN QUALITY MANAGEMENT SYSTEM

B2.2.5 USE AUTHORIZED METHODS TO MAINTAIN YOUR COMPETENCE

69	Share information and knowledge with management system personnel.	DO	DN	NA	
70	Make sure that they are aware of management system plans.	DO	DN	NA	
71	Make sure that they are aware of management system policies.	DO	DN	NA	
72	Make sure that they are aware of management system objectives.	DO	DN	NA	
73	Make sure that they are aware of management system procedures.	DO	DN	NA	
74	Make sure that they are aware of management system documents and records.	DO	DN	NA	
75	Make sure that personnel stay abreast of changes in knowledge and information.	DO	DN	NA	
76	Make sure that they are aware of the important contribution they make.	DO	DN	NA	
77	Make sure that they understand how they affect system performance.	DO	DN	NA	
78	Make sure that they understand how they influence system outputs.	DO	DN	NA	
79	Make sure that they are aware of all relevant requirements.	DO	DN	NA	
80	Explain why compliance is important to your system.	DO	DN	NA	
81	Make sure that they are aware of how they can help.	DO	DN	NA	
82	Explain how they can help enhance system effectiveness.	DO	DN	NA	
83	Acquire competence whenever shortcomings are discovered.	DO	DN	NA	
84	Acquire the necessary competence whenever system personnel fail to meet system competence requirements.	DO	DN	NA	
85	Consider helping your personnel to improve.	DO	DN	NA	
86	Consider providing suitable training.	DO	DN	NA	
87	Consider offering mentoring services.	DO	DN	NA	

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88	Consider hiring competent people.	DO	DN	NA	
89	Consider hiring competent employees.	DO	DN	NA	
90	Consider hiring competent contractors.	DO	DN	NA	
91	Consider reassigning unsuitable personnel.	DO	DN	NA	
92	Maintain the system knowledge that has been acquired.	DO	DN	NA	
93	Consider the need to protect and preserve lessons learned.	DO	DN	NA	
94	Consider the need to protect and preserve intellectual property.	DO	DN	NA	

B2.2.6 USE AUTHORIZED METHODS TO MAINTAIN YOUR TECHNOLOGIES

95	Maintain technology used to perform management system operations.	DO	DN	NA	
96	Maintain tools used to perform management system operations.	DO	DN	NA	
97	Define storage requirements for tools used for system operations.	DO	DN	NA	
98	Define how and when to check the status of tools used for system operations.	DO	DN	NA	
99	Maintain equipment used to perform management system operations.	DO	DN	NA	
100	Define storage requirements for equipment used for system operations.	DO	DN	NA	
101	Define how and when to check the status of equipment used for system operations.	DO	DN	NA	
102	Maintain software used to perform management system operations.	DO	DN	NA	
103	Define how and when to check the status of software used for system operations.	DO	DN	NA	
104	Maintain technology used to automate management system operations.	DO	DN	NA	
105	Maintain tools used to automate management system operations.	DO	DN	NA	
106	Define storage requirements for tools used to automate system operations.	DO	DN	NA	

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107	Maintain equipment used to automate management system operations.	DO	DN	NA	
108	Define storage requirements for equipment used to automate system operations.	DO	DN	NA	
109	Maintain software used to automate management system operations.	DO	DN	NA	
110	Define how and when to check the status of software used for automation.	DO	DN	NA	
111	Maintain technology used to control management system operations.	DO	DN	NA	
112	Maintain tools used to control management system operations.	DO	DN	NA	
113	Maintain equipment used to control management system operations.	DO	DN	NA	
114	Maintain software used to control management system operations.	DO	DN	NA	
115	Maintain technology used to monitor management system operations.	DO	DN	NA	
116	Maintain tools used to monitor management system operations.	DO	DN	NA	
117	Maintain equipment used to monitor management system operations.	DO	DN	NA	
118	Maintain software used to monitor management system operations.	DO	DN	NA	
119	Maintain technology used to measure management system operations.	DO	DN	NA	
120	Maintain software used to measure management system operations.	DO	DN	NA	
121	Maintain tools used to measure management system operations.	DO	DN	NA	
122	Maintain equipment used to measure management system operations.	DO	DN	NA	
123	Define storage requirements for equipment used to measure operations.	DO	DN	NA	
124	Establish an identification system for measurement equipment.	DO	DN	NA	
125	Verify or calibrate your system measurement equipment.	DO	DN	NA	
126	Safeguard your system measurement equipment.	DO	DN	NA	

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B2. MAINTAIN QUALITY MANAGEMENT SYSTEM

B2.2.7 USE AUTHORIZED METHODS TO MAINTAIN YOUR INFRASTRUCTURE

127	Maintain the infrastructure that your system needs in order to achieve conformity of outputs.	DO	DN	NA	
128	Maintain the facilities that your system needs in order to achieve conformity of outputs.	DO	DN	NA	
129	Maintain the utilities that your system needs in order to achieve conformity of outputs.	DO	DN	NA	
130	Maintain the services that your system needs in order to achieve conformity of outputs.	DO	DN	NA	
131	Maintain the technologies that your system needs in order to achieve conformity of outputs.	DO	DN	NA	
132	Maintain the hardware that your system needs in order to achieve conformity of outputs.	DO	DN	NA	
133	Maintain the software that your system needs in order to achieve conformity of outputs.	DO	DN	NA	

B2.2.8 USE AUTHORIZED METHODS TO MAINTAIN YOUR COMMUNICATIONS

134	Maintain the internal communications that system needs to achieve conformity of outputs.	DO	DN	NA	
135	Maintain the external communications that system needs to achieve conformity of outputs.	DO	DN	NA	

Consider each task and select a response. If you haven't done it and it needs to be done, select DO. If you've already done it, select DN. If the task is not applicable in your situation and you can justify and explain why it should be ignored or excluded, select NA.

In the spaces below, please enter the name and location of your organization, who completed this page, who reviewed it, and the dates.

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B3. MEASURE QUALITY MANAGEMENT SYSTEM

B3.1 PLAN HOW YOU'RE GOING TO MEASURE YOUR SYSTEM

B3.1.1 FIGURE OUT WHAT NEEDS TO BE MEASURED

1	Figure out what kind of system activities need to be measured.	DO	DN	NA	
2	Figure out what kind of system characteristics need to be measured.	DO	DN	NA	
3	Figure out what kind of inputs and outputs need to be measured.	DO	DN	NA	
4	Figure out what kind of output characteristics need to be measured.	DO	DN	NA	
5	Figure out what kind of input characteristics need to be measured.	DO	DN	NA	

B3.1.2 FIGURE OUT HOW MEASUREMENTS WILL BE DONE

6	Plan how you're going to measure system elements.	DO	DN	NA	
7	Plan how you're going to measure your system outputs.	DO	DN	NA	
8	Plan how you're going to measure your outputs against expectations.	DO	DN	NA	
9	Plan how you're going to measure how well outputs implement plans.	DO	DN	NA	
10	Plan how you're going to measure how well outputs achieve objectives.	DO	DN	NA	
11	Plan how you're going to measure how well outputs meet requirements.	DO	DN	NA	
12	Plan how you're going to measure how well outputs comply with policies.	DO	DN	NA	
13	Plan how you're going to measure your system inputs.	DO	DN	NA	
14	Plan how you're going to measure your inputs against expectations.	DO	DN	NA	
15	Plan how you're going to measure how well inputs implement plans.	DO	DN	NA	
16	Plan how you're going to measure how well inputs achieve objectives.	DO	DN	NA	
17	Plan how you're going to measure how well inputs meet requirements.	DO	DN	NA	
18	Plan how you're going to measure how well inputs comply with policies.	DO	DN	NA	

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B3. MEASURE QUALITY MANAGEMENT SYSTEM

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

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

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61	Plan how to measure how well system control activities comply with requirements.	DO	DN	NA	
62	Plan how you're going to measure system evaluation activities.	DO	DN	NA	
63	Plan how you're going to measure system audit activities.	DO	DN	NA	
64	Plan how to measure how well system audit activities meet expectations.	DO	DN	NA	
65	Plan how to measure how well system audit activities apply policies.	DO	DN	NA	
66	Plan how to measure how well system audit activities implement plans.	DO	DN	NA	
67	Plan how to measure how well system audit activities follow procedures.	DO	DN	NA	
68	Plan how to measure how well system audit activities achieve objectives.	DO	DN	NA	
69	Plan how to measure how well system audit activities comply with requirements.	DO	DN	NA	
70	Plan how you're going to measure system review activities.	DO	DN	NA	
71	Plan how to measure how well system review activities meet expectations.	DO	DN	NA	
72	Plan how to measure how well system review activities apply policies.	DO	DN	NA	
73	Plan how to measure how well system review activities implement plans.	DO	DN	NA	
74	Plan how to measure how well system review activities follow procedures.	DO	DN	NA	
75	Plan how to measure how well system review activities achieve objectives.	DO	DN	NA	
76	Plan how to measure how well system review activities comply with requirements.	DO	DN	NA	
77	Plan how you're going to measure system change activities.	DO	DN	NA	
78	Plan how you're going to measure system correction activities.	DO	DN	NA	
79	Plan how to measure how well system correction activities meet expectations.	DO	DN	NA	
80	Plan how to measure how well system correction activities apply policies.	DO	DN	NA	
81	Plan how to measure how well system correction activities implement plans.	DO	DN	NA	

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B3. MEASURE QUALITY MANAGEMENT SYSTEM

82	Plan how to measure how well system correction activities follow procedures.	DO	DN	NA	
83	Plan how to measure how well system correction activities achieve objectives.	DO	DN	NA	
84	Plan how to measure how well system correction activities comply with requirements.	DO	DN	NA	
85	Plan how you're going to measure system improvement activities.	DO	DN	NA	
86	Plan how to measure how well system improvement activities meet expectations.	DO	DN	NA	
87	Plan how to measure how well system improvement activities apply policies.	DO	DN	NA	
88	Plan how to measure how well system improvement activities implement plans.	DO	DN	NA	
89	Plan how to measure how well system improvement activities follow procedures.	DO	DN	NA	
90	Plan how to measure how well system improvement activities achieve objectives.	DO	DN	NA	
91	Plan how to measure how well system improvement activities comply with requirements.	DO	DN	NA	
92	Plan how you're going to measure customer satisfaction.	DO	DN	NA	
93	Learn how management system customers feel about your outputs.	DO	DN	NA	
94	Figure out how to gather information about customer satisfaction.	DO	DN	NA	
95	Figure out how to learn about customer satisfaction by doing customer surveys.	DO	DN	NA	
96	Figure out how to learn about customer satisfaction by using face-to-face meetings.	DO	DN	NA	
97	Figure out how to learn about customer satisfaction by studying customer feedback.	DO	DN	NA	
98	Figure out how to use information to evaluate customer satisfaction.	DO	DN	NA	
99	Figure out how to use output information to evaluate customer satisfaction.	DO	DN	NA	
100	Figure out how to use delivery information to evaluate customer satisfaction.	DO	DN	NA	
101	Figure out how to use post-delivery information to evaluate customer satisfaction.	DO	DN	NA	
102	Figure out how to use corrective action information to evaluate customer satisfaction.	DO	DN	NA	

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B3. MEASURE QUALITY MANAGEMENT SYSTEM

B3.1.3 FIGURE OUT WHO WILL PERFORM MEASUREMENT TASKS

103	Allocate responsibility and authority for measuring customer satisfaction.	DO	DN	NA	
104	Allocate responsibility and authority for carrying out customer surveys.	DO	DN	NA	
105	Allocate responsibility and authority for meeting with system customers.	DO	DN	NA	
106	Allocate responsibility and authority for studying feedback from customers.	DO	DN	NA	
107	Allocate responsibility and authority for measuring system elements.	DO	DN	NA	
108	Allocate responsibility and authority for measuring system outputs.	DO	DN	NA	
109	Allocate responsibility and authority for measuring system inputs.	DO	DN	NA	
110	Allocate responsibility and authority for measuring system activities.	DO	DN	NA	
111	Allocate responsibility and authority for measuring system control activities and results.	DO	DN	NA	
112	Allocate responsibility and authority for measuring system operating activities and results.	DO	DN	NA	
113	Allocate responsibility and authority for measuring system maintenance activities and results.	DO	DN	NA	
114	Allocate responsibility and authority for measuring system measurement activities and results.	DO	DN	NA	
115	Allocate responsibility and authority for measuring system monitoring activities and results.	DO	DN	NA	
116	Allocate responsibility and authority for measuring system evaluation activities and results.	DO	DN	NA	
117	Allocate responsibility and authority for measuring system audit activities and results.	DO	DN	NA	
118	Allocate responsibility and authority for measuring system review activities and results.	DO	DN	NA	
119	Allocate responsibility and authority for measuring system change activities and results.	DO	DN	NA	
120	Allocate responsibility and authority for measuring system correction activities and results.	DO	DN	NA	
121	Allocate responsibility and authority for measuring system improvement activities and results.	DO	DN	NA	

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B3. MEASURE QUALITY MANAGEMENT SYSTEM

B3.2 QUALIFY THE RESOURCES NEEDED TO MEASURE SYSTEM

B3.2.1 MAKE SURE THAT RESOURCES CAN MEASURE YOUR SYSTEM

122	Select measurement resources that are fit for purpose.	DO	DN	NA	
123	Select measurement resources that will yield valid and reliable results.	DO	DN	NA	
124	Select measurement resources that can handle your unique circumstances.	DO	DN	NA	
125	Select measurement resources that will ensure that outputs meet requirements.	DO	DN	NA	
126	Select measurement resources that are capable of providing the information you need.	DO	DN	NA	

B3.2.2 MAKE SURE THAT RESOURCES ARE VALIDATED BEFORE USE

127	Validate measurement resources before you use them.	DO	DN	NA	
128	Validate resources that are used to measure management system.	DO	DN	NA	
129	Validate software before it is used to measure management system.	DO	DN	NA	
130	Validate tools before they are used to measure management system.	DO	DN	NA	
131	Validate equipment before it is used to measure management system.	DO	DN	NA	

B3.3 PROVIDE THE RESOURCES NEEDED TO MEASURE SYSTEM

B3.3.1 PROVIDE THE EXPERTISE NEEDED TO MEASURE YOUR SYSTEM

132	Provide the expertise needed to ensure that measuring methods will yield valid and reliable results.	DO	DN	NA	
133	Provide the managers needed to measure your system.	DO	DN	NA	
134	Acquire the knowledge that system managers need to support system measurement activities.	DO	DN	NA	

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B3. MEASURE QUALITY MANAGEMENT SYSTEM

135	Ensure that system managers get the knowledge they need to support measurement activities.	DO	DN	NA	
136	Deliver suitable training and awareness programmes for managers of system measurement activities.	DO	DN	NA	
137	Provide the personnel needed to measure your system.	DO	DN	NA	
138	Acquire the knowledge that personnel need to measure your system.	DO	DN	NA	
139	Consider internal sources of knowledge about system measurement.	DO	DN	NA	
140	Consider external sources of knowledge about system measurement.	DO	DN	NA	
141	Ensure that personnel get the knowledge they need to measure your system.	DO	DN	NA	
142	Deliver suitable training and awareness programmes for system measuring personnel.	DO	DN	NA	

B3.3.2 PROVIDE THE TECHNOLOGY NEEDED TO MEASURE YOUR SYSTEM

143	Provide the technology needed to ensure that measurement methods yield valid and reliable results.	DO	DN	NA	
144	Provide the software needed to measure your system.	DO	DN	NA	
145	Provide the software needed to support system measurement activities.	DO	DN	NA	
146	Provide the hardware needed to measure your system.	DO	DN	NA	
147	Provide the hardware needed to support system measurement activities.	DO	DN	NA	
148	Provide the tools and equipment needed to measure your system.	DO	DN	NA	

B3.3.3 PROVIDE THE INFRASTRUCTURE NEEDED TO MEASURE YOUR SYSTEM

149	Provide the infrastructure needed to ensure that measurement methods yield valid and reliable results.	DO	DN	NA	
150	Provide the infrastructure needed to support system measurement and achieve conformity of outputs.	DO	DN	NA	

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B3. MEASURE QUALITY MANAGEMENT SYSTEM

B3.4 USE AUTHORIZED METHODS TO MEASURE YOUR SYSTEM

B3.4.1 USE AUTHORIZED METHODS TO MEASURE SYSTEM ELEMENTS

151	Use authorized methods to measure system outputs.	DO	DN	NA	
152	Measure your outputs against expectations.	DO	DN	NA	
153	Measure how well outputs meet requirements.	DO	DN	NA	
154	Measure how well outputs achieve objectives.	DO	DN	NA	
155	Measure how well outputs implement plans.	DO	DN	NA	
156	Use authorized methods to measure system inputs.	DO	DN	NA	
157	Measure your inputs against expectations.	DO	DN	NA	
158	Measure how well inputs meet requirements.	DO	DN	NA	
159	Measure how well inputs achieve objectives.	DO	DN	NA	
160	Measure how well inputs implement plans.	DO	DN	NA	
161	Use authorized methods to measure system activities.	DO	DN	NA	
162	Use authorized methods to measure system operating activities.	DO	DN	NA	
163	Measure how well system operating activities meet expectations.	DO	DN	NA	
164	Measure how well system operating activities apply policies.	DO	DN	NA	
165	Measure how well system operating activities implement plans.	DO	DN	NA	
166	Measure how well system operating activities follow procedures.	DO	DN	NA	
167	Measure how well system operating activities achieve objectives.	DO	DN	NA	
168	Measure how well system operating activities comply with requirements.	DO	DN	NA	
169	Use authorized methods to measure system maintenance activities.	DO	DN	NA	

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170	Measure how well system maintenance activities meet expectations.	DO	DN	NA	
171	Measure how well system maintenance activities apply policies.	DO	DN	NA	
172	Measure how well system maintenance activities implement plans.	DO	DN	NA	
173	Measure how well system maintenance activities follow procedures.	DO	DN	NA	
174	Measure how well system maintenance activities achieve objectives.	DO	DN	NA	
175	Measure how well system maintenance activities comply with requirements.	DO	DN	NA	
176	Use authorized methods to measure system measurement activities.	DO	DN	NA	
177	Measure how well system measurement activities meet expectations.	DO	DN	NA	
178	Measure how well system measurement activities apply policies.	DO	DN	NA	
179	Measure how well system measurement activities implement plans.	DO	DN	NA	
180	Measure how well system measurement activities follow procedures.	DO	DN	NA	
181	Measure how well system measurement activities achieve objectives.	DO	DN	NA	
182	Measure how well system measurement activities comply with requirements.	DO	DN	NA	
183	Use authorized methods to measure system monitoring activities.	DO	DN	NA	
184	Measure how well system monitoring activities meet expectations.	DO	DN	NA	
185	Measure how well system monitoring activities apply policies.	DO	DN	NA	
186	Measure how well system monitoring activities implement plans.	DO	DN	NA	
187	Measure how well system monitoring activities follow procedures.	DO	DN	NA	
188	Measure how well system monitoring activities achieve objectives.	DO	DN	NA	
189	Measure how well system monitoring activities comply with requirements.	DO	DN	NA	
190	Use authorized methods to measure system control activities.	DO	DN	NA	

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191	Measure how well system control activities meet expectations.	DO	DN	NA	
192	Measure how well system control activities apply policies.	DO	DN	NA	
193	Measure how well system control activities implement plans.	DO	DN	NA	
194	Measure how well system control activities follow procedures.	DO	DN	NA	
195	Measure how well system control activities achieve objectives.	DO	DN	NA	
196	Measure how well system control activities comply with requirements.	DO	DN	NA	
197	Use authorized methods to measure system evaluation activities.	DO	DN	NA	
198	Use authorized methods to measure system audit activities.	DO	DN	NA	
199	Measure how well system audit activities meet expectations.	DO	DN	NA	
200	Measure how well system audit activities apply policies.	DO	DN	NA	
201	Measure how well system audit activities implement plans.	DO	DN	NA	
202	Measure how well system audit activities follow procedures.	DO	DN	NA	
203	Measure how well system audit activities achieve objectives.	DO	DN	NA	
204	Measure how well system audit activities comply with requirements.	DO	DN	NA	
205	Use authorized methods to measure system review activities.	DO	DN	NA	
206	Measure how well system review activities meet expectations.	DO	DN	NA	
207	Measure how well system review activities apply policies.	DO	DN	NA	
208	Measure how well system review activities implement plans.	DO	DN	NA	
209	Measure how well system review activities follow procedures.	DO	DN	NA	
210	Measure how well system review activities achieve objectives.	DO	DN	NA	
211	Measure how well system review activities comply with requirements.	DO	DN	NA	

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B3. MEASURE QUALITY MANAGEMENT SYSTEM

212	Use authorized methods to measure system change activities.	DO	DN	NA	
213	Use authorized methods to measure system correction activities.	DO	DN	NA	
214	Measure how well system correction activities meet expectations.	DO	DN	NA	
215	Measure how well system correction activities apply policies.	DO	DN	NA	
216	Measure how well system correction activities implement plans.	DO	DN	NA	
217	Measure how well system correction activities follow procedures.	DO	DN	NA	
218	Measure how well system correction activities achieve objectives.	DO	DN	NA	
219	Measure how well system correction activities comply with requirements.	DO	DN	NA	
220	Use authorized methods to measure system improvement activities.	DO	DN	NA	
221	Measure how well system improvement activities meet expectations.	DO	DN	NA	
222	Measure how well system improvement activities apply policies.	DO	DN	NA	
223	Measure how well system improvement activities implement plans.	DO	DN	NA	
224	Measure how well system improvement activities follow procedures.	DO	DN	NA	
225	Measure how well system improvement activities achieve objectives.	DO	DN	NA	
226	Measure how well system improvement activities comply with requirements.	DO	DN	NA	

B3.4.2 USE AUTHORIZED METHODS TO MEASURE SYSTEM PARTICIPANTS

227	Use authorized methods to measure the performance of system personnel.	DO	DN	NA	
228	Measure the competence and effectiveness of your system personnel.	DO	DN	NA	
229	Measure the system knowledge and skill that has been acquired.	DO	DN	NA	
230	Measure how well system personnel meet system expectations.	DO	DN	NA	

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B3. MEASURE QUALITY MANAGEMENT SYSTEM

231	Measure how well system personnel apply system policies.	DO	DN	NA	
232	Measure how well system personnel implement system plans.	DO	DN	NA	
233	Measure how well system personnel follow system procedures.	DO	DN	NA	
234	Measure how well system personnel meet system requirements.	DO	DN	NA	
235	Measure how well system personnel achieve system objectives.	DO	DN	NA	
236	Measure how well system personnel achieve safety objectives.	DO	DN	NA	
237	Measure how well system personnel achieve quality objectives.	DO	DN	NA	
238	Measure how well system personnel achieve privacy objectives.	DO	DN	NA	
239	Measure how well system personnel achieve security objectives.	DO	DN	NA	
240	Measure how well system personnel achieve business objectives.	DO	DN	NA	
241	Measure how well system personnel achieve technical objectives.	DO	DN	NA	
242	Measure how well system personnel achieve continuity objectives.	DO	DN	NA	
243	Use authorized methods to measure the performance of system management.	DO	DN	NA	
244	Use authorized methods to measure system management activities.	DO	DN	NA	
245	Measure how well system management activities meet expectations.	DO	DN	NA	
246	Measure how well system management activities apply policies.	DO	DN	NA	
247	Measure how well system management activities implement plans.	DO	DN	NA	
248	Measure how well system management activities follow procedures.	DO	DN	NA	
249	Measure how well system management activities meet requirements.	DO	DN	NA	
250	Measure how well system management activities achieve objectives.	DO	DN	NA	
251	Measure how well system managers achieve safety objectives.	DO	DN	NA	

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B3. MEASURE QUALITY MANAGEMENT SYSTEM

252	Measure how well system managers achieve quality objectives.	DO	DN	NA	
253	Measure how well system managers achieve privacy objectives.	DO	DN	NA	
254	Measure how well system managers achieve security objectives.	DO	DN	NA	
255	Measure how well system managers achieve business objectives.	DO	DN	NA	
256	Measure how well system managers achieve technical objectives.	DO	DN	NA	
257	Measure how well system managers achieve continuity objectives.	DO	DN	NA	
258	Use authorized methods to measure external product and service providers.	DO	DN	NA	
259	Use authorized criteria to measure the performance of external providers.	DO	DN	NA	
260	Measure the performance of external system, product, and service providers.	DO	DN	NA	
261	Use data and criteria to measure the performance of your external providers.	DO	DN	NA	
262	Document performance measuring activities and retain these documents.	DO	DN	NA	
263	Control documents that describe your performance measuring activities.	DO	DN	NA	
264	Measure external system, product, and service verification activities.	DO	DN	NA	
265	Measure verifications whenever they are delegated to external providers.	DO	DN	NA	
266	Use authorized methods to measure internal product and service providers.	DO	DN	NA	
267	Use authorized criteria to measure the performance of internal providers.	DO	DN	NA	

B3.5 CONTROL THE RESOURCES NEEDED TO MEASURE SYSTEM

B3.5.1 CONTROL THE DOCUMENTS NEEDED TO MEASURE YOUR SYSTEM

268	Control the procedures needed to measure your system and its outputs.	DO	DN	NA	
269	Control the instructions needed to measure your system and its outputs.	DO	DN	NA	
270	Control the manuals needed to measure your system and its outputs.	DO	DN	NA	

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B3. MEASURE QUALITY MANAGEMENT SYSTEM

B3.5.2 CONTROL THE TECHNOLOGY NEEDED TO MEASURE YOUR SYSTEM

271	Control the software needed to measure your system and its outputs.	DO	DN	NA	
272	Control the hardware needed to measure your system and its outputs.	DO	DN	NA	
273	Control the tools needed to measure your system and its outputs.	DO	DN	NA	
274	Control the equipment needed to measure your system and its outputs.	DO	DN	NA	

B3.5.3 CONTROL THE RECORDS NEEDED TO MEASURE YOUR SYSTEM

275	Control the records needed to measure system activities and resources.	DO	DN	NA	
276	Use records to control your system measuring activities and resources.	DO	DN	NA	
277	Establish a register of system measurement activities and resources.	DO	DN	NA	
278	Use this register to record the identity of measurement resources.	DO	DN	NA	
279	Use your register to describe the type or kind of resources being used.	DO	DN	NA	
280	Use your register to specify a unique identifier for each piece of equipment.	DO	DN	NA	
281	Use register to specify the location of your measurement tools and equipment.	DO	DN	NA	
282	Use register to control the calibration of your measurement tools and equipment.	DO	DN	NA	
283	Maintain a register of your system measurement activities and resources.	DO	DN	NA	
284	Use records to keep track of measurement activities and resources.	DO	DN	NA	
285	Establish suitable measurement traceability methods.	DO	DN	NA	
286	Maintain suitable measurement traceability resources.	DO	DN	NA	
287	Establish recall methods for your measurement equipment.	DO	DN	NA	
288	Implement recall methods for your measurement equipment.	DO	DN	NA	
289	Recall measurement equipment that must be verified or calibrated.	DO	DN	NA	
290	Maintain recall records for your system measurement equipment.	DO	DN	NA	

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B4. MONITOR QUALITY MANAGEMENT SYSTEM

B4.1 PLAN HOW YOU'RE GOING TO MONITOR YOUR SYSTEM

B4.1.1 FIGURE OUT WHAT NEEDS TO BE MONITORED

1	Figure out what kind of policies and plans need to be monitored.	DO	DN	NA	
2	Figure out what kind of practices and procedures need to be monitored.	DO	DN	NA	
3	Figure out what kind of issues, factors, and concerns need to be monitored.	DO	DN	NA	
4	Figure out what kind of internal issues and factors need to be monitored.	DO	DN	NA	
5	Figure out what kind of external issues and factors need to be monitored.	DO	DN	NA	
6	Figure out what kind of participants and providers need to be monitored.	DO	DN	NA	
7	Figure out what kind of system participants need to be monitored.	DO	DN	NA	
8	Figure out what kind of system managers need to be monitored.	DO	DN	NA	
9	Figure out what kind of system personnel need to be monitored.	DO	DN	NA	
10	Figure out what kind of system providers need to be monitored.	DO	DN	NA	
11	Figure out what kind of internal system providers need to be monitored.	DO	DN	NA	
12	Figure out what kind of external system providers need to be monitored.	DO	DN	NA	
13	Figure out what kind of system inputs and outputs need to be monitored.	DO	DN	NA	
14	Figure out what kind of output characteristics need to be monitored.	DO	DN	NA	
15	Figure out what kind of input characteristics need to be monitored.	DO	DN	NA	
16	Figure out what kind of internal system resources need to be monitored.	DO	DN	NA	
17	Figure out what kind of data and information needs to be monitored.	DO	DN	NA	
18	Figure out what kind of documents and records need to be monitored.	DO	DN	NA	
19	Figure out what kind of hardware and software needs to be monitored.	DO	DN	NA	

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B4. MONITOR QUALITY MANAGEMENT SYSTEM

20	Figure out what kind of parts and components need to be monitored.	DO	DN	NA	
21	Figure out what kind of products and services need to be monitored.	DO	DN	NA	
22	Figure out what kind of property and supplies need to be monitored.	DO	DN	NA	

B4.1.2 FIGURE OUT HOW MONITORING WILL BE DONE

23	Plan how you're going to monitor customer satisfaction.	DO	DN	NA	
24	Plan how to monitor customer feelings about system outputs.	DO	DN	NA	
25	Plan how to monitor information about customer satisfaction.	DO	DN	NA	
26	Plan how you're going to monitor system performance.	DO	DN	NA	
27	Plan how you're going to monitor system outputs.	DO	DN	NA	
28	Plan how you're going to monitor output deliveries.	DO	DN	NA	
29	Plan how to monitor post-delivery performance.	DO	DN	NA	
30	Plan how you're going to monitor output characteristics.	DO	DN	NA	
31	Plan how you're going to monitor system activities.	DO	DN	NA	
32	Plan how you're going to monitor system management activities.	DO	DN	NA	
33	Plan how to monitor how well system management activities meet expectations.	DO	DN	NA	
34	Plan how to monitor how well system management activities apply policies.	DO	DN	NA	
35	Plan how to monitor how well system management activities implement plans.	DO	DN	NA	
36	Plan how to monitor how well system management activities follow procedures.	DO	DN	NA	
37	Plan how to monitor how well system management activities achieve objectives.	DO	DN	NA	
38	Plan how to monitor how well system management activities comply with requirements.	DO	DN	NA	
39	Plan how you're going to monitor system operating activities.	DO	DN	NA	

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

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

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B4. MONITOR QUALITY MANAGEMENT SYSTEM

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

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B4. MONITOR QUALITY MANAGEMENT SYSTEM

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

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124	Plan how you're going to monitor external system inputs.	DO	DN	NA	
125	Plan how you're going to monitor system technologies.	DO	DN	NA	
126	Plan how you're going to monitor system tools and equipment.	DO	DN	NA	
127	Plan how you're going to monitor system monitoring devices.	DO	DN	NA	
128	Plan how you're going to recall monitoring tools and equipment that must be recalibrated or reverified.	DO	DN	NA	
129	Plan how you're going to monitor system measurement devices.	DO	DN	NA	
130	Plan how you're going to recall measurement tools and equipment that must be recalibrated or reverified.	DO	DN	NA	
131	Plan how you're going to monitor system environment.	DO	DN	NA	
132	Plan how you're going to monitor your system's external context.	DO	DN	NA	
133	Figure out how you're going to monitor the external issues and factors that could affect your system.	DO	DN	NA	
134	Figure out how you're going to monitor the external interested parties that could affect your system.	DO	DN	NA	
135	Plan how you're going to monitor your system's internal context.	DO	DN	NA	
136	Figure out how you're going to monitor the internal issues and factors that could affect your system.	DO	DN	NA	
137	Figure out how you're going to monitor the internal interested parties that could affect your system.	DO	DN	NA	

B4.1.3 FIGURE OUT WHO WILL PERFORM MONITORING TASKS

138	Allocate responsibility and authority for monitoring system plans.	DO	DN	NA	
139	Allocate responsibility and authority for monitoring system policies.	DO	DN	NA	
140	Allocate responsibility and authority for monitoring system outputs.	DO	DN	NA	
141	Allocate responsibility and authority for monitoring system supplies.	DO	DN	NA	

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

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B4. MONITOR QUALITY MANAGEMENT SYSTEM

B4.2 QUALIFY THE RESOURCES NEEDED TO MONITOR SYSTEM

B4.2.1 MAKE SURE THAT RESOURCES CAN MONITOR YOUR SYSTEM

163	Select monitoring resources that are fit for purpose.	DO	DN	NA	
164	Select monitoring resources that will yield valid and reliable results.	DO	DN	NA	
165	Select monitoring resources that can handle your unique circumstances.	DO	DN	NA	
166	Select monitoring resources that will ensure that outputs meet requirements.	DO	DN	NA	
167	Select monitoring resources that are capable of providing the information you need.	DO	DN	NA	

B4.2.2 MAKE SURE THAT RESOURCES ARE VALIDATED BEFORE USE

168	Validate monitoring resources before you use them.	DO	DN	NA	
169	Validate tools before they are used to monitor management system.	DO	DN	NA	
170	Validate equipment before it is used to monitor management system.	DO	DN	NA	
171	Validate software before it is used to monitor management system.	DO	DN	NA	

B4.3 PROVIDE THE RESOURCES NEEDED TO MONITOR SYSTEM

B4.3.1 PROVIDE THE EXPERTISE NEEDED TO MONITOR YOUR SYSTEM

172	Provide the expertise needed to ensure that monitoring methods will consistently yield valid and reliable results.	DO	DN	NA	
173	Provide the managers needed to monitor your system.	DO	DN	NA	
174	Acquire the knowledge that managers need to support system monitoring and achieve conformity of outputs.	DO	DN	NA	
175	Share the knowledge that managers need so that they can support system monitoring and achieve conformity of outputs.	DO	DN	NA	

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B4. MONITOR QUALITY MANAGEMENT SYSTEM

176	Deliver suitable training and awareness programmes for managers of system monitoring activities.	DO	DN	NA	
177	Provide the personnel needed to monitor your system.	DO	DN	NA	
178	Acquire the knowledge that personnel need to monitor your system and achieve conformity of outputs.	DO	DN	NA	
179	Consider internal sources of knowledge about system monitoring.	DO	DN	NA	
180	Consider external sources of knowledge about system monitoring.	DO	DN	NA	
181	Share the knowledge that personnel need to monitor your system and achieve conformity of outputs.	DO	DN	NA	
182	Deliver suitable training and awareness programmes for your system monitoring personnel.	DO	DN	NA	

B4.3.2 PROVIDE THE TECHNOLOGY NEEDED TO MONITOR YOUR SYSTEM

183	Provide the technology needed to ensure that your monitoring methods will yield valid and reliable results.	DO	DN	NA	
184	Provide the software needed to monitor your system.	DO	DN	NA	
185	Provide the software needed to support system monitoring and achieve conformity of outputs.	DO	DN	NA	
186	Provide the hardware needed to monitor your system.	DO	DN	NA	
187	Provide the hardware needed to support system monitoring and achieve conformity of outputs.	DO	DN	NA	

B4.3.3 PROVIDE THE INFRASTRUCTURE NEEDED TO MONITOR YOUR SYSTEM

188	Provide the infrastructure needed to ensure that your monitoring methods will yield valid and reliable results.	DO	DN	NA	
189	Provide the infrastructure needed to support your system monitoring and achieve conformity of outputs.	DO	DN	NA	

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B4. MONITOR QUALITY MANAGEMENT SYSTEM

B4.4 USE AUTHORIZED METHODS TO MONITOR YOUR SYSTEM

B4.4.1 USE AUTHORIZED METHODS TO MONITOR SYSTEM ACTIVITIES

190	Use authorized methods to monitor system management activities.	DO	DN	NA	
191	Monitor how well system management activities meet expectations.	DO	DN	NA	
192	Monitor how well system management activities apply policies.	DO	DN	NA	
193	Monitor how well system management activities implement plans.	DO	DN	NA	
194	Monitor how well system management activities follow procedures.	DO	DN	NA	
195	Monitor how well system management activities achieve objectives.	DO	DN	NA	
196	Monitor how well system management activities comply with requirements.	DO	DN	NA	
197	Use authorized methods to monitor system operating activities.	DO	DN	NA	
198	Monitor how well system operating activities meet expectations.	DO	DN	NA	
199	Monitor how well system operating activities apply policies.	DO	DN	NA	
200	Monitor how well system operating activities implement plans.	DO	DN	NA	
201	Monitor how well system operating activities follow procedures.	DO	DN	NA	
202	Monitor how well system operating activities achieve objectives.	DO	DN	NA	
203	Monitor how well system operating activities comply with requirements.	DO	DN	NA	
204	Use authorized methods to monitor system maintenance activities.	DO	DN	NA	
205	Monitor how well system maintenance activities meet expectations.	DO	DN	NA	
206	Monitor how well system maintenance activities apply policies.	DO	DN	NA	
207	Monitor how well system maintenance activities implement plans.	DO	DN	NA	
208	Monitor how well system maintenance activities follow procedures.	DO	DN	NA	

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209	Monitor how well system maintenance activities achieve objectives.	DO	DN	NA	
210	Monitor how well system maintenance activities comply with requirements.	DO	DN	NA	
211	Use authorized methods to monitor system measurement activities.	DO	DN	NA	
212	Monitor how well system measurement activities meet expectations.	DO	DN	NA	
213	Monitor how well system measurement activities apply policies.	DO	DN	NA	
214	Monitor how well system measurement activities implement plans.	DO	DN	NA	
215	Monitor how well system measurement activities follow procedures.	DO	DN	NA	
216	Monitor how well system measurement activities achieve objectives.	DO	DN	NA	
217	Monitor how well system measurement activities comply with requirements.	DO	DN	NA	
218	Use authorized methods to monitor system monitoring activities.	DO	DN	NA	
219	Monitor how well system monitoring activities meet expectations.	DO	DN	NA	
220	Monitor how well system monitoring activities apply policies.	DO	DN	NA	
221	Monitor how well system monitoring activities implement plans.	DO	DN	NA	
222	Monitor how well system monitoring activities follow procedures.	DO	DN	NA	
223	Monitor how well system monitoring activities achieve objectives.	DO	DN	NA	
224	Monitor how well system monitoring activities comply with requirements.	DO	DN	NA	
225	Use authorized methods to monitor system control activities.	DO	DN	NA	
226	Monitor how well system control activities meet expectations.	DO	DN	NA	
227	Monitor how well system control activities apply policies.	DO	DN	NA	
228	Monitor how well system control activities implement plans.	DO	DN	NA	
229	Monitor how well system control activities follow procedures.	DO	DN	NA	

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230	Monitor how well system control activities achieve objectives.	DO	DN	NA	
231	Monitor how well system control activities comply with requirements.	DO	DN	NA	
232	Use authorized methods to monitor system evaluation activities.	DO	DN	NA	
233	Use authorized methods to monitor system audit activities.	DO	DN	NA	
234	Monitor how well system audit activities meet expectations.	DO	DN	NA	
235	Monitor how well system audit activities apply policies.	DO	DN	NA	
236	Monitor how well system audit activities implement plans.	DO	DN	NA	
237	Monitor how well system audit activities follow procedures.	DO	DN	NA	
238	Monitor how well system audit activities achieve objectives.	DO	DN	NA	
239	Monitor how well system audit activities comply with requirements.	DO	DN	NA	
240	Use authorized methods to monitor system review activities.	DO	DN	NA	
241	Monitor how well system review activities meet expectations.	DO	DN	NA	
242	Monitor how well system review activities apply policies.	DO	DN	NA	
243	Monitor how well system review activities implement plans.	DO	DN	NA	
244	Monitor how well system review activities follow procedures.	DO	DN	NA	
245	Monitor how well system review activities achieve objectives.	DO	DN	NA	
246	Monitor how well system review activities comply with requirements.	DO	DN	NA	
247	Use authorized methods to monitor system change activities.	DO	DN	NA	
248	Use authorized methods to monitor system correction activities.	DO	DN	NA	
249	Monitor how well system correction activities meet expectations.	DO	DN	NA	
250	Monitor how well system correction activities apply policies.	DO	DN	NA	

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251	Monitor how well system correction activities implement plans.	DO	DN	NA	
252	Monitor how well system correction activities follow procedures.	DO	DN	NA	
253	Monitor how well system correction activities achieve objectives.	DO	DN	NA	
254	Monitor how well system correction activities comply with requirements.	DO	DN	NA	
255	Use authorized methods to monitor system improvement activities.	DO	DN	NA	
256	Monitor how well system improvement activities meet expectations.	DO	DN	NA	
257	Monitor how well system improvement activities apply policies.	DO	DN	NA	
258	Monitor how well system improvement activities implement plans.	DO	DN	NA	
259	Monitor how well system improvement activities follow procedures.	DO	DN	NA	
260	Monitor how well system improvement activities achieve objectives.	DO	DN	NA	
261	Monitor how well system improvement activities comply with requirements.	DO	DN	NA	

B4.4.2 USE AUTHORIZED METHODS TO MONITOR SYSTEM OUTPUTS

262	Use authorized methods to monitor how well system outputs meet expectations.	DO	DN	NA	
263	Use authorized methods to monitor how well system outputs apply policies.	DO	DN	NA	
264	Use authorized methods to monitor how well system outputs implement plans.	DO	DN	NA	
265	Use authorized methods to monitor how well system outputs follow procedures.	DO	DN	NA	
266	Use authorized methods to monitor how well system outputs achieve objectives.	DO	DN	NA	
267	Use authorized methods to monitor how well system outputs comply with requirements.	DO	DN	NA	
268	Use authorized methods to monitor how well outputs meet customer requirements.	DO	DN	NA	
269	Use authorized methods to monitor how well outputs meet regulatory requirements.	DO	DN	NA	
270	Use authorized methods to monitor how well outputs meet corporate requirements.	DO	DN	NA	

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B4.4.3 USE AUTHORIZED METHODS TO MONITOR SYSTEM INPUTS

271	Use authorized methods to monitor supplies that have a major impact on outputs.	DO	DN	NA	
272	Use authorized methods to monitor services that have a major impact on outputs.	DO	DN	NA	
273	Use authorized methods to monitor materials that have a major impact on outputs.	DO	DN	NA	
274	Use authorized methods to monitor products that have a major impact on outputs.	DO	DN	NA	
275	Use authorized methods to monitor components that have a major impact on outputs.	DO	DN	NA	
276	Use authorized methods to monitor your “critical items” and “key characteristics”.	DO	DN	NA	

B4.4.4 USE AUTHORIZED METHODS TO MONITOR SYSTEM DOCUMENTS

277	Use authorized methods to monitor documents that specify how system is operated.	DO	DN	NA	
278	Use authorized methods to monitor documents that specify how system is maintained.	DO	DN	NA	
279	Use authorized methods to monitor documents that specify how system is monitored.	DO	DN	NA	
280	Use authorized methods to monitor documents that specify how system is measured.	DO	DN	NA	
281	Use authorized methods to monitor documents that specify how system is controlled.	DO	DN	NA	
282	Use authorized methods to monitor documents that specify how system is audited.	DO	DN	NA	
283	Use authorized methods to monitor documents that specify how system is reviewed.	DO	DN	NA	
284	Use authorized methods to monitor documents that specify how system is corrected.	DO	DN	NA	
285	Use authorized methods to monitor documents that specify how system is improved.	DO	DN	NA	

B4.4.5 USE AUTHORIZED METHODS TO MONITOR SYSTEM RECORDS

286	Use authorized methods to monitor records of personnel performance and competence.	DO	DN	NA	
287	Retain and maintain records of personnel performance and competence.	DO	DN	NA	
288	Use records to show that personnel know how to perform system tasks.	DO	DN	NA	

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289	Use authorized methods to monitor records that track the performance of your system.	DO	DN	NA	
290	Use authorized methods to monitor records that keep track of system operations.	DO	DN	NA	
291	Use authorized methods to monitor records that keep track of system outputs.	DO	DN	NA	
292	Use authorized methods to monitor records that keep track of system activities.	DO	DN	NA	
293	Use authorized methods to monitor records that keep track of system inputs.	DO	DN	NA	
294	Use authorized methods to monitor records that keep track of system maintenance.	DO	DN	NA	
295	Use authorized methods to monitor records that keep track of system measurement.	DO	DN	NA	
296	Use authorized methods to monitor records that keep track of system monitoring.	DO	DN	NA	
297	Use authorized methods to monitor records that keep track of system control.	DO	DN	NA	
298	Use authorized methods to monitor records that keep track of system audits.	DO	DN	NA	
299	Use authorized methods to monitor records that keep track of system reviews.	DO	DN	NA	
300	Use authorized methods to monitor records that keep track of system corrections.	DO	DN	NA	
301	Use authorized methods to monitor records that keep track of system improvements.	DO	DN	NA	

B4.4.6 USE AUTHORIZED METHODS TO MONITOR SYSTEM PROPERTY

302	Use authorized methods to monitor system property owned by your customers and suppliers that is needed to achieve conformity of outputs.	DO	DN	NA	
303	Report problematic property to your customers and external providers.	DO	DN	NA	
304	Report unsuitable property to customers and external providers.	DO	DN	NA	
305	Report lost or damaged property to customers and external providers.	DO	DN	NA	
306	Use authorized methods to monitor system property owned by your organization that is needed to achieve conformity of outputs.	DO	DN	NA	

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B4.4.7 USE AUTHORIZED METHODS TO MONITOR SYSTEM PARTICIPANTS

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

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326	Use authorized methods to monitor interested parties.	DO	DN	NA	
327	Use authorized methods to monitor external parties that could influence system.	DO	DN	NA	
328	Monitor the performance of external system, product, and service providers.	DO	DN	NA	
329	Expect system managers to use data and criteria to monitor the performance of their external providers.	DO	DN	NA	
330	Expect system managers to document performance monitoring activities and retain these documents.	DO	DN	NA	
331	Expect system managers to control documents that describe their performance monitoring activities.	DO	DN	NA	
332	Monitor external system, product, and service verification activities.	DO	DN	NA	
333	Monitor verifications whenever they are delegated to external providers.	DO	DN	NA	
334	Use authorized methods to monitor internal parties that could influence system.	DO	DN	NA	

B4.4.8 USE AUTHORIZED METHODS TO MONITOR SYSTEM TECHNOLOGIES

335	Use authorized methods to monitor technology used to perform system operations.	DO	DN	NA	
336	Use authorized methods to monitor software used to perform system operations.	DO	DN	NA	
337	Use authorized methods to monitor hardware used to perform system operations.	DO	DN	NA	
338	Use authorized methods to monitor technology used to automate system operations.	DO	DN	NA	
339	Use authorized methods to monitor software used to automate system operations.	DO	DN	NA	
340	Use authorized methods to monitor hardware used to automate system operations.	DO	DN	NA	
341	Use authorized methods to monitor technology used to maintain system operations.	DO	DN	NA	
342	Use authorized methods to monitor software used to maintain system operations.	DO	DN	NA	

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343	Use authorized methods to monitor hardware used to maintain system operations.	DO	DN	NA	
344	Use authorized methods to monitor technology used to monitor system operations.	DO	DN	NA	
345	Use authorized methods to monitor software used to monitor system operations.	DO	DN	NA	
346	Use authorized methods to monitor hardware used to monitor system operations.	DO	DN	NA	
347	Use authorized methods to monitor technology used to measure system operations.	DO	DN	NA	
348	Use authorized methods to monitor software used to measure system operations.	DO	DN	NA	
349	Use authorized methods to monitor hardware used to measure system operations.	DO	DN	NA	
350	Use authorized methods to monitor technology used to control system operations.	DO	DN	NA	
351	Use authorized methods to monitor software used to control system operations.	DO	DN	NA	
352	Use authorized methods to monitor hardware used to control system operations.	DO	DN	NA	

B4.4.9 USE AUTHORIZED METHODS TO MONITOR SYSTEM ENVIRONMENT

353	Use authorized methods to monitor your system's external environment.	DO	DN	NA	
354	Use authorized methods to monitor external interested parties and their requirements.	DO	DN	NA	
355	Use authorized methods to monitor your system's internal environment.	DO	DN	NA	
356	Use authorized methods to monitor internal interested parties and their requirements.	DO	DN	NA	

B4.4.10 USE AUTHORIZED METHODS TO MONITOR SYSTEM INFRASTRUCTURE

357	Use authorized methods to monitor system networks and communications.	DO	DN	NA	
358	Use authorized methods to monitor internal system networks and communications.	DO	DN	NA	
359	Use authorized methods to monitor external system networks and communications.	DO	DN	NA	
360	Use authorized methods to monitor system utilities and support services.	DO	DN	NA	

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B4. MONITOR QUALITY MANAGEMENT SYSTEM

B4.5 CONTROL THE RESOURCES NEEDED TO MONITOR SYSTEM

B4.5.1 CONTROL THE TECHNOLOGIES NEEDED TO MONITOR SYSTEM

361	Control the technology needed to monitor your system.	DO	DN	NA	
362	Control the tools needed to monitor your system.	DO	DN	NA	
363	Control the software needed to monitor your system.	DO	DN	NA	
364	Control the equipment needed to monitor your system.	DO	DN	NA	

B4.5.2 CONTROL THE RECORDS NEEDED TO MONITOR SYSTEM

365	Control the records needed to monitor your system.	DO	DN	NA	
366	Establish a register of your system monitoring resources.	DO	DN	NA	
367	Ensure that your monitoring resources continue to be fit for purpose.	DO	DN	NA	
368	Ensure that register describes the type of monitoring tools and equipment in use.	DO	DN	NA	
369	Ensure that register specifies the location of your monitoring tools and equipment.	DO	DN	NA	
370	Ensure that register tracks the calibration of your monitoring tools and equipment.	DO	DN	NA	
371	Ensure that your register records equipment calibration or verification methods.	DO	DN	NA	
372	Ensure that your register records calibration or verification acceptance criteria.	DO	DN	NA	
373	Ensure that register specifies equipment calibration or verification frequency.	DO	DN	NA	
374	Maintain a register of your system monitoring resources.	DO	DN	NA	
375	Maintain records that show that monitoring resources are still fit for purpose.	DO	DN	NA	
376	Control records that show that monitoring resources are still fit for purpose.	DO	DN	NA	

Consider each task and select a response. If you haven't done it and it needs to be done, select DO. If you've already done it, select DN. If the task is not applicable in your situation and you can justify and explain why it should be ignored or excluded, select NA.

In the spaces below, please enter the name and location of your organization, who completed this page, who reviewed it, and the dates.

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B5. CONTROL QUALITY MANAGEMENT SYSTEM

B5.1 PLAN HOW YOU'RE GOING TO CONTROL SYSTEM

B5.1.1 CONSIDER HOW TO CONTROL YOUR SYSTEM OUTPUTS

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

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20	Consider security requirements as you develop output controls.	DO	DN	NA	
21	Consider handling requirements as you develop output controls.	DO	DN	NA	
22	Consider packaging requirements as you develop output controls.	DO	DN	NA	
23	Consider availability requirements as you develop output controls.	DO	DN	NA	
24	Consider preservation requirements as you develop output controls.	DO	DN	NA	
25	Consider obsolescence requirements as you develop output controls.	DO	DN	NA	
26	Consider recycling requirements as you develop output controls.	DO	DN	NA	
27	Consider disposal requirements as you develop output controls.	DO	DN	NA	
28	Consider final disposal requirements as you develop output controls.	DO	DN	NA	
29	Consider production requirements as you develop output controls.	DO	DN	NA	
30	Consider producibility requirements as you develop output controls.	DO	DN	NA	
31	Consider measurement requirements as you develop output controls.	DO	DN	NA	
32	Consider monitoring requirements as you develop output controls.	DO	DN	NA	
33	Consider inspectability requirements as you develop output controls.	DO	DN	NA	

B5.1.2 CONSIDER HOW TO CONTROL YOUR SYSTEM INPUTS

34	Figure out how you're going to control your system inputs.	DO	DN	NA	
35	Consider system input requirements as you develop input controls.	DO	DN	NA	
36	Consider input privacy requirements as you develop input controls.	DO	DN	NA	
37	Consider input safety requirements as you develop input controls.	DO	DN	NA	
38	Consider input security requirements as you develop input controls.	DO	DN	NA	
39	Consider input quality requirements as you develop input controls.	DO	DN	NA	

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40	Consider input reliability requirements as you develop input controls.	DO	DN	NA	
41	Consider input purity requirements as you develop input controls.	DO	DN	NA	
42	Consider the need to control foreign objects that could compromise inputs.	DO	DN	NA	
43	Consider the need to detect foreign objects that could compromise inputs.	DO	DN	NA	
44	Consider the need to remove foreign objects that could compromise inputs.	DO	DN	NA	
45	Consider the need to prevent foreign objects that could compromise inputs.	DO	DN	NA	
46	Consider input availability requirements as you develop input controls.	DO	DN	NA	
47	Consider input suitability requirements as you develop input controls.	DO	DN	NA	
48	Consider suitability requirements for parts and materials to be used by system.	DO	DN	NA	
49	Consider suitability requirements for software programmes to be used by system.	DO	DN	NA	
50	Consider input storage requirements as you develop input controls.	DO	DN	NA	
51	Consider input handling requirements as you develop input controls.	DO	DN	NA	
52	Consider input monitoring requirements as you develop input controls.	DO	DN	NA	
53	Consider input maintenance requirements as you develop input controls.	DO	DN	NA	
54	Consider input measurement requirements as you develop input controls.	DO	DN	NA	
55	Consider input preservation requirements as you develop input controls.	DO	DN	NA	

B5.1.3 CONSIDER HOW TO CONTROL YOUR SYSTEM ACTIVITIES

56	Figure out how you're going to control your system activities.	DO	DN	NA	
57	Consider system safety requirements as you develop system controls.	DO	DN	NA	
58	Consider system privacy requirements as you develop system controls.	DO	DN	NA	
59	Consider system quality requirements as you develop system controls.	DO	DN	NA	

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60	Consider system security requirements as you develop system controls.	DO	DN	NA	
61	Consider system reliability requirements as you develop system controls.	DO	DN	NA	
62	Consider system monitoring requirements as you develop system controls.	DO	DN	NA	
63	Consider system measurement requirements as you develop system controls.	DO	DN	NA	
64	Consider system improvement requirements as you develop system controls.	DO	DN	NA	
65	Consider system maintenance requirements as you develop system controls.	DO	DN	NA	
66	Consider system evaluation requirements as you develop system controls.	DO	DN	NA	
67	Consider system correction requirements as you develop system controls.	DO	DN	NA	
68	Consider system reporting requirements as you develop system controls.	DO	DN	NA	
69	Consider system review requirements as you develop system controls.	DO	DN	NA	
70	Consider system audit requirements as you develop system controls.	DO	DN	NA	

B5.1.4 CONSIDER HOW TO CONTROL YOUR SYSTEM PROVIDERS

71	Figure out how you're going to control your external providers.	DO	DN	NA	
72	Consider the requirements that external process providers must meet.	DO	DN	NA	
73	Consider the requirements that external product providers must meet.	DO	DN	NA	
74	Consider the requirements that external service providers must meet.	DO	DN	NA	
75	Figure out how you're going to control your internal providers.	DO	DN	NA	
76	Consider the requirements that internal process providers must meet.	DO	DN	NA	
77	Consider the requirements that internal product providers must meet.	DO	DN	NA	
78	Consider the requirements that internal service providers must meet.	DO	DN	NA	

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B5.2 DEVELOP WAYS OF CONTROLLING YOUR SYSTEM

B5.2.1 DEVELOP WAYS OF CONTROLLING SYSTEM ELEMENTS

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

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99	Develop ways of ensuring that outputs can be safely used.	DO	DN	NA	
100	Develop ways of ensuring that outputs can be safely repaired.	DO	DN	NA	
101	Develop ways of ensuring that outputs can be safely maintained.	DO	DN	NA	
102	Develop ways of ensuring that outputs can be safely preserved.	DO	DN	NA	
103	Develop ways of ensuring that outputs can be safely destroyed.	DO	DN	NA	
104	Develop ways of ensuring that outputs can be safely recycled.	DO	DN	NA	
105	Develop ways of controlling the security of outputs.	DO	DN	NA	
106	Develop ways of ensuring that outputs can be securely produced.	DO	DN	NA	
107	Develop ways of ensuring that outputs can be securely packaged.	DO	DN	NA	
108	Develop ways of ensuring that outputs can be securely delivered.	DO	DN	NA	
109	Develop ways of ensuring that outputs can be securely handled.	DO	DN	NA	
110	Develop ways of ensuring that outputs can be securely stored.	DO	DN	NA	
111	Develop ways of ensuring that outputs can be securely used.	DO	DN	NA	
112	Develop ways of ensuring that outputs can be securely repaired.	DO	DN	NA	
113	Develop ways of ensuring that outputs can be securely maintained.	DO	DN	NA	
114	Develop ways of ensuring that outputs can be securely preserved.	DO	DN	NA	
115	Develop ways of ensuring that outputs can be securely destroyed.	DO	DN	NA	
116	Develop controlled conditions for system inputs.	DO	DN	NA	
117	Develop ways of controlling your system inputs.	DO	DN	NA	
118	Develop ways of controlling the quality of system inputs.	DO	DN	NA	
119	Develop ways of controlling the purity of system inputs.	DO	DN	NA	
120	Develop ways of controlling foreign objects that compromise the quality of inputs.	DO	DN	NA	

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B5. CONTROL QUALITY MANAGEMENT SYSTEM

121	Develop ways of detecting foreign objects that compromise the quality of inputs.	DO	DN	NA	
122	Develop ways of removing foreign objects that compromise the quality of inputs.	DO	DN	NA	
123	Develop ways of preventing foreign objects that compromise the quality of inputs.	DO	DN	NA	
124	Develop ways of controlling the suitability of system inputs.	DO	DN	NA	
125	Develop ways of controlling the suitability of parts and materials to be used as inputs.	DO	DN	NA	
126	Develop ways of controlling the suitability of software that is embedded in inputs.	DO	DN	NA	
127	Develop ways of controlling the acceptability of system inputs.	DO	DN	NA	
128	Develop acceptance criteria for your system inputs.	DO	DN	NA	
129	Develop methods and procedures for testing system inputs.	DO	DN	NA	
130	Develop methods and procedures for inspecting system inputs.	DO	DN	NA	
131	Develop methods and procedures for monitoring system inputs.	DO	DN	NA	
132	Develop methods and procedures for measuring system inputs.	DO	DN	NA	
133	Develop methods and procedures for evaluating system inputs.	DO	DN	NA	
134	Develop ways of controlling the security of system inputs.	DO	DN	NA	
135	Develop ways of controlling the safety of system inputs.	DO	DN	NA	
136	Develop ways of controlling the privacy of system inputs.	DO	DN	NA	
137	Develop controlled conditions for system activities.	DO	DN	NA	
138	Develop ways of controlling your system activities.	DO	DN	NA	
139	Develop ways of controlling system testing activities.	DO	DN	NA	
140	Develop ways of controlling system control activities.	DO	DN	NA	
141	Develop ways of controlling system inspection activities.	DO	DN	NA	
142	Develop ways of controlling system management activities.	DO	DN	NA	

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143	Develop ways of controlling system measurement activities.	DO	DN	NA	
144	Develop ways of controlling system maintenance activities.	DO	DN	NA	
145	Develop ways of controlling system production activities.	DO	DN	NA	
146	Develop ways of controlling system monitoring activities.	DO	DN	NA	
147	Develop ways of controlling system evaluation activities.	DO	DN	NA	
148	Develop ways of controlling system audit activities.	DO	DN	NA	
149	Develop ways of controlling system review activities.	DO	DN	NA	
150	Develop ways of controlling system change activities.	DO	DN	NA	
151	Develop ways of controlling system correction activities.	DO	DN	NA	
152	Develop ways of controlling system improvement activities.	DO	DN	NA	

B5.2.2 DEVELOP WAYS OF CONTROLLING SYSTEM PROVIDERS

153	Develop ways of controlling external providers.	DO	DN	NA	
154	Plan how to control external processes, products, and services.	DO	DN	NA	
155	Consider the potential impact that externally provided processes, products, and services could have on your ability to consistently meet external requirements.	DO	DN	NA	
156	Consider the potential impact on your ability to meet customer requirements.	DO	DN	NA	
157	Consider the potential impact on statutory and regulatory requirements.	DO	DN	NA	
158	Create controls for external processes, products, and services.	DO	DN	NA	
159	Develop controls for processes that your organization is outsourcing.	DO	DN	NA	
160	Ensure that outsourced processes remain within your organization's control.	DO	DN	NA	
161	Figure out how you're going to control external process providers.	DO	DN	NA	
162	Consider the potential impact that external process providers could have on your ability to consistently meet customer and legal requirements.	DO	DN	NA	

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163	Consider the controls that external process providers have implemented and think about how effective their controls really are in practice.	DO	DN	NA	
164	Develop controls for products that your organization is outsourcing.	DO	DN	NA	
165	Ensure that outsourced products remain within your organization's control.	DO	DN	NA	
166	Figure out how you're going to control external product providers.	DO	DN	NA	
167	Consider the potential impact that external product providers could have on your ability to consistently meet customer and legal requirements.	DO	DN	NA	
168	Consider the controls that external product providers have implemented and think about how effective their controls really are in practice.	DO	DN	NA	
169	Develop controls for services that your organization is outsourcing.	DO	DN	NA	
170	Ensure that outsourced services remain within your organization's control.	DO	DN	NA	
171	Figure out how you're going to control external service providers.	DO	DN	NA	
172	Consider the potential impact that external service providers could have on your ability to consistently meet customer and legal requirements.	DO	DN	NA	
173	Consider the controls that external service providers have implemented and think about how effective their controls really are in practice.	DO	DN	NA	
174	Design external process, product, and service verification methods.	DO	DN	NA	
175	Plan your external process, product, and service verification activities.	DO	DN	NA	
176	Define the scope and extent of external verification and testing activities.	DO	DN	NA	
177	Define requirements whenever verifications are delegated to external providers.	DO	DN	NA	
178	Maintain a register of verification activities delegated to external providers.	DO	DN	NA	
179	Consider risks when you carry out external verification and testing activities.	DO	DN	NA	
180	Consider the risk of external process, product, and service nonconformities.	DO	DN	NA	
181	Consider the risk that counterfeit parts and components are being used.	DO	DN	NA	

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182	Consider the risk that raw materials might fail to meet requirements.	DO	DN	NA	
183	Use objective evidence to verify external processes, products, and services.	DO	DN	NA	
184	Use documents and records to verify processes, products, and services.	DO	DN	NA	
185	Examine related test documents and records.	DO	DN	NA	
186	Examine related statistical documents and records.	DO	DN	NA	
187	Examine related system control documents and records.	DO	DN	NA	
188	Examine related conformance documents and records.	DO	DN	NA	
189	Examine related production documents and records.	DO	DN	NA	
190	Review production verification activities and results.	DO	DN	NA	
191	Review data related to production part approval system.	DO	DN	NA	
192	Develop a process to evaluate the accuracy of test data and test reports.	DO	DN	NA	
193	Validate test data when it is used to verify externally provided products.	DO	DN	NA	
194	Evaluate and validate the accuracy of test data and test reports whenever they are used to confirm that externally provided products meet requirements.	DO	DN	NA	
195	Evaluate and validate the accuracy of test data and test reports whenever a customer or an organization has identified raw material as a “critical item” or a significant operational risk.	DO	DN	NA	
196	Develop ways of controlling internal providers.	DO	DN	NA	
197	Plan how to control internal processes, products, and services.	DO	DN	NA	
198	Consider the potential impact that internally provided processes, products, and services could have on your ability to consistently meet internal requirements.	DO	DN	NA	
199	Consider the potential impact on your ability to meet customer requirements.	DO	DN	NA	
200	Consider the potential impact on statutory and regulatory requirements.	DO	DN	NA	

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201	Consider the controls that internal process, product, and service providers have implemented and think about how effective their controls actually are.	DO	DN	NA	
202	Create controls for internal processes, products, and services.	DO	DN	NA	
203	Design internal system, product, and service verification methods.	DO	DN	NA	
204	Plan your internal process, product, and service verification activities.	DO	DN	NA	
205	Define the scope and extent of internal verification and testing activities.	DO	DN	NA	
206	Consider risks when you carry out internal verification and testing activities.	DO	DN	NA	
207	Use objective evidence to verify internal processes, products, and services.	DO	DN	NA	
208	Develop a process to evaluate the accuracy of test data and test reports.	DO	DN	NA	

B5.3 PROVIDE RESOURCES NEEDED TO CONTROL SYSTEM

B5.3.1 PROVIDE HUMAN RESOURCES NEEDED TO CONTROL SYSTEM

209	Provide the people that are needed in order to control your system.	DO	DN	NA	
210	Provide the training that is needed in order to control your system.	DO	DN	NA	
211	Provide the knowledge that is needed in order to control your system.	DO	DN	NA	
212	Provide the expertise that is needed in order to control your system.	DO	DN	NA	

B5.3.2 PROVIDE TECHNICAL RESOURCES NEEDED TO CONTROL SYSTEM

213	Provide the policies that are needed in order to control your system.	DO	DN	NA	
214	Provide the procedures that are needed in order to control your system.	DO	DN	NA	
215	Provide the technologies that are needed in order to control your system.	DO	DN	NA	
216	Provide the methodologies that are needed in order to control your system.	DO	DN	NA	
217	Provide the infrastructure that is needed in order to control your system.	DO	DN	NA	

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B5.4 USE AUTHORIZED METHODS TO CONTROL SYSTEM

B5.4.1 USE AUTHORIZED METHODS TO CONTROL SYSTEM INPUTS

218	Use authorized methods to control the identity of system inputs.	DO	DN	NA	
219	Establish suitable means for identifying your system inputs.	DO	DN	NA	
220	Specify the identity of inputs when conformity must be ensured.	DO	DN	NA	
221	Identify inputs whenever input conformity must be ensured.	DO	DN	NA	
222	Identify the monitoring and measurement status of inputs.	DO	DN	NA	
223	Record the identity of inputs when traceability is a requirement.	DO	DN	NA	
224	Clarify your organization's specific input traceability requirements.	DO	DN	NA	
225	Retain the documents and records that are needed to facilitate traceability.	DO	DN	NA	
226	Make arrangements to verify inputs at appropriate stages.	DO	DN	NA	
227	Verify that input requirements were met at all appropriate stages.	DO	DN	NA	
228	Retain evidence that shows that input acceptance criteria were met.	DO	DN	NA	
229	Retain evidence that shows that your input meets defined requirements.	DO	DN	NA	
230	Identify the people who may authorize the release of inputs for production.	DO	DN	NA	
231	Retain and control records to facilitate traceability of input releases.	DO	DN	NA	
232	Verify that your input acceptance criteria are being met.	DO	DN	NA	
233	Verify acceptance before inputs are officially released.	DO	DN	NA	
234	Establish a record of your input acceptance activities.	DO	DN	NA	
235	Document your criteria for input acceptance and rejection.	DO	DN	NA	
236	Document where in the sequence input verification is performed.	DO	DN	NA	

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237	Document and retain your input monitoring and measuring results.	DO	DN	NA	
238	Maintain a record of input acceptance and rejection activities.	DO	DN	NA	
239	Document how input monitoring and measuring must be carried out.	DO	DN	NA	
240	Document all required input monitoring and measuring instructions.	DO	DN	NA	
241	Document all required input monitoring and measuring equipment.	DO	DN	NA	
242	Verify that critical input items are being controlled.	DO	DN	NA	
243	Control critical input items in accordance with established methods.	DO	DN	NA	
244	Verify that key input characteristics are being controlled.	DO	DN	NA	
245	Control key input characteristics in accordance with established methods.	DO	DN	NA	
246	Verify that inputs being used in the management system are being controlled.	DO	DN	NA	
247	Identify and record purchased products (inputs) that are released for use in your system whenever verification activities have not yet been completed.	DO	DN	NA	
248	Use your records to recall and replace purchased products (inputs) that have been used but do not actually meet requirements.	DO	DN	NA	
249	Verify that all input inspection and verification activities have been completed.	DO	DN	NA	
250	Maintain a record of your input inspection and verification activities and results.	DO	DN	NA	
251	Use records to show that all input inspections and verifications were completed.	DO	DN	NA	

B5.4.2 USE AUTHORIZED METHODS TO CONTROL SYSTEM OUTPUTS

252	Use authorized methods to control output design and development activities.	DO	DN	NA	
253	Control how output design and development results are defined.	DO	DN	NA	
254	Control how output design and development reviews are carried out.	DO	DN	NA	
255	Ask representatives from all relevant functions to participate in reviews.	DO	DN	NA	
256	Include people concerned with the design and development stage under review.	DO	DN	NA	

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257	Evaluate how well design and development results meet requirements.	DO	DN	NA	
258	Control actions taken to address problems identified during reviews.	DO	DN	NA	
259	Control how output design and development verifications are performed.	DO	DN	NA	
260	Verify that design and development outputs meet input requirements.	DO	DN	NA	
261	Control actions taken to address problems identified during verifications.	DO	DN	NA	
262	Control how output design and development validations are performed.	DO	DN	NA	
263	Confirm that your outputs meet intended use requirements.	DO	DN	NA	
264	Verify that all intended use or application requirements are being met.	DO	DN	NA	
265	Control actions taken to address problems identified during validations.	DO	DN	NA	
266	Reverify your outputs if changes occur that invalidate previous results.	DO	DN	NA	
267	Control how output design and development progression is authorized.	DO	DN	NA	
268	Control progression to the next stage of output design and development.	DO	DN	NA	
269	Control how output design and development work is being documented.	DO	DN	NA	
270	Control output design and development documents and records.	DO	DN	NA	
271	Use authorized methods to control outputs while system is operating.	DO	DN	NA	
272	Establish suitable means and methods for identifying system outputs.	DO	DN	NA	
273	Specify the identity of outputs whenever conformity must be ensured.	DO	DN	NA	
274	Identify outputs whenever output conformity must be ensured.	DO	DN	NA	
275	Establish the specific identity of your output configurations.	DO	DN	NA	
276	Specify the unique identity of all required output configurations.	DO	DN	NA	
277	Specify the unique identity of all actual output configurations.	DO	DN	NA	

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278	Maintain the unique identity of your output configurations.	DO	DN	NA	
279	Determine differences between required and actual configurations.	DO	DN	NA	
280	Identify the monitoring and measurement status of system outputs.	DO	DN	NA	
281	Record the unique identity of outputs when traceability is a requirement.	DO	DN	NA	
282	Clarify your organization's unique output traceability requirements.	DO	DN	NA	
283	Consider whether identities must be maintained throughout output life cycle.	DO	DN	NA	
284	Consider whether or not you need to be able to trace outputs generated from the same inputs to the final destination.	DO	DN	NA	
285	Consider whether or not you need to maintain a sequential production record for your outputs so that they can be retrieved.	DO	DN	NA	
286	Consider whether or not you need to maintain a sequential assembly record.	DO	DN	NA	
287	Consider whether or not you need to maintain a sequential inspection record.	DO	DN	NA	
288	Consider whether or not you need to maintain a sequential verification record.	DO	DN	NA	
289	Consider whether or not you need to maintain a sequential manufacturing record.	DO	DN	NA	
290	Consider whether components need to be traceable to final assemblies.	DO	DN	NA	
291	Consider whether or not you need to be able to trace components to an assembly and from that assembly to the next higher assembly.	DO	DN	NA	
292	Retain the documents and records that are needed to facilitate traceability.	DO	DN	NA	
293	Verify that input items, characteristics, and activities are being controlled.	DO	DN	NA	
294	Verify that "critical items" and "key characteristics" are being controlled.	DO	DN	NA	
295	Control identified "critical items" in accordance with established methods.	DO	DN	NA	
296	Control "key characteristics" in accordance with established methods.	DO	DN	NA	
297	Verify that inputs being used in the management system are being controlled.	DO	DN	NA	

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298	Identify and record purchased products (inputs) that are released for use in your system whenever verification activities have not yet been completed.	DO	DN	NA	
299	Use your records to recall and replace purchased products (inputs) that have been used but do not actually meet requirements.	DO	DN	NA	
300	Verify that all inspection and verification activities have been completed.	DO	DN	NA	
301	Maintain a record of your inspection and verification activities and results.	DO	DN	NA	
302	Use records to show that all inspections and verifications were completed.	DO	DN	NA	
303	Use authorized methods to control how outputs are released.	DO	DN	NA	
304	Verify acceptance before outputs are officially released.	DO	DN	NA	
305	Implement arrangements to verify your system outputs.	DO	DN	NA	
306	Verify that output requirements are met at all appropriate stages.	DO	DN	NA	
307	Retain evidence that shows that output acceptance criteria were met.	DO	DN	NA	
308	Retain evidence that shows that your output meets defined requirements.	DO	DN	NA	
309	Identify the people who may authorize the release of outputs to system customers.	DO	DN	NA	
310	Retain and control records to facilitate the traceability of output releases.	DO	DN	NA	
311	Release outputs only if verifications are finished or if authorized to do so.	DO	DN	NA	
312	Release output to system customers only if planned arrangements were completed or the customer or a relevant authority allows you to do so.	DO	DN	NA	
313	Release outputs only if all the documents and records that should accompany output delivery are, in fact, present at delivery.	DO	DN	NA	
314	Establish a record of your output acceptance activities.	DO	DN	NA	
315	Document your criteria for output acceptance and rejection.	DO	DN	NA	
316	Document where in the sequence output verification is performed.	DO	DN	NA	
317	Document and retain your output monitoring and measuring results.	DO	DN	NA	

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318	Maintain a record of output acceptance and rejection activities.	DO	DN	NA	
319	Document how output monitoring and measuring must be carried out.	DO	DN	NA	
320	Document all required output monitoring and measuring instructions.	DO	DN	NA	
321	Document all required output monitoring and measuring equipment.	DO	DN	NA	

B5.4.3 USE AUTHORIZED METHODS TO CONTROL SYSTEM ACTIVITIES

322	Use authorized methods to control normal system activities.	DO	DN	NA	
323	Use authorized methods to control system control activities.	DO	DN	NA	
324	Use authorized methods to control system management activities.	DO	DN	NA	
325	Use authorized methods to control system maintenance activities.	DO	DN	NA	
326	Use authorized methods to control system measurement activities.	DO	DN	NA	
327	Use authorized methods to control system monitoring activities.	DO	DN	NA	
328	Use authorized methods to control system evaluation activities.	DO	DN	NA	
329	Use authorized methods to control system audit activities.	DO	DN	NA	
330	Use authorized methods to control system review activities.	DO	DN	NA	
331	Use authorized methods to control system change activities.	DO	DN	NA	
332	Use authorized methods to control system correction activities.	DO	DN	NA	
333	Use authorized methods to control system improvement activities.	DO	DN	NA	
334	Use authorized methods to control “special process” activities.	DO	DN	NA	
335	Establish methods for managing “special process” activities.	DO	DN	NA	
336	Validate “special process” activities and results.	DO	DN	NA	
337	Validate your ability to achieve planned results whenever outputs cannot be verified by subsequent monitoring or measurement.	DO	DN	NA	

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338	Identify in-process inspection and verification points whenever adequate verification of conformity cannot be performed at subsequent stages.	DO	DN	NA	
339	Control “special process” activities and results.	DO	DN	NA	
340	Make arrangements to control special process activities.	DO	DN	NA	
341	Use criteria to control your special process activities.	DO	DN	NA	
342	Use criteria to control how special activities are reviewed.	DO	DN	NA	
343	Use criteria to control how all special activities are approved.	DO	DN	NA	
344	Use approvals to control your special process activities.	DO	DN	NA	
345	Approve equipment before it is used by special process activities.	DO	DN	NA	
346	Approve facilities before they are used by special process activities.	DO	DN	NA	
347	Approve personnel before they are assigned to special process activities.	DO	DN	NA	
348	Approve their qualifications before assigning them to special process activities.	DO	DN	NA	
349	Use procedures to control your special process activities.	DO	DN	NA	
350	Follow specific procedures when implementing special process activities.	DO	DN	NA	
351	Follow specific procedures when maintaining special process activities.	DO	DN	NA	
352	Follow specific procedures when monitoring special process activities.	DO	DN	NA	
353	Follow specific procedures when measuring special process activities.	DO	DN	NA	
354	Follow specific procedures when controlling special process activities.	DO	DN	NA	
355	Use methods to control your special process activities.	DO	DN	NA	
356	Follow specific methods when implementing special process activities.	DO	DN	NA	
357	Follow specific methods when maintaining special process activities.	DO	DN	NA	
358	Follow specific methods when monitoring special process activities.	DO	DN	NA	

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359	Follow specific methods when measuring special process activities.	DO	DN	NA	
360	Follow specific methods when controlling special process activities.	DO	DN	NA	
361	Use documents to control your special process activities.	DO	DN	NA	
362	Specify retention requirements for these documents.	DO	DN	NA	
363	Use records to control your special process activities.	DO	DN	NA	
364	Specify retention requirements for these records.	DO	DN	NA	

B5.4.4 USE AUTHORIZED METHODS TO CONTROL SYSTEM TECHNOLOGY

365	Use authorized methods to control system equipment, tools, and software.	DO	DN	NA	
366	Validate technology prior to final release for system operations.	DO	DN	NA	
367	Validate technology that is used to perform system operations.	DO	DN	NA	
368	Validate tools before they are used to perform system operations.	DO	DN	NA	
369	Validate equipment before it is used to perform system operations.	DO	DN	NA	
370	Validate software before it is used to perform system operations.	DO	DN	NA	
371	Validate technology that is used to automate system operations.	DO	DN	NA	
372	Validate tools before they are used to automate system operations.	DO	DN	NA	
373	Validate equipment before it is used to automate system operations.	DO	DN	NA	
374	Validate software before it is used to automate system operations.	DO	DN	NA	
375	Validate technology that is used to maintain system operations.	DO	DN	NA	
376	Validate tools before they are used to maintain system operations.	DO	DN	NA	
377	Validate equipment before it is used to maintain system operations.	DO	DN	NA	
378	Validate software before it is used to maintain system operations.	DO	DN	NA	
379	Validate technology that is used to monitor system operations.	DO	DN	NA	

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380	Validate tools before they are used to monitor system operations.	DO	DN	NA	
381	Validate equipment before it is used to monitor system operations.	DO	DN	NA	
382	Validate software before it is used to monitor system operations.	DO	DN	NA	
383	Validate technology that is used to measure system operations.	DO	DN	NA	
384	Validate tools before they are used to measure system operations.	DO	DN	NA	
385	Validate equipment before it is used to measure system operations.	DO	DN	NA	
386	Validate software before it is used to measure system operations.	DO	DN	NA	
387	Validate technology that is used to control system operations.	DO	DN	NA	
388	Validate tools before they are used to control system operations.	DO	DN	NA	
389	Validate equipment before it is used to control system operations.	DO	DN	NA	
390	Validate software before it is used to control system operations.	DO	DN	NA	

B5.4.5 USE AUTHORIZED METHODS TO CONTROL SYSTEM PERFORMANCE

391	Use authorized methods to control internal personnel.	DO	DN	NA	
392	Identify the people who can affect system performance.	DO	DN	NA	
393	Qualify the people who can affect system performance.	DO	DN	NA	
394	Make sure that they have the competence they need.	DO	DN	NA	
395	Make sure that they have the appropriate training.	DO	DN	NA	
396	Make sure that they have the appropriate education.	DO	DN	NA	
397	Make sure that they have the appropriate experience.	DO	DN	NA	
398	Supervise the people who can affect system performance.	DO	DN	NA	
399	Use authorized methods to control external providers.	DO	DN	NA	

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400	Establish control of all externally provided processes, products, and services.	DO	DN	NA	
401	Ensure that external processes, products, and services meet requirements.	DO	DN	NA	
402	Ensure that externally provided products and services meet requirements if they are incorporated into your system outputs.	DO	DN	NA	
403	Ensure that externally provided products and services meet requirements if external providers deliver them directly to your system customers.	DO	DN	NA	
404	Ensure that externally provided processes and functions meet requirements.	DO	DN	NA	
405	Ensure that outsourced parts of processes and functions meet requirements.	DO	DN	NA	
406	Control the use of externally provided processes, products, and services.	DO	DN	NA	
407	Use customer-designated or customer-approved external providers if required.	DO	DN	NA	
408	Use customer-designated or customer-approved external system sources.	DO	DN	NA	
409	Use customer-designated or customer-approved "special processes".	DO	DN	NA	
410	Manage risks associated with the selection and use of external providers.	DO	DN	NA	
411	Manage risks related to externally provided processes, products, and services.	DO	DN	NA	
412	Tell external providers to control their direct and sub-tier external providers.	DO	DN	NA	
413	Tell your providers to ensure that their own providers meet requirements.	DO	DN	NA	
414	Perform external process, product, and service verification activities.	DO	DN	NA	
415	Carry out product inspections and service verifications upon receipt.	DO	DN	NA	
416	Carry out periodic inspections and audits at external provider's premises.	DO	DN	NA	
417	Accept external processes, products, and services only if they meet requirements.	DO	DN	NA	
418	Complete verifications before processes, products, and services are accepted.	DO	DN	NA	
419	Complete all verifications before accepting products for use in production.	DO	DN	NA	
420	Identify externally provided products that were released for use in production.	DO	DN	NA	

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421	Record externally provided products that have been released for use in production pending completion of required verification activities.	DO	DN	NA	
422	Recall and replace product if it subsequently fails to meet requirements.	DO	DN	NA	

B5.4.6 USE AUTHORIZED METHODS TO CONTROL SYSTEM DOCUMENTATION

423	Use authorized methods to control how documented information is controlled.	DO	DN	NA	
424	Control how management system documents and records are created.	DO	DN	NA	
425	Make sure that system documents and records are suitable for use.	DO	DN	NA	
426	Make sure that documents and records are properly identified.	DO	DN	NA	
427	Make sure that they have the right names and descriptive titles.	DO	DN	NA	
428	Make sure that they have the right dates and reference numbers.	DO	DN	NA	
429	Make sure that documents and records are properly formatted.	DO	DN	NA	
430	Make sure that system documents and records use the appropriate media.	DO	DN	NA	
431	Make sure that system documents and records use the appropriate graphics.	DO	DN	NA	
432	Make sure that system documents and records use the appropriate language.	DO	DN	NA	
433	Make sure that system documents and records use the appropriate software.	DO	DN	NA	
434	Control how system documents and records are identified and described.	DO	DN	NA	
435	Control how internal documents and records are identified and described.	DO	DN	NA	
436	Control how external documents and records are identified and described.	DO	DN	NA	
437	Control how system documents and records are distributed.	DO	DN	NA	
438	Control how system documents and records are stored.	DO	DN	NA	
439	Control how system documents and records are retrieved.	DO	DN	NA	
440	Control how system documents and records are accessed.	DO	DN	NA	

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441	Prevent unauthorized access to system documents and records.	DO	DN	NA	
442	Make sure that documents and records are available for use where needed.	DO	DN	NA	
443	Make sure that documents and records are available for use when needed.	DO	DN	NA	
444	Control how system documents and records are used.	DO	DN	NA	
445	Control how active system documents and records are used.	DO	DN	NA	
446	Control how documents and records are used to plan your system.	DO	DN	NA	
447	Control how internal documents and records are used to plan your system.	DO	DN	NA	
448	Control how external documents and records are used to plan your system.	DO	DN	NA	
449	Control how documents and records are used to operate your system.	DO	DN	NA	
450	Control how internal documents and records are used to operate system.	DO	DN	NA	
451	Control how external documents and records are used to operate system.	DO	DN	NA	
452	Control how documents and records are used to implement your system.	DO	DN	NA	
453	Control how internal documents and records are used to implement system.	DO	DN	NA	
454	Control how external documents and records are used to implement system.	DO	DN	NA	
455	Control how documents and records are used to maintain your system.	DO	DN	NA	
456	Control how internal documents and records are used to maintain system.	DO	DN	NA	
457	Control how external documents and records are used to maintain system.	DO	DN	NA	
458	Control how documents and records are used to monitor your system.	DO	DN	NA	
459	Control how internal documents and records are used to monitor system.	DO	DN	NA	
460	Control how external documents and records are used to monitor system.	DO	DN	NA	
461	Control how documents and records are used to measure your system.	DO	DN	NA	
462	Control how internal documents and records are used to measure system.	DO	DN	NA	

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463	Control how external documents and records are used to measure system.	DO	DN	NA	
464	Control how documents and records are used to control your system.	DO	DN	NA	
465	Control how internal documents and records are used to control system.	DO	DN	NA	
466	Control how external documents and records are used to control system.	DO	DN	NA	
467	Control how documents and records are used to evaluate your system.	DO	DN	NA	
468	Control how documents and records are used to audit your system.	DO	DN	NA	
469	Control how internal documents and records are used to audit system.	DO	DN	NA	
470	Control how external documents and records are used to audit system.	DO	DN	NA	
471	Control how documents and records are used to review your system.	DO	DN	NA	
472	Control how internal documents and records are used to review system.	DO	DN	NA	
473	Control how external documents and records are used to review system.	DO	DN	NA	
474	Control how documents and records are used to change your system.	DO	DN	NA	
475	Control how documents and records are used to correct your system.	DO	DN	NA	
476	Control how internal documents and records are used to correct system.	DO	DN	NA	
477	Control how external documents and records are used to correct system.	DO	DN	NA	
478	Control how documents and records are used to improve your system.	DO	DN	NA	
479	Control how internal documents and records are used to improve system.	DO	DN	NA	
480	Control how external documents and records are used to improve system.	DO	DN	NA	
481	Control how inactive system documents and records are used.	DO	DN	NA	
482	Control how obsolete system documents and records are used.	DO	DN	NA	
483	Prevent the unintended use of obsolete documents and records.	DO	DN	NA	
484	Identify obsolete management system documents and records.	DO	DN	NA	

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485	Control obsolete management system documents and records.	DO	DN	NA	
486	Remove obsolete management system documents and records.	DO	DN	NA	
487	Control how system documents and records are protected.	DO	DN	NA	
488	Control how paper documents and records are protected.	DO	DN	NA	
489	Ensure that paper documents and records are protected.	DO	DN	NA	
490	Protect the integrity of your paper documents and records.	DO	DN	NA	
491	Prevent unauthorized use of paper documents and records.	DO	DN	NA	
492	Protect the confidentiality of paper documents and records.	DO	DN	NA	
493	Protect the legibility of paper documents and records.	DO	DN	NA	
494	Control how electronic documents and records are protected.	DO	DN	NA	
495	Ensure that electronic documents and records are protected.	DO	DN	NA	
496	Define and develop suitable data protection methods.	DO	DN	NA	
497	Protect system documents and records from loss.	DO	DN	NA	
498	Protect system documents and records from corruption.	DO	DN	NA	
499	Protect system documents and records from physical damage.	DO	DN	NA	
500	Protect system documents and records from unauthorized access.	DO	DN	NA	
501	Protect system documents and records from unintended alteration.	DO	DN	NA	
502	Protect system documents and records from inappropriate changes.	DO	DN	NA	
503	Control how system documents and records are changed.	DO	DN	NA	
504	Control how paper documents and records are changed.	DO	DN	NA	
505	Control how electronic documents and records are changed.	DO	DN	NA	

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

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B5. CONTROL QUALITY MANAGEMENT SYSTEM

527	Control all the documents and records needed to evaluate your system.	DO	DN	NA	
528	Control all the documents and records needed to audit your system.	DO	DN	NA	
529	Control all the documents and records used to audit system operations.	DO	DN	NA	
530	Control all the documents and records used to audit output compliance.	DO	DN	NA	
531	Control all the documents and records needed to review your system.	DO	DN	NA	
532	Control all the documents and records used to review system operations.	DO	DN	NA	
533	Control all the documents and records used to review output compliance.	DO	DN	NA	
534	Control all the documents and records needed to modify your system.	DO	DN	NA	
535	Control all the documents and records needed to correct your system.	DO	DN	NA	
536	Control all the documents and records used to correct system operations.	DO	DN	NA	
537	Control all the documents and records used to correct output compliance.	DO	DN	NA	
538	Control all the documents and records needed to improve your system.	DO	DN	NA	
539	Control all the documents and records used to improve system operations.	DO	DN	NA	
540	Control all the documents and records used to improve output compliance.	DO	DN	NA	
541	Control all the external documents and records that your system needs.	DO	DN	NA	
542	Control all external documented information needed in order to plan system.	DO	DN	NA	
543	Control all external documented information needed in order to operate system.	DO	DN	NA	

Consider each task and select a response. If you haven't done it and it needs to be done, select DO. If you've already done it, select DN. If the task is not applicable in your situation and you can justify and explain why it should be ignored or excluded, select NA.

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B6. EVALUATE QUALITY MANAGEMENT SYSTEM

B6.1 PLAN HOW YOU'RE GOING TO EVALAUTE SYSTEM

B6.1.1 PLAN HOW YOU'RE GOING TO AUDIT YOUR SYSTEM

1	Develop an internal audit programme.	DO	DN	NA	
2	Develop a programme that can find out if your system meets requirements.	DO	DN	NA	
3	Make sure it can determine how well your system meets corporate expectations.	DO	DN	NA	
4	Make sure it can determine how well your system meets international standards.	DO	DN	NA	
5	Develop a programme that can determine if your system is actually effective.	DO	DN	NA	
6	Make sure that your programme is capable of producing valid results.	DO	DN	NA	
7	Establish your internal audit programme.	DO	DN	NA	
8	Assign internal audit responsibilities.	DO	DN	NA	
9	Develop your internal audit methods.	DO	DN	NA	
10	Clarify your internal audit standards.	DO	DN	NA	
11	Expect auditors to be objective.	DO	DN	NA	
12	Expect auditors to be impartial.	DO	DN	NA	
13	Specify internal audit planning requirements.	DO	DN	NA	
14	Expect auditors to consider the results of previous audits.	DO	DN	NA	
15	Expect auditors to consider the impact proposed changes could have.	DO	DN	NA	
16	Expect auditors to consider the importance of the processes being audited.	DO	DN	NA	
17	Define internal audit reporting requirements.	DO	DN	NA	
18	Expect auditors to report results to management.	DO	DN	NA	
19	Formulate internal audit schedules.	DO	DN	NA	
20	Expect audits to be done at planned intervals.	DO	DN	NA	

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B6. EVALUATE QUALITY MANAGEMENT SYSTEM

B6.1.2 PLAN HOW YOU'RE GOING TO ANALYZE YOUR SYSTEM

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

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B6. EVALUATE QUALITY MANAGEMENT SYSTEM

41	Plan how you're going to analyze output problems revealed by internal sources.	DO	DN	NA	
42	Plan how you're going to use your analytical results to evaluate effectiveness.	DO	DN	NA	
43	Plan how you're going to analyze the effectiveness of your system operations.	DO	DN	NA	
44	Plan how you're going to determine if you need to improve its effectiveness.	DO	DN	NA	
45	Plan how you're going to analyze the competence and performance of system personnel.	DO	DN	NA	
46	Plan how you're going to analyze the effectiveness of actions taken to acquire competence.	DO	DN	NA	
47	Plan how you're going to analyze the conformance and performance of external providers.	DO	DN	NA	
48	Plan how to analyze process, product, and service conformity of each external provider.	DO	DN	NA	
49	Plan how to analyze the on-time delivery performance of each external provider.	DO	DN	NA	
50	Plan how you're going to analyze the approval status of each external provider.	DO	DN	NA	
51	Plan how to define actions to take when external providers fail to meet requirements.	DO	DN	NA	

B6.1.3 PLAN HOW YOU'RE GOING TO REVIEW YOUR SYSTEM

52	Consider how you're going to review your management system.	DO	DN	NA	
53	Consider how you're going to review the suitability of your system.	DO	DN	NA	
54	Consider how you're going to review the adequacy of your system.	DO	DN	NA	
55	Consider how you're going to review the effectiveness of your system.	DO	DN	NA	
56	Consider the issues that are relevant to your management system.	DO	DN	NA	
57	Consider changes in the external issues that influence your system.	DO	DN	NA	
58	Consider changes in the internal issues that influence your system.	DO	DN	NA	
59	Consider the status of your previous management reviews.	DO	DN	NA	
60	Consider the status of the actions that were previously taken.	DO	DN	NA	

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B6. EVALUATE QUALITY MANAGEMENT SYSTEM

B6.2 PROVIDE RESOURCES NEEDED TO EVALUATE SYSTEM

B6.2.1 PROVIDE THE PEOPLE THAT YOU NEED TO EVALAUTE YOUR SYSTEM

61	Provide the people that you need in order to audit your system.	DO	DN	NA	
62	Provide the people that you need in order to analyze your system.	DO	DN	NA	
63	Provide the people that you need in order to review your system.	DO	DN	NA	

B6.2.2 PROVIDE THE KNOWLEDGE THAT YOU NEED TO EVALUATE YOUR SYSTEM

64	Provide the knowledge that you need in order to audit your system.	DO	DN	NA	
65	Provide the knowledge that you need in order to analyze your system.	DO	DN	NA	
66	Provide the knowledge that you need in order to review your system.	DO	DN	NA	

B6.2.3 PROVIDE THE TECHNOLOGY THAT YOU NEED TO EVALUATE YOUR SYSTEM

67	Provide the technology that you need in order to audit your system.	DO	DN	NA	
68	Provide the technology that you need in order to analyze your system.	DO	DN	NA	
69	Provide the technology that you need in order to review your system.	DO	DN	NA	

B6.2.4 PROVIDE THE INFRASTRUCTURE THAT YOU NEED TO EVALUATE YOUR SYSTEM

70	Provide the infrastructure that you need in order to audit your system.	DO	DN	NA	
71	Provide the infrastructure that you need in order to analyze your system.	DO	DN	NA	
72	Provide the infrastructure that you need in order to review your system.	DO	DN	NA	

B6.3 USE AUTHORIZED METHODS TO EVALUATE SYSTEM

B6.3.1 USE AUTHORIZED METHODS TO AUDIT YOUR SYSTEM

73	Use authorized methods to plan your internal audit activities.	DO	DN	NA	
74	Define the scope for each internal management system audit.	DO	DN	NA	
75	Specify audit criteria for each internal management system audit.	DO	DN	NA	

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B6. EVALUATE QUALITY MANAGEMENT SYSTEM

76	Clarify internal management system audit methods and techniques.	DO	DN	NA	
77	Select impartial and objective internal management system auditors.	DO	DN	NA	
78	Schedule internal management system audits at planned intervals.	DO	DN	NA	
79	Use authorized methods to carry out audits at planned intervals.	DO	DN	NA	
80	Conduct internal conformance audits of management system.	DO	DN	NA	
81	Determine if your system meets relevant requirements.	DO	DN	NA	
82	Determine if your system meets internal requirements.	DO	DN	NA	
83	Determine if your system meets external requirements.	DO	DN	NA	
84	Determine if your system meets external customer requirements.	DO	DN	NA	
85	Determine if your system meets external statutory requirements.	DO	DN	NA	
86	Determine if your system meets external regulatory requirements.	DO	DN	NA	
87	Determine if your system complies with government regulations.	DO	DN	NA	
88	Determine if your system complies with international standards.	DO	DN	NA	
89	Determine how well system meets safety management requirements.	DO	DN	NA	
90	Determine how well system meets privacy management requirements.	DO	DN	NA	
91	Determine how well system meets security management requirements.	DO	DN	NA	
92	Determine how well system meets quality management requirements.	DO	DN	NA	
93	Determine how well system meets business continuity management requirements.	DO	DN	NA	
94	Conduct internal effectiveness audits of your management system.	DO	DN	NA	
95	Determine how effective management system implementation was.	DO	DN	NA	
96	Use performance indicators to see if system was effectively implemented.	DO	DN	NA	

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B6. EVALUATE QUALITY MANAGEMENT SYSTEM

97	Determine how effective management system operations are.	DO	DN	NA	
98	Use performance indicators to see if system is being effectively operated.	DO	DN	NA	
99	Determine how effective management system controls are.	DO	DN	NA	
100	Use performance indicators to see if system is being effectively controlled.	DO	DN	NA	
101	Determine how effective management system maintenance is.	DO	DN	NA	
102	Use performance indicators to see if system is being effectively maintained.	DO	DN	NA	
103	Determine how effective management system monitoring is.	DO	DN	NA	
104	Use performance indicators to see if system is being effectively monitored.	DO	DN	NA	
105	Determine how effective management system measurement is.	DO	DN	NA	
106	Use performance indicators to see if system is being effectively measured.	DO	DN	NA	
107	Determine how effective management system evaluations are.	DO	DN	NA	
108	Use performance indicators to see if system is being effectively evaluated.	DO	DN	NA	
109	Use performance indicators to see if system is being effectively audited.	DO	DN	NA	
110	Use performance indicators to see if system is being effectively reviewed.	DO	DN	NA	
111	Determine how effective management system changes are.	DO	DN	NA	
112	Use performance indicators to see if system is being effectively modified.	DO	DN	NA	
113	Use performance indicators to see if system corrections are effective.	DO	DN	NA	
114	Use performance indicators to see if system improvements are effective.	DO	DN	NA	
115	Use authorized methods to report management system audit results to management.	DO	DN	NA	
116	Use authorized methods to maintain your management system audit programme.	DO	DN	NA	
117	Retain documented information about your audit programme.	DO	DN	NA	

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B6. EVALUATE QUALITY MANAGEMENT SYSTEM

118	Retain your internal audit results and control these results.	DO	DN	NA	
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B6.3.2 USE AUTHORIZED METHODS TO ANALYZE YOUR SYSTEM

119	Use authorized methods to analyze the opinions of customers.	DO	DN	NA	
120	Use your analytical results to evaluate customer satisfaction.	DO	DN	NA	
121	Evaluate the degree of customer satisfaction.	DO	DN	NA	
122	Use authorized methods to analyze system performance.	DO	DN	NA	
123	Use your results to analyze conformance.	DO	DN	NA	
124	Analyze the conformity of system outputs.	DO	DN	NA	
125	Analyze management system output problems.	DO	DN	NA	
126	Analyze output problems reported by external sources.	DO	DN	NA	
127	Analyze output problems reported using advisories.	DO	DN	NA	
128	Analyze output problems reported by means of alerts.	DO	DN	NA	
129	Analyze problems reported by means of industry alerts.	DO	DN	NA	
130	Analyze problems reported by means of government alerts.	DO	DN	NA	
131	Analyze output problems revealed by internal sources.	DO	DN	NA	
132	Use your results to analyze effectiveness.	DO	DN	NA	
133	Analyze the effectiveness of management system operations.	DO	DN	NA	
134	Determine if you need to improve its system effectiveness.	DO	DN	NA	
135	Use authorized methods to analyze the effectiveness of your system.	DO	DN	NA	
136	Use your results to analyze management system effectiveness.	DO	DN	NA	
137	Analyze the effectiveness of management system operations.	DO	DN	NA	

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B6. EVALUATE QUALITY MANAGEMENT SYSTEM

138	Determine if you need to improve management system operations.	DO	DN	NA	
139	Analyze the effectiveness of management system maintenance.	DO	DN	NA	
140	Determine if you need to improve management system maintenance.	DO	DN	NA	
141	Analyze the effectiveness of management system monitoring.	DO	DN	NA	
142	Determine if you need to improve management system monitoring.	DO	DN	NA	
143	Analyze the effectiveness of management system measurement.	DO	DN	NA	
144	Determine if you need to improve management system measurement.	DO	DN	NA	
145	Analyze the effectiveness of management system evaluations.	DO	DN	NA	
146	Analyze the effectiveness of management system audits.	DO	DN	NA	
147	Determine if you need to improve management system audits.	DO	DN	NA	
148	Analyze the effectiveness of management system reviews.	DO	DN	NA	
149	Determine if you need to improve management system reviews.	DO	DN	NA	
150	Analyze the effectiveness of management system changes.	DO	DN	NA	
151	Analyze the effectiveness of management system corrections.	DO	DN	NA	
152	Determine if you need to improve system correction activities.	DO	DN	NA	
153	Analyze the effectiveness of management system improvements.	DO	DN	NA	
154	Determine if you need to improve system improvement activities.	DO	DN	NA	
155	Use your results to analyze management system management.	DO	DN	NA	
156	Analyze the effectiveness of actions taken by managers.	DO	DN	NA	
157	Analyze the effectiveness of actions taken to address system risks.	DO	DN	NA	

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B6. EVALUATE QUALITY MANAGEMENT SYSTEM

158	Analyze the effectiveness of actions taken to address system opportunities.	DO	DN	NA	
159	Analyze the effectiveness of actions taken to address system nonconformities.	DO	DN	NA	
160	Analyze the effectiveness of actions taken to address system performance problems.	DO	DN	NA	
161	Use authorized methods to analyze the competence of system participants.	DO	DN	NA	
162	Analyze the competence and performance of system personnel.	DO	DN	NA	
163	Analyze the effectiveness of actions taken to acquire competence.	DO	DN	NA	
164	Analyze the competence and performance of external providers.	DO	DN	NA	
165	Analyze the system, product, and service conformity of each external provider.	DO	DN	NA	
166	Analyze the on-time delivery performance of each external provider.	DO	DN	NA	
167	Analyze the approval status of each external provider.	DO	DN	NA	
168	Define the actions to take when external providers fail to meet requirements.	DO	DN	NA	

B6.3.3 USE AUTHORIZED METHODS TO REVIEW YOUR SYSTEM

169	Use authorized methods to review the performance of your system.	DO	DN	NA	
170	Review your management system nonconformities.	DO	DN	NA	
171	Review management system output nonconformities.	DO	DN	NA	
172	Review customer perceptions and satisfaction.	DO	DN	NA	
173	Use output conformity information to review customer satisfaction.	DO	DN	NA	
174	Use on-time delivery performance to review customer satisfaction.	DO	DN	NA	
175	Use corrective action requests to review customer satisfaction.	DO	DN	NA	

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B6. EVALUATE QUALITY MANAGEMENT SYSTEM

176	Use customer complaints to review customer satisfaction.	DO	DN	NA	
177	Review the performance of management system personnel.	DO	DN	NA	
178	Review how well objectives are being met.	DO	DN	NA	
179	Review the competence of system personnel.	DO	DN	NA	
180	Review system management activities and results.	DO	DN	NA	
181	Review system control methods and results.	DO	DN	NA	
182	Review system operations methods and results.	DO	DN	NA	
183	Review system monitoring methods and results.	DO	DN	NA	
184	Review system measurement methods and results.	DO	DN	NA	
185	Review system maintenance methods and results.	DO	DN	NA	
186	Review system evaluation methods and results.	DO	DN	NA	
187	Review system audit activities and results.	DO	DN	NA	
188	Review system analysis activities and results.	DO	DN	NA	
189	Review system modification methods and results.	DO	DN	NA	
190	Review actual management system modifications.	DO	DN	NA	
191	Review actions taken to modify management system.	DO	DN	NA	
192	Review the effectiveness of actions taken to improve system.	DO	DN	NA	
193	Review the effectiveness of corrective and preventive actions.	DO	DN	NA	
194	Review corrective actions taken to address system nonconformities.	DO	DN	NA	
195	Review preventive actions taken to address system nonconformities.	DO	DN	NA	

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B6. EVALUATE QUALITY MANAGEMENT SYSTEM

196	Review potential management system changes.	DO	DN	NA	
197	Review potential improvement opportunities.	DO	DN	NA	
198	Review potential corrective and preventive actions.	DO	DN	NA	
199	Review management system risks and opportunities.	DO	DN	NA	
200	Review actions taken to address risks and opportunities.	DO	DN	NA	
201	Review the effectiveness of the actions that were taken.	DO	DN	NA	
202	Review suitability of management system environment.	DO	DN	NA	
203	Review external process, product, and service providers.	DO	DN	NA	
204	Review your external process, product, and service verification activities.	DO	DN	NA	
205	Review verifications whenever they are delegated to external providers.	DO	DN	NA	
206	Review the issues that could influence management system performance.	DO	DN	NA	
207	Review and evaluate the issues and concerns of interested parties.	DO	DN	NA	
208	Review and evaluate their changing needs and expectations.	DO	DN	NA	
209	Review the adequacy of management system resources.	DO	DN	NA	
210	Generate suitable management system review outputs.	DO	DN	NA	

B6.4 RECORD THE RESULTS OF SYSTEM EVALUATIONS

B6.4.1 RECORD THE RESULTS OF MANAGEMENT SYSTEM AUDITS

211	Record your management system audit activities and results.	DO	DN	NA	
212	Maintain your quality management system audit records.	DO	DN	NA	
213	Control your quality management system audit records.	DO	DN	NA	

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B6. EVALUATE QUALITY MANAGEMENT SYSTEM

B6.4.2 RECORD THE RESULTS OF MANAGEMENT SYSTEM ANALYSES

214	Record your management system analysis activities and results.	DO	DN	NA	
215	Maintain your quality management system analysis records.	DO	DN	NA	
216	Control your quality management system analysis records.	DO	DN	NA	

B6.4.3 RECORD THE RESULTS OF MANAGEMENT SYSTEM REVIEWS

217	Record your management system review activities and results.	DO	DN	NA	
218	Maintain your quality management system review records.	DO	DN	NA	
219	Control your quality management system review records.	DO	DN	NA	

Consider each task and select a response. If you haven't done it and it needs to be done, select DO. If you've already done it, select DN. If the task is not applicable in your situation and you can justify and explain why it should be ignored or excluded, select NA.

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B7. CHANGE QUALITY MANAGEMENT SYSTEM

B7.1 ESTABLISH CHANGE MANAGEMENT METHODS

B7.1.1 ESTABLISH METHODS FOR CORRECTING SYSTEM AND OUTPUTS

1	Establish appropriate corrective action methods and procedures.	DO	DN	NA	
2	Document your system's corrective action methods and procedures.	DO	DN	NA	
3	Maintain documents that describe corrective action methods and procedures.	DO	DN	NA	
4	Establish appropriate corrective action record keeping methods and procedures.	DO	DN	NA	
5	Figure out how you're going to record the actions taken to correct system and outputs.	DO	DN	NA	
6	Figure out how you're going to record the system and output corrections that are made.	DO	DN	NA	

B7.1.2 ESTABLISH METHODS FOR IMPROVING SYSTEM AND OUTPUTS

7	Establish appropriate system and output improvement methods and procedures.	DO	DN	NA	
8	Document your system and output improvement methods and procedures.	DO	DN	NA	
9	Maintain documents describing system and output improvement methods and procedures.	DO	DN	NA	
10	Establish appropriate system and output improvement record keeping methods.	DO	DN	NA	
11	Figure out how you're going to record the actions taken to improve system and outputs.	DO	DN	NA	
12	Figure out how you're going to record the system and output improvements that are made.	DO	DN	NA	

B7.2 GENERATE OPPORTUNITIES TO CHANGE SYSTEM

B7.2.1 DISCOVER OPPORTUNITIES TO CHANGE SYSTEM AND OUTPUTS

13	Discover opportunities to correct your management system and outputs.	DO	DN	NA	
14	Discover opportunities to make corrections by examining audit reports.	DO	DN	NA	
15	Discover opportunities to make corrections by examining review results.	DO	DN	NA	
16	Discover opportunities to make corrections by examining best practices.	DO	DN	NA	

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17	Discover opportunities to make corrections by examining lessons learned.	DO	DN	NA	
18	Discover opportunities to make corrections by examining nonconformities.	DO	DN	NA	
19	Discover opportunities to make corrections by examining customer feedback.	DO	DN	NA	
20	Discover opportunities to improve your management system and outputs.	DO	DN	NA	
21	Discover systemic improvement opportunities by examining audit reports.	DO	DN	NA	
22	Discover systemic improvement opportunities by examining review results.	DO	DN	NA	
23	Discover systemic improvement opportunities by examining best practices.	DO	DN	NA	
24	Discover systemic improvement opportunities by examining lessons learned.	DO	DN	NA	
25	Discover systemic improvement opportunities by examining nonconformities.	DO	DN	NA	
26	Discover systemic improvement opportunities by examining customer feedback.	DO	DN	NA	

B7.2.2 CONFIRM THAT SYSTEM AND OUTPUT CHANGES ARE NEEDED

27	Confirm that proposed management system modifications are necessary.	DO	DN	NA	
28	Confirm that proposed management system modifications would be feasible.	DO	DN	NA	
29	Confirm that proposed management system modifications would be appropriate.	DO	DN	NA	
30	Confirm that proposed management system modifications would be effective.	DO	DN	NA	
31	Confirm that proposed management system modifications would be cost-effective.	DO	DN	NA	
32	Confirm that proposed management system output modifications would be necessary.	DO	DN	NA	
33	Confirm that proposed management system output modifications would be feasible.	DO	DN	NA	
34	Confirm that proposed management system output modifications would be appropriate.	DO	DN	NA	
35	Confirm that proposed management system output modifications would be effective.	DO	DN	NA	
36	Confirm that proposed management system output modifications would be cost-effective.	DO	DN	NA	

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B7.2.3 APPROVE OPPORTUNITIES TO CHANGE SYSTEM AND OUTPUTS

37	Authorize proposed management system corrections and improvements.	DO	DN	NA	
38	Authorize proposed management output corrections and improvements.	DO	DN	NA	

B7.3 PLAN CHANGES TO YOUR MANAGEMENT SYSTEM

B7.3.1 PLAN HOW YOU'RE GOING TO CORRECT SYSTEM AND OUTPUTS

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

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54	Plan how you're going to make sure that your actions are feasible.	DO	DN	NA	
55	Plan how you're going to make sure that your actions are appropriate.	DO	DN	NA	
56	Plan how you're going to make sure that actions consider consequences.	DO	DN	NA	
57	Plan how you're going to make sure that your actions are effective.	DO	DN	NA	
58	Plan how you're going to make sure that your actions are cost-effective.	DO	DN	NA	
59	Plan how you're going to get managers to authorize corrective action.	DO	DN	NA	
60	Plan how you're going to submit corrective action requests.	DO	DN	NA	
61	Plan how you're going to take corrective actions to deal with causes.	DO	DN	NA	
62	Plan how you're going to correct your system and its outputs.	DO	DN	NA	
63	Plan how you're going to review the effectiveness of corrective actions.	DO	DN	NA	
64	Plan how you're going to respond when correction actions aren't taken.	DO	DN	NA	
65	Plan how you're going to update your list of system and output risks.	DO	DN	NA	

B7.3.2 PLAN HOW YOU'RE GOING TO IMPROVE SYSTEM AND OUTPUTS

66	Plan improvements and other changes to your management system.	DO	DN	NA	
67	Identify people authorized to approve changes in your system.	DO	DN	NA	
68	Use your system purpose and scope to guide system improvements.	DO	DN	NA	
69	Use system policy statements to guide system improvements.	DO	DN	NA	
70	Use your quality policy to guide your system improvements.	DO	DN	NA	
71	Use your quality objectives to guide system improvements.	DO	DN	NA	

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72	Use your privacy policy to guide your system improvements.	DO	DN	NA	
73	Use your privacy objectives to guide system improvements.	DO	DN	NA	
74	Use your safety policy to guide your system improvements.	DO	DN	NA	
75	Use your safety objectives to guide system improvements.	DO	DN	NA	
76	Use your security policy to guide your system improvements.	DO	DN	NA	
77	Use your security objectives to guide system improvements.	DO	DN	NA	
78	Use your business continuity policy to guide your system improvements.	DO	DN	NA	
79	Use your business continuity objectives to guide system improvements.	DO	DN	NA	
80	Consider improvements and other changes to your management system.	DO	DN	NA	
81	Consider the purpose and effects of the changes you intend to make.	DO	DN	NA	
82	Consider responsibilities and authorities whenever you make changes.	DO	DN	NA	
83	Consider allocating or reallocating responsibilities and authorities.	DO	DN	NA	
84	Consider the consequences that changes could potentially produce.	DO	DN	NA	
85	Consider the availability of resources whenever you make changes.	DO	DN	NA	
86	Consider the integrity of your system whenever you make changes.	DO	DN	NA	
87	Figure out how you're going to control changes in your management system.	DO	DN	NA	
88	Ensure that system continues to meet requirements even though changes are being made.	DO	DN	NA	
89	Plan improvements and other changes to management system outputs.	DO	DN	NA	
90	Identify people authorized to approve changes in system outputs.	DO	DN	NA	

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91	Use your system purpose and scope to guide output improvements.	DO	DN	NA	
92	Use system policy statements to guide system improvements.	DO	DN	NA	
93	Use your quality policy to guide your output improvements.	DO	DN	NA	
94	Use your quality objectives to guide output improvements.	DO	DN	NA	
95	Use your privacy policy to guide your output improvements.	DO	DN	NA	
96	Use your privacy objectives to guide output improvements.	DO	DN	NA	
97	Use your safety policy to guide your output improvements.	DO	DN	NA	
98	Use your safety objectives to guide output improvements.	DO	DN	NA	
99	Use your security policy to guide your output improvements.	DO	DN	NA	
100	Use your security objectives to guide output improvements.	DO	DN	NA	
101	Use your business continuity policy to guide your output improvements.	DO	DN	NA	
102	Use your business continuity objectives to guide output improvements.	DO	DN	NA	
103	Consider improvements and other changes to management system outputs.	DO	DN	NA	
104	Consider the purpose and effects of the output changes you intend to make.	DO	DN	NA	
105	Consider responsibilities and authorities whenever you make output changes.	DO	DN	NA	
106	Consider the consequences that output changes could potentially produce.	DO	DN	NA	
107	Consider the availability of resources whenever you make output changes.	DO	DN	NA	
108	Consider the integrity of your outputs whenever you make changes.	DO	DN	NA	
109	Figure out how you're going to control changes in your system's outputs.	DO	DN	NA	
110	Ensure that outputs continue to meet requirements even though changes are being made.	DO	DN	NA	

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B7.4 USE APPROVED METHODS TO CHANGE SYSTEM

B7.4.1 USE APPROVED METHODS TO CORRECT SYSTEM AND OUTPUTS

111	Apply your corrective action methods and procedures.	DO	DN	NA	
112	Evaluate the need to eliminate causes of nonconformity.	DO	DN	NA	
113	Review and analyze your system and output nonconformities.	DO	DN	NA	
114	Determine the causes of system and output nonconformities.	DO	DN	NA	
115	Determine if human factors are responsible for the nonconformity.	DO	DN	NA	
116	Determine if external providers are responsible for the nonconformity.	DO	DN	NA	
117	Flow down corrective action requirements to your external providers.	DO	DN	NA	
118	Decide if the causes of system or output nonconformity must be addressed.	DO	DN	NA	
119	Develop corrective actions to address causes of nonconformity.	DO	DN	NA	
120	Make sure that your corrective actions are feasible.	DO	DN	NA	
121	Make sure that your corrective actions are appropriate.	DO	DN	NA	
122	Make sure that actions also consider effects.	DO	DN	NA	
123	Make sure that your corrective actions are effective.	DO	DN	NA	
124	Make sure that your corrective actions are cost-effective.	DO	DN	NA	
125	Take corrective action to address the causes of nonconformity.	DO	DN	NA	
126	Provide the resources needed to correct system and outputs.	DO	DN	NA	
127	Provide suitable resources needed to correct system outputs.	DO	DN	NA	
128	Provide suitable resources needed to correct system activities.	DO	DN	NA	
129	Control your corrective action activities and results.	DO	DN	NA	
130	Monitor your corrective action activities and results.	DO	DN	NA	

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131	Record your corrective action activities and results.	DO	DN	NA	
132	Document the actions taken and the results achieved.	DO	DN	NA	
133	Retain and control your record of corrective actions taken.	DO	DN	NA	

B7.4.2 USE APPROVED METHODS TO IMPROVE SYSTEM AND OUTPUTS

134	Apply system and output improvement methods and procedures.	DO	DN	NA	
135	Evaluate the need to make system and output improvements.	DO	DN	NA	
136	Provide the resources needed to make system and output improvements.	DO	DN	NA	
137	Provide suitable resources needed to improve your system outputs.	DO	DN	NA	
138	Provide suitable resources needed to improve your system activities.	DO	DN	NA	
139	Develop improvements to your system and system outputs.	DO	DN	NA	
140	Make sure that your system and output improvements are feasible.	DO	DN	NA	
141	Make sure that your system and output improvements are appropriate.	DO	DN	NA	
142	Make sure that system and output improvements also consider effects.	DO	DN	NA	
143	Make sure that your system and output improvements are effective.	DO	DN	NA	
144	Make sure that your system and output improvements are cost-effective.	DO	DN	NA	
145	Implement improvements to your management system and system outputs.	DO	DN	NA	
146	Improve the suitability, adequacy, and effectiveness of your management system.	DO	DN	NA	
147	Improve the quality, safety, privacy, and security of management system outputs.	DO	DN	NA	
148	Control improvements to your management system and system outputs.	DO	DN	NA	
149	Control improvements and other changes affecting system software.	DO	DN	NA	
150	Control improvements and other changes affecting system operations.	DO	DN	NA	
151	Control improvements and other changes affecting system equipment.	DO	DN	NA	

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152	Control improvements and other changes affecting system tools.	DO	DN	NA	
153	Monitor improvements to your management system and system outputs.	DO	DN	NA	
154	Monitor the implementation of system and output improvement activities.	DO	DN	NA	
155	Record improvements to your management system and system outputs.	DO	DN	NA	

B7.5 REVIEW AND EVALUATE CHANGES TO SYSTEM

B7.5.1 REVIEW AND EVALUATE SYSTEM AND OUTPUT CORRECTIONS

156	Review and evaluate actions taken to correct your management system.	DO	DN	NA	
157	Document your system correction reviews and the actions that are taken.	DO	DN	NA	
158	Establish a record of system correction reviews and actions taken.	DO	DN	NA	
159	Review and evaluate actions taken to correct system outputs.	DO	DN	NA	
160	Document your output correction reviews and the actions that are taken.	DO	DN	NA	
161	Establish a record of output correction reviews and actions taken.	DO	DN	NA	

B7.5.2 REVIEW AND EVALUATE SYSTEM AND OUTPUT IMPROVEMENTS

162	Review and evaluate improvements and changes to management system.	DO	DN	NA	
163	Document management system improvement reviews and the actions that are taken.	DO	DN	NA	
164	Establish a record of management system improvement reviews and the actions taken.	DO	DN	NA	
165	Review and evaluate improvements and changes to management system outputs.	DO	DN	NA	
166	Document your output improvement reviews and the actions that are taken.	DO	DN	NA	
167	Establish a record of output improvement reviews and the actions taken.	DO	DN	NA	

Consider each task and select a response. If you haven't done it and it needs to be done, select DO. If you've already done it, select DN. If the task is not applicable in your situation and you can justify and explain why it should be ignored or excluded, select NA.

In the spaces below, please enter the name and location of your organization, who completed this page, who reviewed it, and the dates.

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