

# ISO 9001 2015 GAP ANALYSIS TOOL

## 9. EVALUATION GAP ANALYSIS QUESTIONNAIRE

### 9.1 MONITOR, MEASURE, ANALYZE, AND EVALUATE QMS PERFORMANCE

#### 9.1.1 PLAN HOW YOU'RE GOING TO MONITOR, MEASURE, ANALYZE, AND EVALUATE

1	Did you plan how to monitor, measure, analyze, and evaluate your QMS?		
2	Did you plan how to <i>monitor</i> QMS performance and effectiveness?		
3	Did you figure out what needs to be monitored and did you select methods?		
4	Did you determine your organization's QMS monitoring requirements?		
5	Do you select monitoring methods that can produce valid results?		
6	Did you establish when monitoring should be done and who should do it?		
7	Did you plan how to <i>measure</i> QMS performance and effectiveness?		
8	Did you figure out what needs to be measured and did you select methods?		
9	Did you determine your organization's QMS measurement requirements?		
10	Do you select measurement methods that can produce valid results?		
11	Did you establish when measuring should be done and who should do it?		
12	Did you plan how to <i>analyze</i> QMS performance and effectiveness?		
13	Did you select analytical methods that are capable of producing valid results?		
14	Did you decide when monitoring and measurement results are analyzed?		
15	Did you plan how to <i>evaluate</i> QMS performance and effectiveness?		
16	Did you select evaluation methods that are capable of producing valid results?		
17	Did you decide when monitoring and measurement results are evaluated?		
18	Do you monitor, measure, analyze, and evaluate your organization's QMS?		
19	Do you <i>monitor</i> the performance and effectiveness of your organization's QMS?		
20	Do you record monitoring results and do you retain and control these records?		

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21	Do you <i>measure</i> the performance and effectiveness of your organization's QMS?		
22	Do you record measurement results and do you retain and control these records?		
23	Do you <i>analyze</i> the performance and effectiveness of your organization's QMS?		
24	Do you record analytical results and do you retain and control these records?		
25	Do you <i>evaluate</i> the performance and effectiveness of your organization's QMS?		
26	Do you record evaluation results and do you retain and control these records?		
<b>9.1.2 FIND OUT HOW WELL CUSTOMER NEEDS AND EXPECTATIONS ARE BEING MET</b>			
27	Do you establish methods that you can use to monitor customer perceptions?		
28	Do you figure out how you're going to <i>obtain</i> information about how customers feel about how well you're meeting their needs and expectations?		
29	Do you figure out how you're going to <i>review</i> information about how customers feel about how well you're meeting their needs and expectations?		
30	Do you monitor how well customer needs and expectations are being fulfilled?		
31	Do you monitor how your customers feel about how well you're meeting their needs and expectations (do you monitor your customers' perceptions)?		
<b>9.1.3 EVALUATE PERFORMANCE, EFFECTIVENESS, CONFORMITY, AND SATISFACTION</b>			
32	Do you analyze your monitoring and measurement results?		
33	Do you analyze and evaluate appropriate data and information?		
34	Do you use your analytical results to evaluate performance?		
35	Do you evaluate the performance of your organization's QMS?		
36	Do you determine if you need to improve its performance?		
37	Do you evaluate the performance of your external providers?		
38	Do you use your analytical results to evaluate effectiveness?		
39	Do you evaluate the effectiveness of your organization's QMS?		

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40	Do you determine if you need to improve its effectiveness?		
41	Do you evaluate the effectiveness of your organization's planning?		
42	Do you determine if your plans were effectively implemented?		
43	Do you evaluate the effectiveness of your organization's actions?		
44	Do you evaluate the effectiveness of actions taken to address risks?		
45	Do you evaluate the effectiveness of actions taken to address opportunities?		
46	Do you use your analytical results to evaluate conformity?		
47	Do you evaluate the conformity of products and services?		
48	Do you use your analytical results to evaluate satisfaction?		
49	Do you evaluate the degree of customer satisfaction?		

#### 9.2 USE INTERNAL AUDITS TO EXAMINE CONFORMANCE AND PERFORMANCE

##### 9.2.1 AUDIT YOUR QUALITY MANAGEMENT SYSTEM AT PLANNED INTERVALS

50	Do you conduct internal conformance audits at planned intervals?		
51	Do you determine if your organization's QMS meets requirements?		
52	Do you see if your QMS meets your organization's own requirements?		
53	Do you see if your QMS meets the requirements of this ISO 9001 2015 standard?		
54	Do you examine the effectiveness of your organization's QMS?		
55	Do you see if your organization's QMS was effectively <i>implemented</i> ?		
56	Do you see if your organization's QMS is being effectively <i>maintained</i> ?		

##### 9.2.2 DEVELOP AN INTERNAL AUDIT PROGRAM FOR YOUR ORGANIZATION

57	Did you plan the development of your internal audit program (or programme)?		
58	Did you develop a program that can find out if your QMS meets requirements?		

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59	Is it capable of determining if QMS meets your organization's requirements?		
60	Is it capable of determining if QMS meets the ISO 9001 2015 requirements?		
61	Did you develop a program that can determine if your QMS is effective?		
62	Did you establish an internal audit program for your organization?		
63	Did you establish internal audit responsibilities?		
64	Did you establish internal audit methods?		
65	Do you expect auditors to be objective?		
66	Do you expect auditors to be impartial?		
67	Did you establish internal audit planning requirements?		
68	Do you expect auditors to consider the results of previous audits?		
69	Do you expect auditors to consider the impact proposed changes could have?		
70	Do you expect auditors to consider the importance of processes being audited?		
71	Did you establish internal audit reporting requirements?		
72	Do you expect auditors to report results to management?		
73	Did you establish internal audit schedules?		
74	Do you expect audits to be done at planned intervals?		
75	Did you implement your organization's internal audit program?		
76	Do you define the scope for each internal audit?		
77	Do you specify audit criteria for each internal audit?		
78	Do you select impartial and objective internal auditors?		
79	Do you carry out internal audits at planned intervals?		
80	Do you report internal audit results to management?		

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81	Do you correct nonconformities and take corrective action?		
82	Do you expect action to be taken without undue delay?		
83	Do you maintain your organization's internal audit program?		
84	Do you retain documented information about your audit program?		
85	Do you retain your internal audit results and do you control these results?		
86	Do you retain a record of implementation and do you control these records?		

#### 9.3 CARRY OUT MANAGEMENT REVIEWS AND DOCUMENT YOUR RESULTS

##### 9.3.1 REVIEW SUITABILITY, ADEQUACY, EFFECTIVENESS, AND DIRECTION

87	Do you review your quality management system at regular intervals?		
88	Do you review the suitability of your organization's QMS?		
89	Do you review the adequacy of your organization's QMS?		
90	Do you review the effectiveness of your organization's QMS?		
91	Do you review the direction of your organization's QMS?		
92	Do you review how well it's aligned with your strategic direction?		

##### 9.3.2 PLAN AND PERFORM MANAGEMENT REVIEWS AT PLANNED INTERVALS

93	Do you plan your organization's management review activities?		
94	Do you consider the issues that are relevant to your organization's QMS?		
95	Do you consider changes in the <i>external</i> issues that influence your QMS?		
96	Do you consider changes in the <i>internal</i> issues that influence your QMS?		
97	Do you consider the status of your previous management reviews?		
98	Do you consider the status of the actions that were previously taken?		
99	Do you schedule your organization's reviews at planned intervals?		

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100	Do you review your organization's quality management system?		
101	Do you review QMS performance and effectiveness (including trends)?		
102	Do you review customer satisfaction data and information?		
103	Do you review feedback from relevant interested parties?		
104	Do you review how well quality objectives are being met?		
105	Do you review nonconformities and corrective actions?		
106	Do you review product and service conformity issues?		
107	Do you review relevant process performance issues?		
108	Do you review monitoring and measurement results?		
109	Do you review quality audit results and activities?		
110	Do you review the performance of external providers?		
111	Do you review actions taken to address risks and opportunities?		
112	Do you review the effectiveness of the actions that were taken?		
113	Do you review potential improvement opportunities?		
114	Do you review the adequacy of resource allocations?		
<b>9.3.3 GENERATE MANAGEMENT REVIEW OUTPUTS AND DOCUMENT RESULTS</b>			
115	Do you generate suitable management review outputs?		
116	Do you make decisions and take actions to address improvement opportunities?		
117	Do you make decisions and take actions to address the need to change QMS?		
118	Do you make decisions and take actions to address QMS resource requirements?		
119	Do you document the results of your management reviews?		
120	Do you retain and control your management review records?		

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