

## B. PROCESS AUDIT PROGRAM

### 3. PROCESS AUDIT QUESTIONS

#### 1. DEVELOP PROCESS

**PROCESS:**

1.1 ORGANIZATION						N
1	Has the responsibility for this process been defined?	YES	NO	N/A		
2	Was a member of management given the authority and responsibility to develop this process?	YES	NO	N/A		
3	Did management support the development of this process?	YES	NO	N/A		
4	Did you plan how to manage this process?	YES	NO	N/A		
5	Did you plan the development of this process?	YES	NO	N/A		
6	Did you identify process planning responsibilities?	YES	NO	N/A		
7	Did you plan how this process would be performed?	YES	NO	N/A		
8	Did you plan how this process would be organized?	YES	NO	N/A		
9	Did you plan how this process would interact with other processes?	YES	NO	N/A		
10	Did you define process reporting responsibilities?	YES	NO	N/A		
11	Did you define the duties and responsibilities of your process personnel?	YES	NO	N/A		
12	Did you define work routines and patterns of interaction for your process personnel?	YES	NO	N/A		
13	Have you defined how process personnel should interact with one another?	YES	NO	N/A		
1.2 DOCUMENTS						N
14	Do you have a manual that documents this process?	YES	NO	N/A		
15	Does your process manual describe this process?	YES	NO	N/A		
16	Has the purpose of this process been defined?	YES	NO	N/A		
17	Have you established goals and objectives for this process?	YES	NO	N/A		
18	Does your process manual describe the steps or stages that make up this process?	YES	NO	N/A		

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19	Does your process manual describe how this process is connected with other processes?	YES	NO	N/A		
20	Does your process manual describe how this process interacts with other processes?	YES	NO	N/A		
21	Have you created a procedure to control this process?	YES	NO	N/A		
22	Have you documented your process control procedure?	YES	NO	N/A		
23	Do your documents consider the size and complexity of this process?	YES	NO	N/A		
24	Do your documents consider the interactions between this process and other processes?	YES	NO	N/A		
25	Do your documents consider the skill and training of the process personnel who use these documents?	YES	NO	N/A		
26	Do your documents describe how your process personnel communicate with process customers? (Process customers are people from other processes who receive outputs from this process.)	YES	NO	N/A		
27	Do your documents describe how your process personnel communicate with process suppliers? (Process suppliers are people from other processes who generate outputs that this process needs.)	YES	NO	N/A		
28	Have you developed methods and procedures to manage and control your process documents?	YES	NO	N/A		
29	Did you identify the records that will be needed to support this process?	YES	NO	N/A		
30	Did you identify the records that will be needed in order to be able to prove that this process meets requirements?	YES	NO	N/A		
31	Did you define how process records must be maintained?	YES	NO	N/A		
32	Did you define process record keeping responsibilities?	YES	NO	N/A		
33	Have you developed methods and procedures to manage and control process record keeping activities?	YES	NO	N/A		

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**PROCESS:**

1.3 OUTPUTS						N
34	Did you identify the outputs that this process must produce for other processes? (Outputs become inputs for other processes.)	YES	NO	N/A		
35	Did you identify process output requirements and obligations (what other processes expect)?	YES	NO	N/A		
36	Did you identify and define the output requirements that this process must meet for other processes?	YES	NO	N/A		
37	Do your process output definitions specify essential or crucial output characteristics and requirements?	YES	NO	N/A		
38	Did you identify the output requirements that external agencies expect this process to meet?	YES	NO	N/A		
39	Did you identify the output requirements that regulators expect this process to meet?	YES	NO	N/A		
40	Did you identify the output requirements that statutes expect this process to meet?	YES	NO	N/A		
41	Did you identify the output requirements that your organization expects this process to meet?	YES	NO	N/A		
42	Did you plan how monitoring methods will be used to demonstrate that process outputs meet requirements?	YES	NO	N/A		
43	Did you plan how measurement methods will be used to demonstrate that process outputs meet requirements?	YES	NO	N/A		
44	Did you plan how analytical methods will be used to demonstrate that process outputs meet requirements?	YES	NO	N/A		
45	Did you plan how statistical methods will be used to demonstrate that process outputs meet requirements?	YES	NO	N/A		
46	Have you developed a way of controlling the quality of your process outputs?	YES	NO	N/A		
47	Have you figured out how to identify nonconforming process outputs?	YES	NO	N/A		
48	Have you figured out who should be responsible for identifying nonconforming process outputs?	YES	NO	N/A		

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**PROCESS:**

49	Have you figured out who should be responsible for controlling nonconforming process outputs?	YES	NO	N/A		
50	Have you figured out how to preserve and protect outputs while they are being delivered to your process customers?	YES	NO	N/A		
51	Have you figured out how you're going to cope with the potential consequences that may result from the delivery or use of nonconforming outputs?	YES	NO	N/A		
52	Have you established a way of controlling what is done with outputs when they are returned to you?	YES	NO	N/A		
53	Did you identify the work environment that this process needs in order to ensure that your process outputs meet requirements?	YES	NO	N/A		
54	Did you develop and document procedures or work instructions to monitor process working conditions when contact between these conditions and your outputs can adversely affect output quality?	YES	NO	N/A		
55	Did you identify the records that will be needed in order to monitor and control process outputs?	YES	NO	N/A		
56	Have you figured out how your process output records will be maintained?	YES	NO	N/A		
<b>1.4 INPUTS</b>						<b>N</b>
57	Did you identify and define the inputs that this process needs in order to produce the outputs that are required by your process customers? (Outputs from this process are used by customers from other processes.)	YES	NO	N/A		
58	Do your input definitions consider and support the types of outputs that this process must produce?	YES	NO	N/A		
59	Do your input definitions consider requirements that your process outputs must meet?	YES	NO	N/A		
60	Do your input definitions consider performance requirements that process outputs must meet?	YES	NO	N/A		
61	Do your input definitions consider safety requirements that process outputs must meet?	YES	NO	N/A		

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**PROCESS:**

62	Do your input definitions consider requirements that are imposed by external regulatory agencies?	YES	NO	N/A		
63	Have you developed a way of controlling the quality of process inputs?	YES	NO	N/A		
64	Did you specify the requirements that process inputs must meet?	YES	NO	N/A		
65	Have you defined input verification methods?	YES	NO	N/A		
66	Did you specify the approval requirements that process inputs must meet?	YES	NO	N/A		
67	Did you identify the records that will be needed in order to monitor and control process inputs?	YES	NO	N/A		
68	Have you figured out how your process input records will be maintained?	YES	NO	N/A		
<b>1.5 INFORMATION</b>						<b>N</b>
69	Have you figured out what kind of information you need to have about this process?	YES	NO	N/A		
70	Have you figured out what kind of information you need to have in order to be able to evaluate the effectiveness and suitability of this process?	YES	NO	N/A		
71	Have you figured out what kind of information you need to have in order to be able to identify opportunities to improve the effectiveness and suitability of this process?	YES	NO	N/A		
72	Have you figured out how you're going to <i>collect</i> information about this process?	YES	NO	N/A		
73	Have you figured out how you're going to <i>protect</i> information about this process?	YES	NO	N/A		
74	Have you figured out how you're going to <i>control</i> information about this process?	YES	NO	N/A		
75	Have you figured out how you're going to control access to process information?	YES	NO	N/A		
76	Have you figured out how you're going to share process information with process personnel?	YES	NO	N/A		

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**PROCESS:**

1.6 MONITORING						N
77	Have you identified your process monitoring needs and requirements?	YES	NO	N/A		
78	Have you identified the monitoring that should be performed in order to ensure that process outputs meet specified requirements?	YES	NO	N/A		
79	Have you developed methods to monitor the effectiveness and suitability of this process?	YES	NO	N/A		
80	Did you identify methods that you can use to monitor how this process meets customer requirements? (Customers are people from other processes who use process outputs.)	YES	NO	N/A		
81	Did you plan how you were going to monitor the effectiveness and suitability of this process?	YES	NO	N/A		
82	Did you plan how monitoring methods will be used to demonstrate that this process meets requirements?	YES	NO	N/A		
83	Did you plan how monitoring methods will be used to maintain the effectiveness of this process?	YES	NO	N/A		
84	Did you plan how monitoring methods will be used to improve the effectiveness of this process?	YES	NO	N/A		
85	Have you developed a way of monitoring process outputs?	YES	NO	N/A		
86	Have you developed a way of monitoring process output characteristics?	YES	NO	N/A		
87	Have you developed a way of gathering feedback from your process customers?	YES	NO	N/A		
88	Have you developed methods to monitor the effectiveness of this process?	YES	NO	N/A		
89	Can your monitoring methods demonstrate that this process meets specified requirements?	YES	NO	N/A		
90	Can your monitoring methods prove that this process is capable of achieving planned results?	YES	NO	N/A		
91	Can your monitoring methods demonstrate that process outputs meet planned requirements?	YES	NO	N/A		

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**PROCESS:**

1.7 MEASUREMENT						N
92	Have you identified process measurement needs and requirements?	YES	NO	N/A		
93	Have you identified the measurements that should be performed in order to ensure that process outputs meet specified requirements?	YES	NO	N/A		
94	Have you established a procedure to control your process measurement activities?	YES	NO	N/A		
95	Did you plan how measurement methods will be used to demonstrate that this process meets requirements?	YES	NO	N/A		
96	Did you plan how you were going to measure the effectiveness and suitability of this process?	YES	NO	N/A		
97	Did you plan how measurement methods will be used to maintain the effectiveness and suitability of this process?	YES	NO	N/A		
98	Did you plan how measurement methods will be used to improve the effectiveness and suitability of this process?	YES	NO	N/A		
99	Have you developed methods to measure process effectiveness and suitability?	YES	NO	N/A		
100	Can your measurement methods demonstrate that this process meets specified requirements?	YES	NO	N/A		
101	Have you developed a way of measuring how well process goals and objectives are being achieved?	YES	NO	N/A		
102	Have you developed a way of measuring process outputs?	YES	NO	N/A		
103	Have you developed a way of measuring process output characteristics?	YES	NO	N/A		
104	Can your measurement methods demonstrate that process outputs meet specified requirements?	YES	NO	N/A		
105	Can your measurement methods prove that this process is capable of achieving planned results?	YES	NO	N/A		

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**PROCESS:**

106	Did you identify methods that you can use to measure how well this process meets customer requirements?	YES	NO	N/A		
107	Did you document your customer feedback procedure?	YES	NO	N/A		
108	Did you identify how you're going to gather data about how well this process meets customer requirements?	YES	NO	N/A		
109	Did you identify how you're going to use data to measure how well this process meets customer requirements?	YES	NO	N/A		
110	Did you plan how analytical methods will be used to demonstrate that this process meets requirements?	YES	NO	N/A		
111	Did you plan how analytical methods will be used to maintain the effectiveness of this process?	YES	NO	N/A		
112	Did you plan how analytical methods will be used to improve the effectiveness of this process?	YES	NO	N/A		
113	Did you plan how statistical methods will be used to demonstrate that this process meets requirements?	YES	NO	N/A		
114	Did you plan how statistical methods will be used to maintain the effectiveness of this process?	YES	NO	N/A		
115	Did you plan how statistical methods will be used to improve the effectiveness of this process?	YES	NO	N/A		
<b>1.8 TRAINING</b>						<b>N</b>
116	Have you identified your training and awareness needs and requirements?	YES	NO	N/A		
117	Have you identified output oriented training needs and requirements?	YES	NO	N/A		
118	Have you identified output management training needs and requirements?	YES	NO	N/A		
119	Have you identified output monitoring training needs and requirements?	YES	NO	N/A		
120	Have you identified output measurement training needs and requirements?	YES	NO	N/A		
121	Have you identified input oriented training needs and requirements?	YES	NO	N/A		

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**1. DEVELOP PROCESS**

**PROCESS:**

122	Have you identified input management training needs and requirements?	YES	NO	N/A		
123	Have you identified input monitoring training needs and requirements?	YES	NO	N/A		
124	Have you identified input measurement training needs and requirements?	YES	NO	N/A		
125	Have you defined acceptable levels of competence for your process personnel?	YES	NO	N/A		
126	Have you developed training programs to support this process?	YES	NO	N/A		
127	Have you developed awareness programs to support this process?	YES	NO	N/A		
128	Have you developed training and awareness programs to show personnel how to achieve process goals and objectives?	YES	NO	N/A		
<b>1.9 RESOURCES</b>						<b>N</b>
129	Did you have the resources that were needed to properly develop this process?	YES	NO	N/A		
130	Did you identify the resources that this process needs?	YES	NO	N/A		
131	Did you identify the resources needed to support this process?	YES	NO	N/A		
132	Did you identify the resources needed to manage and control this process?	YES	NO	N/A		
133	Did you identify the resources needed to train process personnel?	YES	NO	N/A		
134	Did you identify the resources needed to turn inputs into process outputs?	YES	NO	N/A		
135	Did you identify the resources needed to monitor the effectiveness of this process?	YES	NO	N/A		
136	Did you identify the resources needed to measure the effectiveness of this process?	YES	NO	N/A		

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137	Did you identify the resources needed to evaluate the effectiveness of this process?	YES	NO	N/A		
138	Did you identify the resources needed to meet the regulatory requirements that affect this process?	YES	NO	N/A		
139	Did you identify the infrastructure that this process needs in order to ensure that your outputs meet requirements?	YES	NO	N/A		
140	Did you identify the buildings needed by this process?	YES	NO	N/A		
141	Did you identify the workspaces needed by this process?	YES	NO	N/A		
142	Did you identify the technology needed by this process?	YES	NO	N/A		
143	Did you identify the equipment needed by this process?	YES	NO	N/A		
144	Did you identify the hardware needed by this process?	YES	NO	N/A		
145	Did you identify the software needed by this process?	YES	NO	N/A		
146	Did you identify the utilities needed by this process?	YES	NO	N/A		
147	Did you identify the support services needed by this process?	YES	NO	N/A		
148	Did you identify the transportation services needed by this process?	YES	NO	N/A		
149	Did you identify the communication services needed by this process?	YES	NO	N/A		
150	Did you identify the maintenance services needed by this process?	YES	NO	N/A		

The above questionnaire covers only the *first part* of a *six part* audit questionnaire. If you would like to see the rest of this Process Audit Questionnaire, please consider purchasing our complete *Plain English Process Audit Program*. For more information, please see <http://www.praxiom.com>.

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