

## PROCESS BEING AUDITED:

### 7. PROCESS CONTROL QUESTIONS

#### 7.1 PLAN HOW YOU'RE GOING TO CONTROL PROCESS

##### 7.1.1 CONSIDER HOW TO CONTROL YOUR PROCESS OUTPUTS

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

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

**7.1.2 CONSIDER HOW TO CONTROL YOUR PROCESS INPUTS**

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

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

**7.1.3 CONSIDER HOW TO CONTROL YOUR PROCESS ACTIVITIES**

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

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

#### 7.1.4 CONSIDER HOW TO CONTROL YOUR PROCESS PROVIDERS

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

#### 7.2 DEVELOP WAYS OF CONTROLLING YOUR PROCESS

##### 7.2.1 DEVELOP WAYS OF CONTROLLING PROCESS ELEMENTS

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

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

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

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

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

#### 7.2.2 DEVELOP WAYS OF CONTROLLING PROCESS PROVIDERS

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

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

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

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206	Do you evaluate and validate the accuracy of test data and test reports whenever they are used to confirm that externally provided products meet requirements?	Y	N	X
207	Do you evaluate and validate the accuracy of test data and test reports whenever a customer or an organization has identified raw material as a “critical item” or a significant operational risk?	Y	N	X
208	Do you develop ways of controlling internal providers?	Y	N	X
209	Do you plan how to control internal processes, products, and services?	Y	N	X
210	Do you consider the potential impact that internally provided processes, products, and services could have on your ability to consistently meet internal requirements?	Y	N	X
211	Do you consider the potential impact on your ability to meet customer requirements?	Y	N	X
212	Do you consider the potential impact on statutory and regulatory requirements?	Y	N	X
213	Do you consider the controls that internal process, product, and service providers have implemented and think about how effective their controls actually are?	Y	N	X
214	Do you create controls for internal processes, products, and services?	Y	N	X
215	Do you design internal process, product, and service verification methods?	Y	N	X
216	Do you plan your internal process, product, and service verification activities?	Y	N	X
217	Do you define the scope and extent of internal verification and testing activities?	Y	N	X
218	Do you consider risks when you carry out internal verification and testing activities?	Y	N	X
219	Do you use objective evidence to verify internal processes, products, and services?	Y	N	X
220	Do you develop a process to evaluate the accuracy of test data and test reports?	Y	N	X

**7.3 PROVIDE RESOURCES NEEDED TO CONTROL PROCESS**

221	Do you provide the people that are needed in order to control your process?	Y	N	X
222	Do you provide the training that is needed in order to control your process?	Y	N	X
223	Do you provide the policies that are needed in order to control your process?	Y	N	X

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

#### 7.4 USE AUTHORIZED METHODS TO CONTROL PROCESS

##### 7.4.1 USE AUTHORIZED METHODS TO CONTROL PROCESS INPUTS

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

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243	Do you release inputs only if verifications are finished or if authorized to do so?	Y	N	X	
244	Do you verify that your input acceptance criteria are being met?	Y	N	X	
245	Do you verify acceptance before inputs are officially released?	Y	N	X	
246	Do you establish a record of your input acceptance activities?	Y	N	X	
247	Do you document your criteria for input acceptance and rejection?	Y	N	X	
248	Do you document where in the sequence input verification is performed?	Y	N	X	
249	Do you document and retain your input monitoring and measuring results?	Y	N	X	
250	Do you maintain a record of input acceptance and rejection activities?	Y	N	X	
251	Do you document how input monitoring and measuring must be carried out?	Y	N	X	
252	Do you document all required input monitoring and measuring instructions?	Y	N	X	
253	Do you document all required input monitoring and measuring equipment?	Y	N	X	
254	Do you verify that critical input items are being controlled?	Y	N	X	
255	Do you control critical input items in accordance with established methods?	Y	N	X	
256	Do you verify that key input characteristics are being controlled?	Y	N	X	
257	Do you control key input characteristics in accordance with established methods?	Y	N	X	
258	Do you verify that inputs being used in the process are being controlled?	Y	N	X	
259	Have you identified and recorded purchased products (inputs) that are released for use in your process whenever verification activities have not yet been completed?	Y	N	X	
260	Do you use your records to recall and replace purchased products (inputs) that have been used but do not actually meet requirements?	Y	N	X	
261	Do you verify that all input inspection and verification activities have been completed?	Y	N	X	
262	Do you maintain a record of input inspection and verification activities and results?	Y	N	X	
263	Do you use records to show that input inspections and verifications were completed?	Y	N	X	

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## PROCESS BEING AUDITED:

### 7. PROCESS CONTROL QUESTIONS

#### 7.4.2 USE AUTHORIZED METHODS TO CONTROL PROCESS OUTPUTS

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

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**7. PROCESS CONTROL QUESTIONS**

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

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**PROCESS BEING AUDITED:**

**7. PROCESS CONTROL QUESTIONS**

306	Do you verify that input items, characteristics, and activities are being controlled?	Y	N	X	
307	Do you verify that “critical items” and “key characteristics” are being controlled?	Y	N	X	
308	Do you control identified “critical items” in accordance with established methods?	Y	N	X	
309	Do you control “key characteristics” in accordance with established methods?	Y	N	X	
310	Do you verify that inputs being used in the process are being controlled?	Y	N	X	
311	Have you identified and do you record purchased products (inputs) that are released for use in your process whenever verification activities have not yet been completed?	Y	N	X	
312	Do you use your records to recall and replace purchased products (inputs) that have been used but do not actually meet requirements?	Y	N	X	
313	Do you verify that all inspection and verification activities have been completed?	Y	N	X	
314	Do you maintain a record of your inspection and verification activities and results?	Y	N	X	
315	Do you use records to show that inspections and verifications were completed?	Y	N	X	
316	Do you control how outputs are officially released?	Y	N	X	
317	Do you verify acceptance before outputs are officially released?	Y	N	X	
318	Do you implement arrangements to verify your process outputs?	Y	N	X	
319	Do you verify that output requirements were met at all appropriate stages?	Y	N	X	
320	Do you retain evidence that shows that output acceptance criteria were met?	Y	N	X	
321	Do you retain evidence that shows that your output meets defined requirements?	Y	N	X	
322	Do you identify people who may authorize release of outputs to process customers?	Y	N	X	
323	Do you retain and control records to facilitate the traceability of output releases?	Y	N	X	
324	Do you release outputs only if verifications are finished or if authorized to do so?	Y	N	X	
325	Do you release output to process customers only if planned arrangements were completed or the customer or a relevant authority allows you to do so?	Y	N	X	

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**7. PROCESS CONTROL QUESTIONS**

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

**7.4.3 USE AUTHORIZED METHODS TO CONTROL PROCESS ACTIVITIES**

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

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**7. PROCESS CONTROL QUESTIONS**

346	Do you use authorized methods to control process evaluation activities?	Y	N	X	
347	Do you use authorized methods to control process audit activities?	Y	N	X	
348	Do you use authorized methods to control process review activities?	Y	N	X	
349	Do you use authorized methods to control process modification activities?	Y	N	X	
350	Do you use authorized methods to control process correction activities?	Y	N	X	
351	Do you use authorized methods to control process improvement activities?	Y	N	X	
352	Do you use authorized methods to control "special process" activities?	Y	N	X	
353	Do you establish methods for managing "special process" activities?	Y	N	X	
354	Do you validate "special process" activities and results?	Y	N	X	
355	Do you validate your ability to achieve planned results whenever outputs cannot be verified by subsequent monitoring or measurement?	Y	N	X	
356	Have you identified in-process inspection and verification points whenever adequate verification of conformity cannot be performed at subsequent stages?	Y	N	X	
357	Do you control "special process" activities and results?	Y	N	X	
358	Do you make arrangements to control special process activities?	Y	N	X	
359	Do you use criteria to control your special process activities?	Y	N	X	
360	Do you use criteria to control how special activities are reviewed?	Y	N	X	
361	Do you use criteria to control how special activities are approved?	Y	N	X	
	Etcetera ...	Y	N	X	
<p>Now that you've seen a sample of our approach, please consider purchasing our complete Plain English Process Audit Tool (Title 8). If you purchase our audit tool, you'll find that it's integrated, detailed, exhaustive, easy to understand, and simple to use. We guarantee it.</p> <p>Title 8 comes in both MS Word and pdf file formats.</p>					

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