KONSILO

ISO 9001 Myths

We didn't invent them, we just collected them from a specific LinkedIn discussion. Have fun reading, discussing, quoting …

Just so you know: the myths date back from the 2008 version, but I like to think most of them are just as alive and kicking now with the 2015 version.

Source: https://www.linkedin.com/groupItem?type=member&gid=1268337&view=&report%2Esuccess=8ULbKyXO6NDvmoK7o030UNOYGZKrvdhBhypZ_w8EpQrrQI-BBjkmxwkEOwBjLE28YyDIxcyEO7_TA_giuRN&commentID=5807407237475377152&item=5799524455378075651#commentID_5807407237475377152

1. ISO 9001 requires document numbers.
2. ISO 9001 requires a training matrix.
3. Internal auditors cannot audit their own departments.
4. Internal auditors must be trained through some outside provider.
5. Welding is always a special process.
6. Corrective action and preventive action must be separate activities.
7. Root cause must include 5 Why analysis.
8. Consultants cannot attend 3rd party conformity audits.
9. Emails are not a sufficient form of record.
10. Management review must be a physical meeting.
11. Preventive maintenance of equipment is required.
12. All measurement devices, including process equipment, must be calibrated.
13. Post delivery support includes warranty repairs.
14. Post delivery support does NOT include warranty repairs.
15. Customer satisfaction surveys are required.
16. An approved vendor list is required.
17. Management reviews must be annual, at least.
18. Internal audits must be annual, at least.
19. Nonconforming product must be physically segregated, in a locked cage.
20. Authors cannot review and approve their own documents.
21. All timepieces that 'could' be used for manufacturing processes must be calibrated, including clocks in smartphones, manually-wound and battery-operated wristwatches, computers (desktops and laptops), electric wall clocks, battery-operated wall clocks, and any hand-wound egg timers in the cafeteria. All procedures must be documented. All documents must be managed with a cross-reference table. Quality manuals must replicate the prevailing QMS standard. Quality manuals cannot be one or two pages. Quality manuals cannot have a business or operations section. Quality manuals must have "Quality Manual" printed on the cover page. Quality manuals can only be created by the Quality Department.
22. Only six written procedures are required.

23. Anything at all you use to measure anything -no matter how rough the result required - must be calibrated, this includes ordinary desk 1 foot rulers and yes, the egg timers.
24. Management review is a single meeting once a year, at which you must cover all the topics listed under that clause, in the same order.
25. A procedure for nonconformance must be a separate procedure from the one for corrective action and the one for preventive action. And each of them must be correctly named, viz, 'Nonconformance Procedure', 'Corrective Action Procedure' etc.
26. While we're on the topic, you must use a form called a CAR. And you must keep a log of all your CARs, which of course must be individually numbed.
27. You must have someone with the title of Quality Manager. And someone with the title of Management Representative. But one person can do both these roles.
28. You must have an Approved Supplier List, even if you don't buy in any products or services that matter, and your purchasing is limited to office stationery.
29. You must have hand-written signatures to approve documents before they are official.
30. All quality documents must be as ugly as possible, with more multi-level numbering than you can shake a stick at.
31. The passive tense is to be used throughout, in order to be as remote and difficult to comprehend as possible.
32. The more shalls you can include, the better.
33. Avoid short, clear documents in favour of verbose incomprehensibility.
34. You must liberally plaster the phrases Quality Document and Controlled Document liberally throughout your documentation. If it doesn't have these, it isn't a quality document.
35. Internal auditors must attend an auditing course. They cannot be competent if they haven't.
36. Every part of the system must be audited at least once a year. This includes internal audit and management review, even in a small company where the owner does the audits and the reviews.
37. All company documents, procedures, work instructions, etc must be written in 10-point Courier (typewriter) font.
38. All normally-used verbs must be expunged and shall be replaced with only three: facilitate, utilise, implement.
39. "Shall" shall be utilized as often as necessay. "Must" shall also be utilized as it facilitates implementation and compliance.
40. Internal auditors shall only become qualified and certified though attending a short company auditor training class. This facilitates alignment to the QMS.
41. Controlled documents shall be and must be electronic to facilitate compliance to QMS.
42. Uncontrolled documents shall display the warning "If Printed, this is uncontrolled."
43. The conditional verb tense shall be used to facilitate implementation of the content of this controlled procedure.
44. All signatures for document approval must utilize red ink.
45. All internal audits shall utilize the process approach.
46. Forms are required to make valid a record
47. Forms must be controlled
48. The only way to approve a document is signing it

49. For documents, records, forms, ext. documents there must exist a master list
50. Quality representative is the guy who receive the 3rd party audits
51. Just Quality people could be Quality representative.
52. The minute of MR shall list all the inputs (5.6.2) and outputs (5.6.3) required in the standard.
53. Work environment is related to occupational safety, labor relations and health topics.
54. Traceability is always needed to ensure production's control
55. FIFO system is needed in any warehouse
56. As big the number of internal audit's findings, as effective the audit process
57. Quality department must fill and follow all the corrective actions
58. Continuous improvement shall be demonstrated recorded in a form
59. All forms and checklists, regardless of purpose, must be rev controlled.
60. The simpler the form, the more often it must be revised to improve complexity.
61. Attempting "intent to comply" with the standard shall be equivalent to "does comply."
62. The ISO auditor shall provide OFI to reduce the numer of future findings in the next sureveillance audit.
63. The ISO auditor shall advise/inform the Mgmt Representative on process/product improvements.
64. Nonconforming material shall be scrapped in a manner approved by the surveillance auditor.
65. Internal audits shall be conducted as quickly as possible while attempting to show intent to comply with Clause 8.2. *(version 2008, that would be §9.2 under version 2015)*
66. Internal audits that are consistently conducted the day before the sureveillance audit begins shall demonstrate an effective QMS.
67. All processes shall have a documented process flow.
68. All processes, especially non-production processes such as operating the copier, coffee machine or telephone, shall have documented, rev-controlled work aids.
69. The job comptency training matrix shall be managed and controlled by the MR, who also works as the QM, purchasing manager, and onsite EHS focal.
70. Training records of all employees must demonstrate competency with using the master document control matrix.
71. When calibrating equipment such as an egg timer and/or wooden 12" ruler, calibration accuracy shall extend to the finest level to the right of the decimal point.
72. All incoming materials, including staples, copying paper, and Scotch tape, must have a sample inspection performed to establish comformity of product to purchasing requirements.
73. Leadership is exempt from demonstrating competency.
74. CA must be closed in less than 30 days
75. number of PA < number of CA means that the QMS is in maturing stage
76. All calibrations must be done by an ISO IEC 17025 accredited lab
77. Is required to classify the suppliers in direct and indirect sources
78. All the operations in the floorshop requires a work instruction
79. The pyramidal documentation model (you know: policy - quality manual - proced....blah, blah, blah) is the only one approved by ISO to design a QMS
80. Only effective companies implement ISO 9001.
81. Being ISO means you cannot make bad product.

82. Being ISO means you cannot ship bad product.
83. Only unscrupulous companies refuse to be ISO.
84. Being ISO means there is only one way to manufacture product.
85. Use-as-is allows nonconforming product to be shipped.
86. Use-as-is allows nonconforming inventory to be used.
87. All eqmt shall display PM (preventive maintenance) stickers.
88. All documents of external origin, including those from the public domain, must be placed under rev-control and access control.
89. All documents of external origin, accessed by the internet, must be placed under rev-control and access control.
90. All documents of external origin must be duplicated into procedures, using only single spaced Courier 10-point font.
91. ISO won't let us do that.
92. 3rd party auditors are always right
93. The customer is always right
94. The customer auditors are always right (they still being the customer, so how can they go wrong?)
95. When all is ok, everybody done their job. If something go wrong, quality people has fail again!!
96. We have some procedures and then we have some ISO procedures.
97. Internal auditors role is to catch the auditee out.
98. CAR must be resolved in XX days
99. Quality Policy hand signed by our MD - 'cos ISO sez so'
100. Management review must be held exactly in the same sequence as the input agenda in clause 5.6 *(of the 2008 version that would be 9.3 in the 2015 version)*
101. Records are the only objective evidence to demonstrate everything
102. Inspection records must be hand-written, because electronic forms aren't valid.
103. Job descriptions are required to evaluate people's competence
104. The single form to document a CAR (8D's, 5W's, etc) is not enough evidence of your actions, so you must attach all the evidence possible, even the latest e-mail answering at your partner that the related issue was solved right
105. Something named "standarized" must be written in a procedure
106. You have to fill out these 3 forms, ISO says so
107. You have to use the clause number when numbering your documents
108. We can't change the way we work, we're ISO now"
109. Root cause analysis must be done through 5 Why analysis. Apparently, if you ask "Why?" a sixth time, the earth opens up and swallows you.
110. The external auditor is God. They know Everything. Their word is Law. And is never to be questioned.
111. The consultant is God. They know Everything. Their word is Law. And is never to be questioned.
112. The quality manager is god. He (not she) knows everything. His word is law. He is never to be questioned.
113. "Let's map our processes...
    Process n° 1 = technical dept

Process n° 2 = HR dept
Process n° 3 = sales
..."

114. "All quality documents must be as ugly as possible, with more multi-level numbering than you can shake a stick at." ... and the actual sheet surface used for the procedure or information cannnot be more than 40%
115. Any blank to fill handwritten information in a form must be short and small enough to ensure the actual writing overflows and overlaps any marked boundary
116. The Quality Policy must be known word by word by all janitors and displayed everywhere
117. Non Conformance Reports are to be used as punishment and understood as such
118. White-out shall not be used to correct/change a test or inspection record.
119. Pen and ink changes to controlled documents are not permitted.
120. The customer contract or order must be initialed to evidence review.
121. The purchase order must be initialed/signed to evidence review.
122. Internal auditing is a stand-alone activity, independent of all other monitoring and measuring activities.
123. Documents, e.g. procedures, work instructions, must be reviewed for continuing suitability on an annual/biannual/triannual basis.
124. Supervision and verbal direction is not acceptable as a sole means of process control.
125. A records matrix/list is required.
126. Uncalibrated inspection, measuring and test equipment must be physically identified as such.
127. Preventive maintenance is required.
128. Recording data with pencil is not permitted.
129. Calibration reports, incoming inspection reports, internal audit reports (records) must be signed as 'reviewed' and 'approved'.
130. The employee's profiles must contain one record per each item determined as competence.
131. No matter if the competence is 'leadership' (attributes), we have to demonstrate to the auditor that this people were trained in 'leadership' showing a certificate or something like that.
132. Turtle diagram is required to prove that the QMS's processes were designed properly.
133. The lowest level work instructions must replicate the job description to ensure proper alignment between training, competence, and process.
134. Work instructions must be as technical as possible to ensure that the auditor can determine if they are necessary for an efective QMS.
135. All records must be under revision control.
136. Only blue or black ink is allowed by ISO for reviewing and approving documents and records.
137. "we have HR files for 'ISO purposes' and HR files for 'corporate office purposes'.

Source:
https://www.linkedin.com/groupItem?type=member&gid=1268337&view=&report%2Esuccess=8ULbKyXO6NDvmoK7o030UNOYGZKrvdhBhypZ_w8EpQrrQI-BBjkmxwkEOwBjLE28YyDIxcyEO7_TA_giuRN&commentID=5807407237475377152&item=5799524455378075651#commentID_5807407237475377152

(collected in september 2014)