**Frequency of the object families that are mentioned in ISO 9001:2015 DIS**

Green = First 50% of requirements

Blue = Next 25% of requirements

**Table 1** Frequency of object families

| **Object family** | **Number of requirements (2)** | **Number of requirements cumulative (3)** | **Percentage (4) = (3) / 337** |
| --- | --- | --- | --- |
| Documented information | **33** | 33 | 10% |
| Quality management system | **29** | 62 | 18% |
| Products and services | **28** | 90 | 27% |
| Process | **26** | 116 | 34% |
| Requirements | **18** | 134 | 40% |
| Design and development | **16** | 150 | 45% |
| Monitoring and measurement | **15** | 165 | **49%** |
| Customer | **13** | 178 | 53% |
| Quality objectives | **12** | 190 | 56% |
| Resources | **12** | 202 | 60% |
| Quality policy | **11** | 213 | 63% |
| External provider | 9 | 222 | 66% |
| Risk and opportunities | 9 | 231 | 69% |
| Nonconformities | 8 | 239 | 71% |
| Audits | 7 | 246 | 73% |
| Personnel/persons | 7 | 253 | **75%** |
| Improvement | 6 | 259 | 77% |
| Issue | 6 | 265 | 79% |
| Actions | 5 | 270 | 80% |
| Management review | 5 | 275 | 82% |
| Organization | 5 | 280 | 83% |
| Changes | 4 | 284 | 84% |
| External provided processes | 4 | 288 | 85% |
| Interested parties | 4 | 292 | 87% |
| Responsibilities and authorities | 4 | 296 | 88% |
| Analysis and evaluation | 3 | 299 | 89% |
| Corrective actions | 3 | 302 | 90% |
| Production and service provision | 3 | 305 | 91% |
| Property | 3 | 308 | 91% |
| Scope | 3 | 311 | 92% |
| Top management | 3 | 314 | 93% |
| Communication | 2 | 316 | 94% |
| Contracts | 2 | 318 | 94% |
| Infrastructure | 2 | 320 | 95% |
| Knowledge | 2 | 322 | 96% |
| Planning | 2 | 324 | 96% |
| Quality performance | 2 | 326 | 97% |
| Criteria for acceptance | 1 | 327 | 97% |
| Data and information | 1 | 328 | 97% |
| Education | 1 | 329 | 98% |
| Effects | 1 | 330 | 98% |
| Enquiries | 1 | 331 | 98% |
| Failure | 1 | 332 | 99% |
| Reporting | 1 | 333 | 99% |
| Results | 1 | 334 | 99% |
| Standards | 1 | 335 | 99% |
| Tools and methodologies | 1 | 336 | 100% |
| Validation | 1 | 337 | 100% |
|  | 337 |  |  |

**Object-oriented view on ISO 9001:2015 DIS, chapter 4-10.**

In table 2, chapter 4-10 of ISO 9001:2015 DIS is analysed. The OQRM has been applied to this standard by distinguishing the objects to which the requirements are related. Purpose of this analysis is to get another view on the standard.

Column 1: **Nr.** Sequence number in ISO 9001

Column 2: **Object family or Object**

Column 3: **Characteristic** of the object.

Column 4: **State.** Required state of the object.

Column 5: **Reference**  to a section of ISO 9001:2015 DIS

**Table 2** Families of objects

| **Nr** | **Object family/Object** | **Characteristic** | **State** | **Ref.** |
| --- | --- | --- | --- | --- |
|  | **Actions** |  |  |  |
| 328 | Actions needed |  | Implemented | 10.2.1.c |
| 129 | Actions to acquire competence |  | Taken | 7.2.c |
| 149 | Actions to address risks and opportunities | Completeness | Implemented | 8.1.a-e |
| 130 | Actions to evaluate | Effectiveness | Taken | 7.2.c |
| 158 | Actions to mitigate adverse effects |  | Taken | 8.1 |
|  | **Analysis and evaluation** |  |  |  |
| 333 | Analysis and evaluation, outputs of |  | Considered | 10.3 |
| 277 | Analysis and evaluation, output of | Completeness | Used | 9.1.3.a-g |
| 285 | Analysis and evaluation, results of |  | Used | 9.1.3 |
|  | **Audits** |  |  |  |
| 290 | Audit criteria and scope |  | Defined | 9.2.2.b |
| 292 | Audit process | Objectivity | Ensured | 9.2.2.c |
| 289 | Audit programme |  | Planned  Established  Implemented  Maintained | 9.2.2.a |
| 303 | Audit result |  | Considered | 9.3.1.c3 |
| 293 | Audit results |  | Reported | 9.2.2.d |
| 291 | Auditors and conducts audits |  | Selected | 9.2.2.c |
| 286 | Audits, internal | Completeness | Conducted | 9.1.3.a-b |
|  | **Changes** |  |  |  |
| 252 | Changed, unplanned |  | Reviewed  Controlled | 8.5.6 |
| 209 | Changes to the design inputs, process or outputs |  | Reviewed  Controlled  Identified | 8.3.6 |
| 157 | Changes, consequences of unintended changes |  | Reviewed | 8.1 |
| 156 | Changes, planned |  | Controlled | 8.1 |
|  | **Communication** |  |  |  |
| 136 | Communication, internal and external | Completeness | Determined | 7.4.1-d |
| 310 | Continual improvement, opportunities for |  | Considered | 9.3.1.e |
|  | **Contracts** |  |  |  |
| 172 | Contracts or order requirements |  | Reviewed | 8..2.3.d |
| 174 | Contracts or order requirements |  | Resolved | 8.2.3 |
|  | **Corrective actions** |  |  |  |
| 294 | Corrections and corrective actions | Necessity | Taken | 9.2.2.e |
| 260 | Corrective actions | Appropriateness | Taken | 8.7 |
| 329 | Corrective actions | Effectiveness | Reviewed | 10.2.1.d |
|  | **Criteria** |  |  |  |
| 206 | Criteria, acceptance |  | Included  Referenced | 8.3.5.c |
|  | **Customer** |  |  |  |
| 279 | Customer | Satisfaction | Enhanced | 9.1.3.b |
| 304 | Customer | Satisfaction | Considered | 9.3.1.c4 |
| 250 | Customer feedback |  | Considered | 8.5.5.c |
| 76 | Customer focus |  | Promoted | 5.3.d |
| 273 | Customer perception |  | Monitored | 9.1.2 |
| 164 | Customer property, handling or treatment |  |  | 8.2.1.d |
| 53 | Customer satisfaction | Ability to enhance |  | 5.1.2.b |
| 317 | Customer satisfaction, actions to enhance | Completeness | Implemented | 10.1.a-c |
| 95 | Customer satisfaction, enhancement of |  |  | 6.2.1.d |
| 56 | Customer satisfaction, focus on enhancing |  | Maintained | 5.1.2.d |
| 163 | Customer views and perceptions |  | Obtained | 8.2.1.c |
| 274 | Customer views/opinion of the organization and the products and services, information relating to |  | Obtained | 9.1.2 |
| 275 | Customer views/opinion of the organization and the products and services, methods for obtaining information relating to | Use | Determined | 9.1.2 |
|  | **Data and information** |  |  |  |
| 276 | Data and information | Appropriateness | Analyzed  Evaluated | 9.1.3 |
|  | **Design and development** |  |  |  |
| 181 | Design and development activities | Nature  Duration  Complexity |  | 8.3.2.a |
| 196 | Design and development activities, results of the |  | Defined | 8.3.4.a |
| 195 | Design and development controls | Completeness | Applied | 8.3.4.a-d |
| 193 | Design and development inputs | Adequacy  Complete  Unambiguity |  | 8.3.3 |
| 194 | Design and development inputs, conflicts among |  | Resolved | 8.3.3 |
| 199 | Design and development outputs | Conformity with design and development input requirements |  | 8.3.4.c |
| 202 | Design and development outputs | Conformity with input requirements |  | 8.3.5.a |
| 203 | Design and development outputs | Adequacy |  | 8.3.5.b |
| 204 | Design and development outputs | Completeness |  | 8.3.5.c |
| 200 | Design and development outputs, validation of the |  | Conducted | 8.3.4.d |
| 198 | Design and development outputs, verification of the |  | Conducted | 8.3.4.c |
| 180 | Design and development planning | Completeness | Considered | 8.3.2.a-g |
| 179 | Design and development process |  | Established  Implemented  Maintained | 8.3.1 |
| 192 | Design and development process, control of the | Level | Determined | 8.3.3 |
| 197 | Design and development reviews |  | Planned  Conducted | 8.3.4.b |
| 183 | Design and development verification and validation |  |  | 8.3.2.c |
|  | **Documented information** |  |  |  |
| 30 | Documented information |  | Retained | 4.4 |
| 66 | Documented information | Completeness |  | 5.2.2.a |
| 138 | Documented information |  | Included in the QMS | 7.5.1 |
| 142 | Documented information | Suitability  Adequacy |  | 7.5.2.c |
| 143 | Documented information |  | Controlled | 7.5.3.1 |
| 144 | Documented information | Availability  Suitability for use |  | 7.5.3.1.a |
| 145 | Documented information | Adequacy of protection |  | 7.5.3.1.b |
| 154 | Documented information |  | Retained | 8.1.e |
| 177 | Documented information |  | Amended | 8.2.3 |
| 258 | Documented information |  | Provided | 8.6 |
| 130 | Documented information about competence | Appropriateness | Retained | 7.2.d |
| 99 | Documented information about quality objectives |  | Retained | 6.2.1 |
| 121 | Documented information about the monitoring and measurement resources | Appropriateness | Retained | 7.1.5 |
| 16 | Documented information about the scope | Availability | Maintained | 4.3 |
| 230 | Documented information defining activities and results | Availability | Included | 8.5.1.b |
| 229 | Documented information defining the characteristics of the products and services | Availability | Included | 8.5.1.a |
| 176 | Documented information describing the results of the review |  | Retained | 8.2.3 |
| 253 | Documented information describing the review of changes, authorizing the changes and actions |  | Retained | 8.5.6 |
| 263 | Documented information of actions taken on nonconformities |  | Retained | 8.7 |
| 147 | Documented information of external origin | Appropriateness | Identified  Controlled | 7.5.3.2 |
| 215 | Documented information of the results of the evaluations, monitoring and re-evaluation of the external providers | Appropriateness | Retained | 8.4.1 |
| 270 | Documented information regarding monitoring and measurement | Appropriateness | Retained | 9.1.1 |
| 295 | Documented information related to audits |  | Retained | 9.2.2.f |
| 331 | Documented information related to nonconformities | Completeness | Retained | 10.2.2 |
| 208 | Documented information resulting from the design and development process |  | Retained | 8.3.5 |
| 210 | Documented information resulting from the design and development process |  | Retained | 8.3.6 |
| 187 | Documented information to confirm that design and development requirements have been met. |  |  | 8.3.2.g |
| 240 | Documented information to maintain traceability |  | Retained | 8.5.2 |
| 29 | Documented information to support the operation of the process |  | Maintained | 4.4 |
| 146 | Documented information, control of | Completeness |  | 7.5.3.2.a-d |
| 140 | Documented information, format of | Appropriateness | Ensured | 7.5.2.b |
| 139 | Documented information, identification and description | Appropriateness | Ensured | 7.5.2.a |
| 141 | Documented information, review and approval | Appropriateness | Ensured | 7.5.2.c |
|  | **Education** |  |  |  |
| 128 | Education, training or experience | Appropriateness |  | 7.2.b |
|  | **Effects** |  |  |  |
| 82 | Effects, undesired |  | Prevented  Reduces | 6.1.1.b |
|  | **Enquiries** |  |  |  |
| 162 | Enquiries, contracts or order handling |  |  | 8.2.1.b |
|  | **Environment** |  |  |  |
| 114 | Environment |  | Determined  Provided  Maintained | 7.1.4 |
|  | **External provider** |  |  |  |
| 218 | External provider, controls applied by the | Effectiveness |  | 8.4.2.b |
| 223 | External provider, controls applied to the |  | Defined | 8.4.2 |
| 221 | External provider, processes or functions outsourced to an |  | Remained within the scope of the QMS | 8.4.2 |
| 214 | External providers | Ability to provide in accordance with specified requirements |  | 8.4.1 |
| 225 | External providers, requirement applicable to | Completeness | Communicated | 8.4.3.a-f |
| 226 | External providers, requirement applicable to | Adequacy | Ensured | 8.4.3 |
| 213 | External providers, criteria for evaluation, selection, monitoring and re-evaluation of |  | Established  Applied | 8.4.1 |
| 283 | External providers, performance of |  | Assessed | 9.1.3.f |
| 108 | Providers, support from |  | Considered | 7.1.1.b |
|  | **External provided processes** |  |  |  |
| 216 | External provision of processes, products and services, controls to be applied to | Completeness  Type  Extent | Determined | 8.4.2 |
| 211 | Externally provided processes, products and services | Conformity to requirements |  | 8.4.1 |
| 219 | Externally provided processes, products and services, verification of |  | Established  Implemented | 8.4.2 |
| 212 | Externally provided products and services, requirements for the control of |  | Specified  Applied | 8.4.1.a-c |
|  | **Failure** |  |  |  |
| 191 | Failure, consequences of |  | Determined | 8.3.3 |
|  | **Improvement** |  |  |  |
| 45 | Improvement | Continuality | Promoted | 5.1.1.j |
| 83 | Improvement | Continuality | Achieved | 6.1.1.c |
| 312 | Improvement opportunities, decisions and actions related to continual |  | Included into the MR | 9.3.2.a |
| 64 | Improvement, a commitment to continual |  | Included | 5.2.1.d |
| 315 | Improvement, opportunities for |  | Determined  Selected | 10.1 |
| 74 | Improvement, reporting on opportunities for |  | Ensured | 5.3.c |
|  | **Infrastructure** |  |  |  |
| 112 | Infrastructure |  | Determined  Provided  Maintained | 7.1.3 |
| 232 | Infrastructure and process environment, use and control of |  | Included | 8.5.1.d |
|  | **Interested parties** |  |  |  |
| 3 | Interested parties |  | Determined | 4.2.a |
| 5 | Interested parties and their requirements, information about |  | Monitored  Reviewed | 4.2 |
| 9 | Interested parties, requirements of |  | Considered | 4.3.b |
| 4 | Interested parties, requirements of the | Relevance to the QMS | Determined | 4.2.b |
|  | **Issues** |  |  |  |
| 78 | Issues |  | Considered | 6.1.1 |
| 305 | Issues concerning external providers and other relevant interested parties. |  | Considered | 9.3.1.c5 |
| 299 | Issues, changes in external |  | Considered | 9.3.1.b |
| 1 | Issues, external an internal | Relevance  Degree of Influence | Determined | 4.1 |
| 8 | Issues, external en internal |  | Considered | 4.3.a |
| 2 | Issues, information about external an internal |  | Monitored  Reviewed | 4.1 |
|  | **Knowledge** |  |  |  |
| 124 | Knowledge | Availability | Determined  Maintained | 7.1.6 |
| 125 | Knowledge, acquirement of additional |  | Determined | 7.1.6 |
|  | **Management review** |  |  |  |
| 297 | Management review | Completeness | Planned  Carried out | 9.3.1.a-e |
| 311 | Management reviews outputs | Completeness |  | 9.3.2.a-b |
| 334 | Management reviews, output of |  | Considered | 10.3 |
| 298 | Management reviews, status of actions from previous |  | Considered | 9.3.1.a |
| 46 | Management roles, other |  | Supported | 5.1.1.k |
|  | **Monitoring and measurement** |  |  |  |
| 123 | Measurement results | Validity |  | 7.1.5 |
| 122 | Measuring instruments |  | Verified  Calibrated  Identified  Safeguarded | 7.1.5 |
| 264 | Monitored and measured, objects to be |  | Determined | 9.1.1.a |
| 269 | Monitoring and measurement activities | Accordance with requirements | Implemented | 9.1.1.e |
| 118 | Monitoring and measurement result | Validity  Reliability | Ensured | 7.1.5 |
| 267 | Monitoring and measurement, period |  | Determined  Performed | 9.1.1.c |
| 231 | Monitoring and measuring activities |  | Included | 8.5.1.c |
| 205 | Monitoring and measuring equipment |  | Included Referenced | 8.3.5.c |
| 233 | Monitoring and measuring resources | Availability  Use | Included | 8.5.1.e |
| 302 | Monitoring and measuring results |  | Considered | 9.3.1.c2 |
| 265 | Monitoring, measurement, analysis and evaluation, methods for |  | Determined | 9.1.1.b |
| 266 | Monitoring, measurement, analysis and evaluation, results from | Validity |  | 9.1.1.b |
| 268 | Monitoring, measurement, date of the results from |  | Determined | 9.1.1.d |
| 186 | Need for involvement of customer and user groups |  |  | 8.3.2.f |
| 185 | Need to control interfaces between individuals and parties |  |  | 8.3.2.e |
|  | **Nonconformities** |  |  |  |
| 301 | Nonconformities and corrective actions |  | Considered | 9.3.1.c1 |
| 322 | Nonconformities, actions to control and correct |  | Taken | 10.2.1.a1 |
| 323 | Nonconformities, consequences |  | Dealt with | 10.2.1.a2 |
| 321 | Nonconformities, reactions to | Completeness |  | 10.2.1 |
| 327 | Nonconformities, similar exiting |  | Determined | 10.2.1.b3 |
| 325 | Nonconformity |  | Reviewed | 10.2.1.b1 |
| 324 | Nonconformity, actions to eliminate the causes of the |  |  | 10.2.1.b |
| 326 | Nonconformity, causes of |  | Determined | 10.2.1.b2 |
|  | **Organization** |  |  |  |
| 41 | Organization | Conformance to the QMS requirements | Communicated | 5.1.1.g |
| 168 | Organization | Ability to meet the defined requirements  Ability to substantiate the claims for the products and services offer |  | 8.2.2.b |
| 217 | Organization | Ability to meet requirements |  | 8.4.2.a |
| 220 | Organization | Ability to deliver conforming products and services |  | 8.4.2 |
| 62 | Organization, commitment to requirements |  | Included | 5.2.1.c |
|  | **Personnel/persons** |  |  |  |
| 178 | Personnel | Awareness of changed requirements |  | 8.2.3 |
| 43 | Persons | Contribution to the QMS | Engaged  Directed  Supported | 5.1.1.i |
| 109 | Persons |  | Provided | 7.1.2 |
| 126 | Persons | Competence | Determined | 7.2.a |
| 127 | Persons | Competence | Ensured | 7.2.b |
| 131 | Persons | Awareness |  | 7.3.a-d |
| 234 | Persons | Competence  Qualification | Included | 8.5.1.f |
|  | **Planning** |  |  |  |
| 281 | Planning |  | Implemented | 9.1.3.d |
| 155 | Planning and control, output of operational | Suitability |  | 8.1 |
|  | **Process** |  |  |  |
| 38 | Process approach | Awareness | Promoted | 5.1.1.e |
| 245 | Process output | Conformity to requirements | Maintained | 8.5.4 |
| 224 | Process output of external providers, controls applied to the |  | Defined | 8.4.2 |
| 259 | Process output, products and services, nonconforming |  | Identified  Controlled | 8.7 |
| 261 | Process output, products and services, nonconforming |  | Dealt with | 8.7.a-d |
| 238 | Process output, status of |  | Identified | 8.5.2 |
| 244 | Process outputs |  | Preserved | 8.5.4 |
| 239 | Process outputs, identification of | Uniqueness | Controlled | 8.5.2 |
| 237 | Process outputs, means to identify |  | Used | 8.5.2 |
| 307 | Process performance |  | Considered | 9.3.1.c7 |
| 72 | Processes |  | Delivering intended output | 5.3.b |
| 160 | Processes for communicating with customers | Completeness | Established | 8.2.1.a-d |
| 148 | Processes for operational planning and control |  | Planned  Implemented  Controlled | 8.1 |
| 18 | Processes needed for the QMS |  | Determined | 4.4 |
| 166 | Processes to determine the requirements for products and services |  | Established  Implemented  Maintained | 8.2.2. |
| 153 | Processes, control of |  | Implemented | 8.1.d |
| 21 | Processes, criteria and method to operate and control |  | Determined | 4.4.c |
| 151 | Processes, criteria for the and for acceptance of the |  | Established | 8.1.b |
| 318 | Processes, improving |  | Included | 10.1.a |
| 19 | Processes, inputs and outputs |  | Determined | 4.4.a |
| 26 | Processes, methods for monitoring, measuring and evaluation of and changes of |  | Determined | 4.4.g |
| 27 | Processes, opportunities for improvement of the |  | Determined | 4.4.h |
| 159 | Processes, outsources | Accordance with 8.4 | Controlled | 8.1 |
| 282 | Processes, performance of |  | Assessed | 9.1.3.e |
| 24 | Processes, responsibilities and authorities |  | Determined  Assigned | 4.4.e |
| 20 | Processes, sequence and interaction |  | Determined | 4.4.b |
|  | **Production and services provision** |  |  |  |
| 227 | Production and services provision, controlled conditions for |  | Implemented | 8.5.1 |
| 228 | Production and services provision, controlled conditions for | Completeness |  | 8.5.1.a-h |
|  | **Products and services** |  |  |  |
| 10 | Product and services |  | Considered | 4.3.c |
| 55 | Product and services, providing | Conformity with requirements  Consistence |  | 5.1.2.c |
| 13 | Products and services | Conformity | Ensured | 4.3 |
| 15 | Products and services |  | Documented | 4.3.a |
| 51 | Products and services | Conformity |  | 5.1.2.b |
| 88 | Products and services | Conformity |  | 6.1.2 |
| 94 | Products and services | Conformity |  | 6.2.1.d |
| 113 | Products and services | Conformity |  | 7.1.3 |
| 115 | Products and services | Conformity |  | 7.1.4 |
| 117 | Products and services | Conformity |  | 7.1.5 |
| 201 | Products and services | Capability of meeting the requirements |  | 8.3.4.d |
| 207 | Products and services | Fit for purpose  Safety  Proper use |  | 8.3.5.d |
| 249 | Products and services | Nature  Use  Lifetime | Considered | 8.5.5.b |
| 262 | Products and services | Conformity to requirements | Verified | 8.7 |
| 278 | Products and services | Conformity |  | 9.1.3.a |
| 308 | Products and services | Conformity | Considered | 9.3.1.c7 |
| 236 | Products and services release, delivery and post-delivery activities |  | Included  Implemented | 8.5.1.h |
| 254 | Products and services requirements, planned arrangements to verify |  | Implemented | 8.6 |
| 255 | Products and services, evidence of conformity with the acceptance criteria of the |  | Retained | 8.6 |
| 54 | Products and services, focus on providing |  | Maintained | 5.1.2.c |
| 319 | Products and services, improving |  | Included | 10.1.b |
| 161 | Products and services, information relating to |  |  | 8.2.1.a |
| 246 | Products and services, post-delivery activities associated with | Conformity to requirements |  | 8.5.5 |
| 247 | Products and services, post-delivery activities associated with | Completeness |  | 8.5.5 |
| 256 | Products and services, release of the | Timeliness |  | 8.6 |
| 150 | Products and services, requirements |  | Determined | 8.1.a |
| 248 | Products and services, risks associated with |  | Considered | 8.5.5.a |
| 257 | Products and services, verification of the |  | Completed | 8.6 |
|  | **Property** |  |  |  |
| 242 | Property belonging to customers or external providers |  | Identified  Verified  Protected  Safeguarded | 8.5.3 |
| 241 | Property belonging to customers or external providers, care with |  | Exercised | 8.5.3 |
| 243 | Property belonging to customers or external providers, incorrectly used, damaged or otherwise unsuitable for use |  | Reported | 8.5.3 |
|  | **QMS** |  |  |  |
| 40 | QM | Effectiveness | Communicated | 5.1.1.g |
| 17 | QMS | Accordance with the ISO standard | Established  Implemented  Maintained  Improved | 4.4 |
| 33 | QMS | Effectiveness |  | 5.1.1.a |
| 44 | QMS | Effectiveness |  | 5.1.1.i |
| 71 | QMS | Conformity to the ISO standard |  | 5.3.a |
| 77 | QMS | Integrity | Maintained | 5.3.e |
| 103 | QMS | Integrity | Considered | 6.3.b |
| 134 | QMS | Contribution to the effectiveness |  | 7.3.c |
| 137 | QMS | Completeness |  | 7.5.1 |
| 222 | QMS | Scope |  | 8.4.2 |
| 272 | QMS | Effectiveness | Evaluated | 9.1.1 |
| 280 | QMS | Conformity  Effectiveness |  | 9.1.3.c |
| 287 | QMS | Conformity to organization’s and ISO requirements |  | 9.1.3.a |
| 288 | QMS | Effectiveness | Implemented  Maintained | 9.1.3.b |
| 296 | QMS | Suitability  Adequacy  Effectiveness | Reviewed | 9.3.1 |
| 332 | QMS | Suitability  Adequacy  Effectiveness | Improved | 10.3 |
| 110 | QMS operation | Effectiveness |  | 7.1.2 |
| 37 | QMS requirements |  | Integrated into the processes | 5.1.1.d |
| 135 | QMS requirements, implication of not conforming with the | Awareness |  | 7.3.d |
| 320 | QMS results, improving |  | Included | 10.1.c |
| 42 | QMS results, intended |  | Achieved | 5.1.1.h |
| 101 | QMS, change of the | Systematic | Planned | 6.3 |
| 330 | QMS, changes to |  | Made | 10.2.1.e |
| 313 | QMS, decisions and actions related to need for changes to the |  | Included into the MR | 9.3.2.b |
| 314 | QMS, decisions and actions related to need for resources for the |  | Included into the MR | 9.3.2.b |
| 284 | QMS, need or opportunities for improvement within |  | Determined | 9.1.3.g |
| 28 | QMS, opportunities for improvement of the |  | Determined | 4.4.h |
| 102 | QMS, purpose and any of its potential consequences of the change of |  | Considered | 6.3.a |
| 73 | QMS, reporting on the performance of |  | Ensured | 5.3.c |
|  | **Quality objectives** |  |  |  |
| 93 | Quality objective | Relevance |  | 6.2.1.d |
| 35 | Quality objectives | Compatibility with strategic direction and the context of the organization | Established | 5.1.1.b |
| 89 | Quality objectives |  | Established | 6.2.1 |
| 90 | Quality objectives | Consistency with the quality policy |  | 6.2.1.a |
| 91 | Quality objectives | Measurability |  | 6.2.1.b |
| 92 | Quality objectives |  | Taken into account | 6.2.1.c |
| 96 | Quality objectives |  | Monitored | 6.2.1.e |
| 97 | Quality objectives |  | Communicated | 6.2.1.f |
| 98 | Quality objectives |  | Updated | 6.2.1.g |
| 133 | Quality objectives | Awareness  Relevance |  | 7.3.b |
| 60 | Quality objectives, framework for |  |  | 5.2.1.b |
| 100 | Quality objectives, planning of achievement of | Completeness | Determined | 6.2.2.a-e |
|  | **Quality performance** |  |  |  |
| 271 | Quality performance |  | Evaluated | 9.1.1 |
| 300 | Quality performance, information on the |  | Considered | 9.3.1.c |
|  | **Quality policy** |  |  |  |
| 34 | Quality policy | Compatibility with strategic direction and the context of the organization | Established | 5.1.1.b |
| 36 | Quality policy |  | Communicated  Understood  Applied | 5.1.1.c |
| 57 | Quality policy |  | Established  Reviewed  Maintained | 5.2.1 |
| 58 | Quality policy | Appropriateness |  | 5.2.1.a |
| 59 | Quality policy | Completeness |  | 5.2.1.b |
| 61 | Quality policy | Completeness |  | 5.2.1.c |
| 63 | Quality policy | Completeness |  | 5.2.1.d |
| 65 | Quality policy | Availability |  | 5.2.2.a |
| 67 | Quality policy |  | Communicated  Understood  Applied | 5.2.2.b |
| 68 | Quality policy | Availability to interested parties |  | 5.2.2.c |
| 132 | Quality policy | Awareness |  | 7.3.a |
|  | **Reporting** |  |  |  |
| 75 | Reporting to top management |  | Ensured | 5.3.c |
|  | **Requirements** |  |  |  |
| 11 | Requirement of the ISO standard | Applicability |  | 4.3 |
| 12 | Requirement of the ISO standard | Applicability |  | 4.3 |
| 169 | Requirement specified by the customer |  | Reviewed | 8.2.3.a |
| 48 | Requirement, customer |  | Determined  Met | 5.1.2.a |
| 173 | Requirement, review |  | Conducted | 8.2.3 |
| 79 | Requirements |  | Considered | 6.1.1 |
| 111 | Requirements |  | Met | 7.1.2 |
| 165 | Requirements for contingency actions |  |  | 8.2.1.e |
| 188 | Requirements for the specific type of products and services |  | Determined | 8.3.3 |
| 170 | Requirements not stated by the customer |  | Reviewed | 8.2.3.b |
| 182 | Requirements that specify process stages |  |  | 8.3.2.b |
| 316 | Requirements, actions to meet customer | Necessity | Implemented | 10.1.a-c |
| 175 | Requirements, customer |  | Confirmed | 8.2.3 |
| 167 | Requirements, product and services and statutory and regulatory |  | Defined | 8.2.2.a |
| 49 | Requirements, statutory and regulatory |  | Determined  Met | 5.1.2.a |
| 171 | Requirements, statutory and regulatory |  | Reviewed | 8.2.3.c |
| 189 | Requirements, statutory and regulatory |  | Determined | 8.3.3 |
| 251 | Requirements, statutory and regulatory |  | Considered | 8.5.5.d |
|  | **Resources** |  |  |  |
| 22 | Resources |  | Determined | 4.4.d |
| 23 | Resources | Availability | Ensured | 4.4.d |
| 104 | Resources | Availability | Considered | 6.3.c |
| 152 | Resources |  | Determined | 8.1.c |
| 106 | Resources for the QMS |  | Determined  Provided | 7.1.1 |
| 39 | Resources needed for the QMS | Availability | Ensured | 5.1.1.f |
| 306 | Resources required for maintaining an effective QMS, adequacy of | Adequacy | Considered | 9.3.1.c6 |
| 107 | Resources, capabilities of and constraints on |  | Considered | 7.1.1.a |
| 191 | Resources, internal and external |  | Determined | 8.3.3 |
| 116 | Resources, monitoring and measuring |  | Determined | 7.1.5 |
| 119 | Resources, monitoring and measuring | Suitability | Provided | 7.1.5.a |
| 120 | Resources, monitoring and measuring | Fitness for purpose | Maintained | 7.1.5.b |
|  | **Responsibilities and authorities** |  |  |  |
| 69 | Responsibilities and authorities |  | Assigned  Communicated  Understood | 5.3 |
| 70 | Responsibilities and authorities | Completeness | Assigned | 5.3.a-e |
| 184 | Responsibilities and authorities | Involvement in the design and development process |  | 8.3.2.d |
| 105 | Responsibilities and authorities, allocation of |  | Considered | 6.3.d |
|  | **Results** |  |  |  |
| 81 | Results, intended |  | Assured | 6.1.1.a |
|  | **Risk and opportunities** |  |  |  |
| 25 | Risk and opportunities |  | Determined | 4.4.f |
| 50 | Risk and opportunities |  | Determined  Addressed | 5.1.2.b |
| 52 | Risk and opportunities |  | Determined  Addressed | 5.1.2.b |
| 80 | Risk and opportunities | Completeness |  | 6.1.1.a-c |
| 84 | Risks and opportunities, actions to address |  | Planned | 6.1.2.a |
| 85 | Risks and opportunities, actions to address |  | Planned  Integrated  Implemented | 6.1.2.b.1 |
| 86 | Risks and opportunities, actions to address | Effectiveness | Evaluated | 6.1.2.b.2 |
| 87 | Risks and opportunities, actions to address | Proportionateness |  | 6.1.2 |
| 309 | Risks and opportunities, actions to address | Effectiveness | Considered  Taken | 9.3.1.d |
|  | **Scope** |  |  |  |
| 14 | Scope | Availability  Completeness | Maintained | 4.3 |
| 6 | Scope of the QMS |  | Established | 4.3 |
| 7 | Scope of the QMS | Completeness |  | 4.3.a-c  See 4.1 and 4.2 |
|  | **Standards** |  |  |  |
| 190 | Standards or codes of practice |  | Determined | 8.3.3 |
|  | **Tools** |  |  |  |
| 335 | Tools and methodologies for investigation of the causes of underperformance and for supporting continual improvement |  | Selected  Utilized | 103. |
|  | **Top management** |  |  |  |
| 31 | Top management | Commitment | Leadership demonstrated | 5.1.1 |
| 32 | Top management | Accountability |  | 5.1.1.a |
| 47 | Top management | Commitment with respect to customer focus | Leadership demonstrated | 5.1.2 |
|  | **Validation** |  |  |  |
| 235 | Validation and revalidation |  | Included | 8.5.1.g |

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| Nested requirement |
| Object family |

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