**Quiz “Requirements of ISO 19443 version 2018”**

**28v18 With answers**

**The quiz is available on this** [**page**](https://www.pqbweb.eu/page-iso-19443-version-2018-requirements-nuclear-safety-management-systems.php)**. Have a good exercise!**

1. A design and development process shall be established, implemented and maintained - 8.3.1 General (Design and development)
2. A documented information to control external processes shall be maintained NO
3. A member of the management shall be appointed as management representative NO
4. A register to determine the risks when selecting suppliers shall be maintained NO
5. A review of product and service requirements shall be conducted - 8.2.3 Review of requirements related to product and services
6. A risk management process shall be established NO
7. Actions to address risks and opportunities shall be planned - 6.1 Actions to address risks and opportunities
8. Changes for production or service provision shall be reviewed and controlled - 8.5.6 Control of changes
9. Changes shall be planned - 6.3 Planning of changes
10. Changes to the quality management system shall be managed to ensure nuclear safety is not compromised – 6.3 Planning of changes
11. Competence shall also address qualification of person(s) when necessary – 7.2 Competence
12. Continual improvement shall encompass nuclear safety culture – 10.3 Continual improvement
13. Control of monitoring and measuring equipment shall be determined NO
14. Controlled conditions shall take into account the graded approach outputs – 8.5.1 Control of production and service provision
15. Criteria for the evaluation, selection and monitoring of performance of external providers shall be determined and applied - 8.4 External providers
16. Customer perception of the degree to which their needs shall be monitored - 9.1.2 Customer satisfaction
17. Design and development changes shall be controlled - 8.3.6 Design and development changes
18. Design and development shall be planned - 8.3.2 Design and development planning
19. Determination and provisions of resources shall ensure that nuclear safety is not compromised – 7.1.1 General (Resources)
20. Documents of external origin shall be approved NO
21. External and internal issues shall be determined - 4.1 Context of the organization
22. Externally provided processes, products and services shall be controlled - 8.4 External providers
23. For items and activities, the organization shall grade the application of requirements – 6.1.4 Graded approach to the application of quality requirements
24. For ITNS items and activities, monitoring and measurement intended for product acceptance shall be performed by competent persons different from those who performed the work - 8.5.1 Control of production and service provision
25. Information communicated to external providers shall be adequate - 8.4.3 Information for external providers
26. Infrastructure needed to achieve product conformity shall be monitored NO
27. Interested parties shall be determined - 4.2 Interested parties
28. Internal and external communication needs shall be determined - 7.4 Communication
29. Internal audits shall be conducted at planned intervals - 9.2 Internal audit
30. Measuring equipment shall be calibrated or verified - 7.1.5 Monitoring and measuring resources
31. Monitoring and measurement data shall be analyzed and evaluated - 9.1.3 Analysis and evaluation
32. Nonconforming outputs shall be identified and controlled - 8.7 Control of non-conforming outputs
33. Nonconformities shall be controlled - 10.2 Nonconformity and corrective action
34. Nuclear safety shall receive the attention warranted by its significance – 9.3.1 General (Management review)
35. Opportunities for improvement shall be determined - 10.1 General (Improvement)
36. Organizational knowledge shall be determined - 7.1.6 Organizational knowledge
37. Outputs shall be preserved during production and service provision - 8.5.4 Preservation
38. Personnel shall be made aware - 7.3 Awareness
39. Persons involved in the realization of ITNS products or services shall be trained on the importance of their tasks, including the potential nuclear safety consequences of errors in their activities – 7.3 Awareness
40. Planned arrangements to verify that the product and service requirements have been met shall be implemented - 8.6 Release of products and services
41. Post-delivery requirements shall be met - 8.5.5 Post-delivery activities
42. Process mapping shall be established and documented NO
43. Production and service provision shall be implemented under controlled conditions - 8.5.1 Control of production and service provision
44. Property belonging to customers or external providers shall be respected - 8.5.3 Property belonging to customers or external providers
45. Quality objectives shall be established - 6.2 Quality objectives
46. Requirements for products and services shall be defined - 8.2.2 Determining the requirements related to products and services
47. Resources needed for monitoring and measurement shall be provided - 7.1.5 Monitoring and measuring resources
48. Resources needed for the management of the QMS shall be provided - 7.1.1 General (Resources)
49. The audit program shall be planned, implemented and maintained - 9.2 Internal audit
50. The design and development process shall be controlled - 8.3.4 Design and development controls
51. The following also applies nuclear safety culture aspects – 9.1.3 Analysis and evaluation
52. The necessary competence of personnel shall be determined - 7.2 Competence
53. The necessary documented information shall be controlled - 7.5.3 Control of documented information
54. The necessary process environment shall be provided - 7.1.4 Process environment
55. The necessary process infrastructure shall be provided - 7.1.3 Infrastructure
56. The necessary processes shall be planned and controlled - 8.1 Operational planning and control
57. The organization shall be responsible for the conformity of all externally provided processes, products and/or services – 8.4.2 Type and extent of control
58. The organization shall break down ITNS products and services into items and activities – 6.1.3 Determination of ITNS items and activities
59. The organization shall communicate to external providers its requirements for passing down relevant requirements to all levels of its supply chain – 8.4.3 Information for external providers
60. The organization shall ensure an appropriate nuclear safety culture – 5.1.3 Nuclear safety culture
61. The organization shall ensure that all required documented information is present at delivery – 8.6 Release of products and services
62. The organization shall ensure that design and development outputs specify the conditions under which commercial grade items or activities can be used as ITNS items or activities – 8.3.5 Design and development outputs
63. The organization shall prevent CFS items at all levels of operations including selection of external providers – 8.1.1 Provisions for counterfeit, fraudulent or suspect (CFS) items
64. The organization shall provide adequate resources for improvement plans – 10.1 General (Improvement)
65. The organization shall share with its customer and disseminate to its supply chain organizations relevant learning from experience – 10.1 General (Improvement)
66. The performance and the effectiveness of the QMS shall be evaluated - 9.1 Monitoring, measurement, analysis and evaluation
67. The processes needed for the QMS shall be determined - 4.4 QMS and its processes
68. The quality manual shall be established and maintained NO
69. The quality policy shall be available, communicated, understood and applied - 5.2.2 Communicating the quality policy
70. The result of evaluation of external providers shall be valid for a limited period of time and a stated scope – 8.4.1 General (External providers)
71. The risks and opportunities that need to be addressed shall be determined - 6.1 Actions to address risks and opportunities
72. The scope of the QMS shall be determined - 4.3 Scope of the QMS
73. The suitability, adequacy and effectiveness of the QMS shall be continually improved - 10.3 Continual improvement
74. The unique identification of the outputs shall be controlled when traceability is a requirement - 8.5.2 Identification and traceability
75. Top management shall appoint a member of the organization's management who has the organizational independence and authority to manage nuclear safety and quality issues– 5.3 Organizational roles, responsibilities and authorities
76. Top management shall appoint a member of the organization's management who has unrestricted access to top management– 5.3 Organizational roles, responsibilities and authorities
77. Top management shall demonstrate leadership - 5.1 Leadership and commitment
78. Top management shall demonstrate leadership and commitment with respect to customer focus - 5.1.2 Customer focus
79. Top management shall ensure that nuclear safety is taken into account in decision making and is not compromised by any decision taken – 5.1.1 General (Leadership)
80. Top management shall ensure that the responsibilities and authorities are assigned, understood and implemented - 5.3 Roles, responsibilities and authorities
81. Top management shall establish, implement and maintain a quality policy that includes appropriate nuclear safety considerations – 5.2.1 Establishing the quality policy
82. Top management shall establish, implement and maintain a quality policy that includes a commitment to ensure that nuclear safety is not compromised by other priorities– 5.2.1 Establishing the quality policy
83. Top management shall manage the quality policy - 5.2.1 Establishing the quality policy
84. Top management shall review the QMS - 9.3 Management Review
85. Top management shall take accountability for the effectiveness of the QMS - 5.1 Leadership and commitment
86. Where design tools (e.g. computation codes or computerized models) are used, the organization shall demonstrate that these are fit for purpose – 8.3.1 General (Design and development)