Audit Checklist (Preview)

Quality Management System conformance to ISO 9001:2015 requirements

ISO 9001:2015 Clause	Questions	Conforms	Verified Process	Auditor's tips (recommendations)
		Yes/ No		What is being verified (explanations)?
1	2	3	4	5
1 Scope			Management review	*This clause does not contain any requirements.* A good practice is to initiate management response to the question: 'What goals are set (expected) by Management for the QMS?' Any answer is acceptable (e.g., the need for certification, customer satisfaction improvement, increase of efficiency, and so forth).
...				
6.1 Actions to address risks and opportunities	1. How the QMS risks and opportunities are distributed? 2. How the risks and opportunities are defined in the audited process? How often they are reviewed?	☐ ☐ ☐	Quality management QMS Processes	Actions to address risks and opportunities in the QMS could be regulated: - by the availability of elements of the risk - management system in accordance with the principles and guidance of ISO 31000; - in the 'Actions to address risks and opportunities'

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	3. What illustrates the results of actions to address risks and opportunities in the audited process?	☐		QSP;
				- via personnel risk management training.
				An illustration of actions to address risks and opportunities could be: avoiding risk, accepting risk to use the opportunity, eliminating the source of risk, changing the probability or the consequences, distributing the risk or retaining the risk based on the decision made.
	How often the results of actions are evaluated?	☐		
	How the evaluation is conducted?	☐		Opportunities may lead to the adoption of new practices, launching of new products, opening new markets, addressing new customers, business partnership, use of new technology and other desirable and viable options to address the needs of the organization or consumers.
	4. How and how often the actions to address risks and opportunities in the verified process are evaluated?	☐		
				Actions taken to address risks and opportunities should correspond to the possible effect on the conformity of products and services.
				It is beneficial to link sec.6.1 questions to the sec.4.4 questions.
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7.1.5 Monitoring and measuring resources				**Important**: 1. Audit of Monitoring and measuring resources should be linked to the national metrology legislature. 2. When auditing monitoring and measuring resources, the following should be verified: - Equipment and measuring media; - Approved measuring techniques, including software; - Prepared (trained) personnel carrying out the measurement.
...				
7.2 Competence			Control of personnel	The components of competence are: education, training and experience.
	1. In which QMS documents the required staff competence is defined?	☐		The required staff competence can be defined: - In the job description section (for all employees); - Under the provision of subdivisions (for the managers); - In the technology, labor instructions, etc. section (working category requirements).

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	2. How in the QMS the requirements for the competence of persons who are not employees but perform work under the control of the organization are defined?	☐		The requirements for the competence of persons who are not employees but perform work under the control of the organization (for example, equipment start-up) can be defined by internal or external regulatory documents or in the contract.
	3. How the staff competence is ensured?	☐		Competence of employees can be ensured via: - The procedure of competitive recruitment, including audit records of education, training and experience, and conducting interviews; - Development and testing of the training program. Wherein it is necessary to evaluate the effectiveness of training and make changes to the training program, if necessary.
	4. How the competence is ensured for the persons who are not employees but perform work under the control of the organization?	☐		The competence of persons who are not employees but perform work under the control of the organization can be ensured via work permits.
	5. How and on what basis the necessary competence (training, continuous	☐		Acquiring of the necessary competence can be planned, for example, in 'Annual staff training plan',

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	professional development) is planned to be acquired?			'Internship Program', etc.
	6. How the effectiveness of measures on the acquisition (increase) of competence is evaluated?	☐		The effectiveness of measures on the acquisition of competence can be evaluated via: - Personnel certification; - Accreditation of subdivisions; - Employees testing.
	7. Please, provide the documented information as evidence of competence of the verified process operators.	☐	QMS processes + Control of personnel	Examples of the documented information: - Evidence of education - certificates, diplomas, graduation certificates; - Evidence of training – continuous professional development certificates, reference letters; - Evidence of experience - records of work experience, letters of recommendation.
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				What is being verified (explanations)?
8.5.4 Preservation	1. What are the requirements to preserve processes' outputs (including products)?	☐	Production and service provision	The requirements to preserve processes' outputs (including products) are included in design and development outputs. In this regard, the question#1 sec.8.5.4 should be linked to the Design and development outputs question #4– sec.8.3.5, where the requirements for the processes' outputs preservation appear. *Preservation can include activities to identify, transfer (including loading and unloading operations), packing, storage, transmission or transportation, and protection.*
	2. What monitoring and measuring activities are carried out to ensure processes' outputs preservation requirements?	☐		Verify carrying out monitoring and measuring of storage conditions characteristics, which are part of the requirements for the process outputs preservation. Such characteristics may be temperature, humidity, and others.
	3. Do the methods used for ME storage conditions measuring and monitoring correspond to the measurement traceability requirements?	☐		Questions #1 – 3 on measurement traceability – sec.7.1.5.2 should be checked.

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	4. How the parameters are regulated if the characteristics of the storage conditions are out of range?	☐		For example, when temperature is reduced below the acceptable level the air can be heated.
...				

Notes:

1. The audit program is usually compiled based on the QMS processes (or structural subdivisions) of the Organization. In this case it is beneficial to assemble questions from different section of this 'Checklist', that refer to the verified Process (or structural subdivision). To do this, column #4 contains Process name, where the questions should be attributed. Moreover the Process names are specified in accordance with good practices and may differ from the actual names of the Organization's processes.

Important – if column #4 says 'QMS Processes', those questions should be asked when auditing **all** QMS processes!

2. QMS audit is the compliance spot check, so when planning internal audits, the questions can be spread into several audits.

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