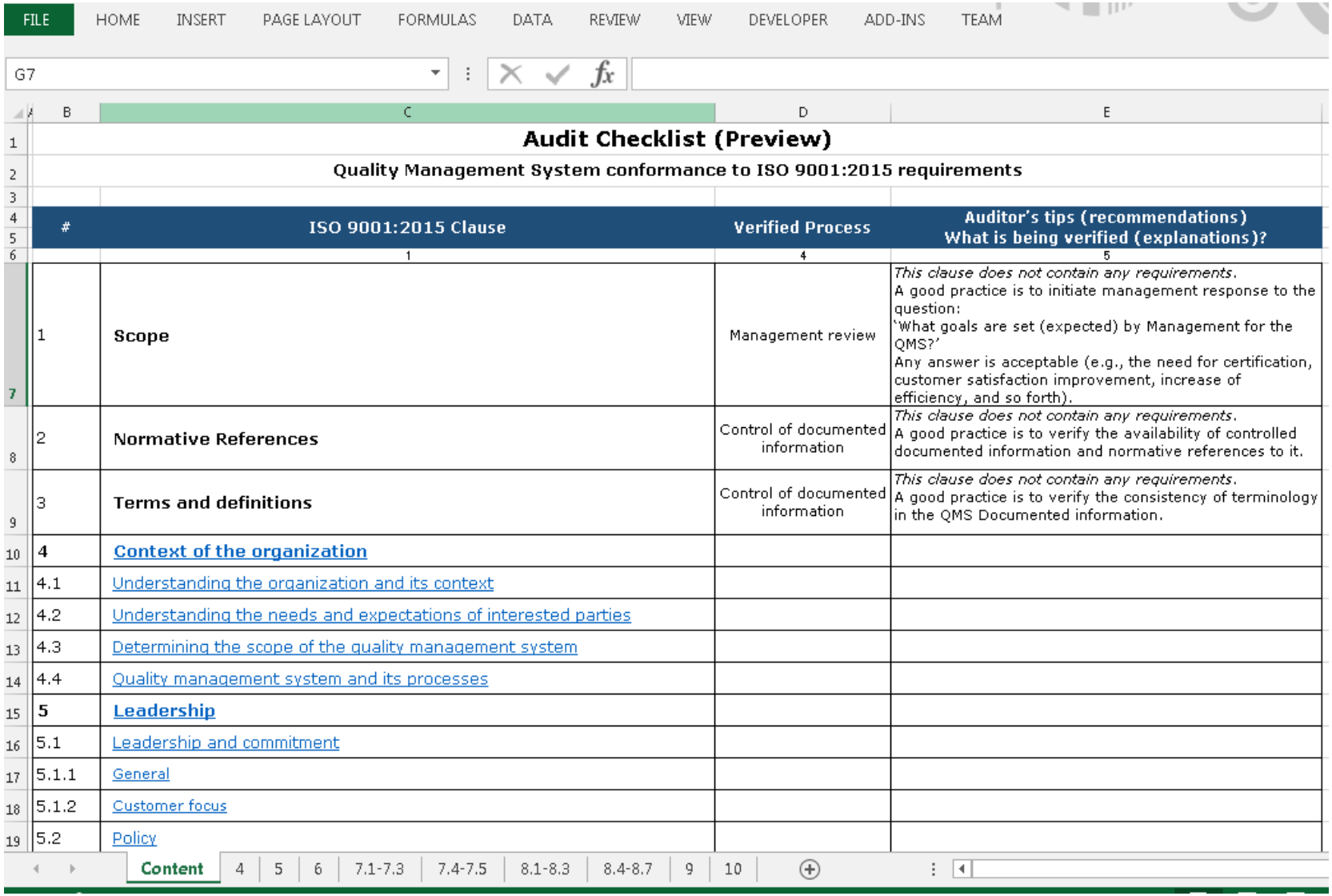

FILE HOME INSERT PAGE LAYOUT FORMULAS DATA REVIEW VIEW DEVELOPER ADD-INS TEAM

G7

Audit Checklist (Preview)

Quality Management System conformance to ISO 9001:2015 requirements

#	ISO 9001:2015 Clause	Verified Process	Auditor's tips (recommendations) What is being verified (explanations)?
	1	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).
2	**Normative References**	Control of documented information	*This clause does not contain any requirements.* A good practice is to verify the availability of controlled documented information and normative references to it.
3	**Terms and definitions**	Control of documented information	*This clause does not contain any requirements.* A good practice is to verify the consistency of terminology in the QMS Documented information.
4	**Context of the organization**		
4.1	Understanding the organization and its context		
4.2	Understanding the needs and expectations of interested parties		
4.3	Determining the scope of the quality management system		
4.4	Quality management system and its processes		
5	**Leadership**		
5.1	Leadership and commitment		
5.1.1	General		
5.1.2	Customer focus		
5.2	Policy		

Content | 4 | 5 | 6 | 7.1-7.3 | 7.4-7.5 | 8.1-8.3 | 8.4-8.7 | 9 | 10

19	5.2	Policy		
20	5.2.1	Establishing the quality policy		
21	5.2.2	Communicating the quality policy		
22	5.3	Organizational roles, responsibilities and authorities		
23	**6**	**Planning**		
24	6.1	Actions to address risks and opportunities		
25	6.2	Quality objectives and planning to achieve them		
26	6.3	Planning of changes		
27	**7**	**Support**		
28	7.1	Resources		
29	7.1.1	General		
30	7.1.2	People		
31	7.1.3	Infrastructure		
32	7.1.4	Environment for the operation of processes		
33	7.1.5	Monitoring and measuring resources		
34	7.1.5.1	General		
35	7.1.5.2	Measurement traceability		
36	7.1.6	Organizational knowledge		
37	7.2	Competence		
38	7.3	Awareness		
39	7.4	Communication		
40	7.5	Documented information		
41	7.5.1	General		
42	7.5.2	Creating and updating		
43	7.5.3	Control of documented information		

	A	B	C	D	E	F	G
1							
2	#	ISO 9001:2015 Clause	Questions	Conforms Yes/ No	Verified Process	Notes	Auditor's tips (recommendations) What is being verified (explanations)?
3							
4		1	2	3	4		5
5	6		**Planning**				
6	6.1	Actions to address risks and opportunities	1. How the QMS risks and opportunities are distributed?	☐	Quality management		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' QSP; - via personnel risk management training.
7			2. How the risks and opportunities are defined in the audited process?	☐	QMS Processes		
8			How often they are reviewed?	☐			
9			3. What illustrates the results of actions to address risks and opportunities in the audited process?	☐			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. 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. 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.
10			How often the results of actions are evaluated?	☐			
11			How the evaluation is conducted?	☐			
12			4. How and how often the actions to address risks and opportunities in the verified process are evaluated?	☐			
	6.2	Quality objectives and planning to achieve them	1. Please, provide the 'Quality objectives' document.	☐	QMS processes, Management review		Verification of the formation, planning and monitoring of quality objectives implementation is done on every process level as well as on the QMS level (when auditing 'Management review' process — sec.9.3)

Content | 4 | 5 | 6 | 7.1-7.3 | 7.4-7.5 | 8.1-8.3 | 8.4-8.7 | 9 | 10

	A	B	C	D	E	F	G
1							
2	#	ISO 9001:2015 Clause	Questions	Conforms Yes/ No	Verified Process	Notes	Auditor's tips (recommendations) What is being verified (explanations)?
3							
4		1	2	3	4		5
5	7	**Support**					
6	7.1	**Resources**					
7	7.1.1	General	1. In what way and how often the adequacy of internal QMS resources is analyzed and ensured?	☐	Management review		*It is beneficial that question #1 sec.7.1.1 is linked to the Leadership and commitment questions sec.5.1.1 (question #4) and Management review - sec.9.3.*
8			What has to be obtained from the external providers?	☐			
9			2. How the internal and external resources needed to the process are defined?	☐	QMS processes		*Question #2 sec.7.1.1 should be linked to the QMS process approach implementation sec. 4.4 (question #7).*
10			How the availability of resources is ensured?	☐			
11	7.1.2	People	1. Where the requirements to the personnel, necessary for the efficient functioning and QMS process control, are formulated?	☐	Control of personnel		The requirements to the personnel could be formulated in: - job instructions (for all employees); - provisions of subdivisions (for managers). Providing the QMS processes with the required personnel is usually defined in the hiring procedure, including initial evaluation of personnel compliance to the requirements as per provided documentation, conducting of interview, etc.
12			2. How the QMS processes are provided with the required personnel?	☐			
13	7.1.3	Infrastructure	1. How the equipment necessary for the Process is determined?	☐	Technical maintenance, Production		The equipment necessary for the Process can be determined in the 'Design and development' process. It is necessary to verify that the available equipment type corresponds to the required.
			2. Is technical maintenance carried out on the planned regular basis?	☐			It is a good practice to develop equipment maintenance schedules. The frequency and content of equipment maintenance is

Content | 4 | 5 | 6 | 7.1-7.3 | 7.4-7.5 | 8.1-8.3 | 8.4-8.7 | 9 | 10

	A	B	C	D	E	F	G
1							
2	#	ISO 9001:2015 Clause	Questions	Conforms Yes/ No	Verified Process	Notes	Auditor's tips (recommendations)
3							What is being verified (explanations)?
4		1	2	3	4		5
5	7	**Support**					
6	7.4	**Communication**	1. How the internal communication on the QMS relevant questions is carried out?	☐	Quality management		When verifying questions #1 and #2 on internal and external communication, the mandatory requirement is to check the availability of information about: a) the subject of communication; b) the time of communication; c) who is being informed; d) the method of communication; e) who is informing Internal communication on the issues relevant to the QMS can be carried out via: - intranet; - quality days; - meetings and conferences at all levels; - training; - briefings before commencing work; - internal mass media; - informational posters, etc.
7			2. How is QMS relevant external communication is carried out?	☐			External communication on the issues relevant to the QMS can be carried out via: - letters; - info sheets; - ads; - mass media, etc..
8	7.5	**Documented information**					
	7.5.1	General	1. How the volume and structure of QMS documented information, including that of external origin, is defined?	☐	Control of documented information		The structure of the QMS documented information should include: - documented information, the necessity of which is defined by ISO 9001 requirements; - documented information, defined by the Organization as necessary for QMS efficiency.

Content | 4 | 5 | 6 | 7.1-7.3 | **7.4-7.5** | 8.1-8.3 | 8.4-8.7 | 9 | 10

	A	B	C	D	E	F	G
1							
2	#	ISO 9001:2015 Clause	Questions	Conforms Yes/ No	Verified Process	Notes	Auditor's tips (recommendations) What is being verified (explanations)?
4		1	2	3	4		5
5	8	**Operation**					
6	8.1	Operational planning and control				Sec.8.1 requirements can be implemented in a separate 'Planning and control of operation' process, as well as on the stages of the 'Contract analysis', 'Design and development of products', 'Purchases', ('Control of External Processes' if applicable), 'Production', and 'Product release' processes. In the second case, it is good practice to describe the connection between the stages, for example, in section 8.1 of QM. A good practice is to link the Planning and control of operation to the Quality objectives.	
7			1. How the conformity of activities to define product requirements is ensured in the Contract analysis > design > purchases > production processes?	☐	Contract analysis Design and development of products Purchases (Control of External Processes) Production Product release		The connection of activities to define product requirements is verified in different processes. Original product requirements that were defined in the Contract analysis (cl.8.2.2 - ISO 9001:2015), have to be a part of the Design and development inputs (cl.8.3.3 - ISO 9001:2015), have to be transformed into design and development process output data (cl.8.3.5.d - ISO 9001:2015) and further: - presented as information for external providers (cl.8.4.3.a - ISO 9001:2015), - included in mandatory documented information (documentation), confirming controlled conditions of operation (cl.8.5.1.a - ISO 9001:2015).
8			*In case product requirements were changed in Contract analysis or Design processes:* 1.a. Were the corresponding changes made to all consequent processes?	☐			
9			2. How the conformity of activities to establish the production processes criteria is ensured in Design and development processes?	☐	Design and development of product Production		The connection of actions to set production processes criteria is verified in different processes. Processes criteria, that are part of design output data (cl.8.3.5.b - ISO 9001:2015) have to be monitored and measured when managing operation (cl.8.5.1.c - ISO 9001:2015).

Content | 4 | 5 | 6 | 7.1-7.3 | 7.4-7.5 | **8.1-8.3** | 8.4-8.7 | 9 | 10

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', the 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 distributed over several audits.