

## Risk Management in QMS Processes

### Quick Reference Guide

(Meeting the requirements of ISO 9001:2015 cl. 4.4.1.f; 6.1.2.b.1)

ISO 9001:2015 Clauses	QMS Process	Key Risks Wording	Risk Treatment Areas
5 Leadership 9.3 Management Review (including cl. 9.3.2.e - take into account the efficiency of actions to address risks and opportunities)	'Management Review'	<ul style="list-style-type: none"> <li>• failure to achieve strategic goals;</li> <li>• failure to fulfill quality objectives;</li> <li>• slowdown in company activity performance indicator growth;</li> <li>• undesirable and not timely recognized QMS changes;</li> <li>• ...</li> </ul>	<ul style="list-style-type: none"> <li>• regularity and depth of Context of Organization analysis, communication and consideration for the decision-making;</li> <li>• analysis and review of QMS processes resources, including resources for monitoring and measuring; ...</li> </ul>
7.1 Resources	'Technical Maintenance'	<ul style="list-style-type: none"> <li>• emergency stops;</li> <li>• exceeding the period of technical maintenance and equipment repair;</li> <li>• ...</li> </ul>	<ul style="list-style-type: none"> <li>• maintenance programs correction, including the period between scheduled repairs;</li> <li>• improvement of equipment tuning methods;</li> <li>• ...</li> </ul>
	'Control of Personnel'	<ul style="list-style-type: none"> <li>• suboptimal personnel competence (including education, confirmed qualification, additional training, work experience); ...</li> </ul>	<ul style="list-style-type: none"> <li>• correction of procedures for determining the necessary expertise;</li> <li>• ...</li> </ul>

ISO 9001:2015 Clauses	QMS Process	Key Risks Wording	Risk Treatment Areas
7.4 Communication	'Internal Communication'	<ul style="list-style-type: none"> <li>• failure in QMS processes caused by communication;</li> <li>• lack of or delay in receiving information;</li> <li>• ...</li> </ul>	<ul style="list-style-type: none"> <li>• revision and improvement of methods, frequency and volume of communication,</li> <li>• revision of methods and terms of information storage;</li> <li>• ...</li> </ul>

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