

QSP 6.1 Actions to address risks and opportunities

01. Purpose

Make actions to address risks and opportunities a part of decision making on all levels of the Organization and one of the improvement mechanisms of processes and quality management system (QMS).

02. Scope

This procedure covers all processes of QMS and regulates the activity of the Organization's Leadership, Quality Manager, Risk Manager, Process Owners, Risk Owners, experts regarding risk management.

03. Responsibility and Authority

The responsibility and authority of the Organization's Leadership, Quality Manager, Risk Manager, Process Owners, Risk Owners, experts to ensure this procedure are given below, in the sec. 4.2.4.

04. Procedure

4.1 General

Inputs:

- Data of the processes operations, including criteria – from QMS Processes;
- Information flow about the internal and external context of the Organization (see sec. 4.2.1);
- Information on changes and Risk management tasks in QMS – from the 'Management Review' Process.

Outputs:

- Process control decisions – to QMS Processes;
- Data to evaluate effectiveness of the processes - to QMS Processes;
- Suggestions for changes to the QMS, including resource needs – to 'Management Review' Process;
- Suggestions to initiate breakthrough projects - to 'Management Review' Process;
- Data to evaluate effectiveness of the processes and the QMS as a whole - to 'Management Review' Process.

Actions to address risks and opportunities (Fig. 1) consist of carrying out the 'PDCA' cycles related to risks on two levels:

- QMS level – 'Actions to address risks and opportunities' Process (1st level process);
- Each Process Level – 'Risk management processes' (2nd level processes).

Quality System Procedure

QSP **6.1**
Subject: **Risks**

'Risk management processes' are the constituent parts of the 'Actions to address risks and opportunities' Process.

'Actions to address risks and opportunities' Process is implemented in four phases:

- Planning actions to address risks and opportunities. Project of risk management framework.
- Integration and implementation of actions to address risks and opportunities into QMS processes.
- Evaluation of the effectiveness of actions to address risks and opportunities. Monitoring and analysis of risk management framework.
- Achieving improvement

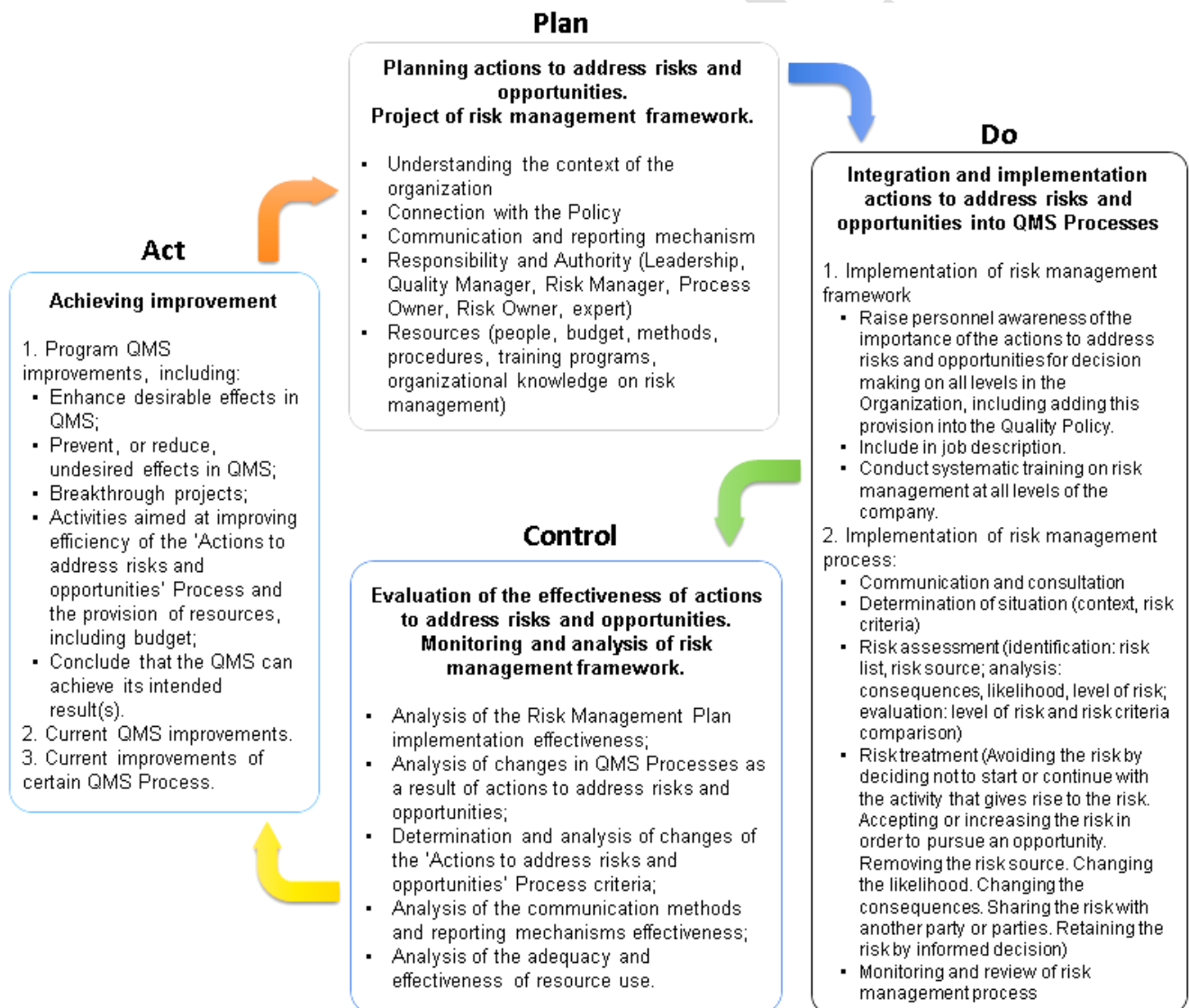


Fig. 1. Actions to Address Risks and Opportunities Diagram

4.2 Planning actions to address risks and opportunities. Project of risk management framework.

4.2.1 Understanding the Context of the Organization It is a prerequisite for the risk management framework project, defining the levels of risk and risk criteria, as well as risk treatment.

Information flows on internal and external context include:

- Information on the applicable laws ('Control of documented information' Process);
- Standards ('Control of documented information' Process);
- Information on markets and market trends ('Marketing Activity' Process);
- Information on competitors including technology ('Marketing Activity' Process);
- Information about the policy, objectives, strategies, promising business opportunities ('Management Review' Process);
- Information about the organizational structure and resources ('Management Review' and 'Personnel Management' Processes);
- Information about the technologies and future developments ('Design and Development' Process);
- Information about the personnel qualification ('Personnel Management' Process);
- Other information, specific to the particular case.

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