01. Purpose

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

a) planning actions to address risks;
b) taking risks into account;
c) integrating and implementing actions into QMS processes;
d) evaluating the effectiveness of actions to address risks.

The following **terms and definitions** are used in this procedure.

Risk — effect of uncertainty.

For practical assessment, a risk is formulated (risk title) as a potential event. An event may occur with a certain *likelihood* and have certain *consequences*.

Risk level — the magnitude of a risk expressed in terms of a combination of the likelihood of occurrence and the consequence of the risk.

Likelihood — the assessed chance that an event will occur or that a specified circumstance will arise, based on available information and expressed using the defined assessment scale.

Consequence — the assessed effect of an event or circumstance on intended results, objectives, or other relevant outcomes, expressed using the defined assessment scale.

Risk criteria — the terms of reference used to evaluate the significance of a risk and determine whether the level of risk is acceptable or requires further measures.

Risk treatment — the process of selecting and implementing appropriate measures to eliminate or reduce risks that may affect the achievement of intended results.

Environmental risk (E-risk) – risk associated with the potential negative impact of processes, materials, or resources on the environment and climate change.

Environment - surroundings in which an organization operates, including air, water, land, natural resources, flora, fauna, humans and their interrelationships.

Environmental impact - *change to the environment* whether adverse or beneficial, wholly or partially resulting from an organization's environmental aspects.

Examples of environmental impacts: increased content of carbon oxides in the air; pollution of groundwater with heavy metals; acid rain in the region; reduction of fish species in the river near the organization.

Environmental aspect - element of an organization's *activities or products* or services that interacts or can interact with the environment.

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.

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[End of preview. Section 4.0: Procedure — the full PDCA risk-management cycle (planning, integration and implementation into QMS processes, risk identification/analysis/evaluation, risk treatment, and performance evaluation, including environmental risk (E-risk) assessment) — along with Section 5.0 (Process Criteria), Section 6.0 (Documented Information), Section 7.0 (Revision History), and the Risk List and Risk Treatment Plan annexes — is included in the full purchased document. Visit the product page to purchase the complete QPS 6.1-01 Actions to Address Risks procedure]