# PLANNING IN ISO 9001:2015

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**Abstract:** The aim of the paper is to carry out an analysis of planning process in an organisation that has implemented the ISO 9001:2015 system. In the paper, we described elements of this planning, which is essential to achieve the intended benefits of a quality management system. Planning needs to be done by everyone in the organisation, but it is significant for the process owner, considering the impacts on achieving the planned outputs of quality management processes. The aim of the paper is to analyse the problems connected with the planning of the organisation in the ISO 9001:2015 implementation process.

**Keywords:** quality management, ISO 9001:2015, ISO 9001, planning, interested parties, needs and expectations, risk.

## 1. Introduction

Planning is an intellectual process of thinking before acting. This is essential to achieve the intended benefits of a quality management system. Planning needs to be done by everyone in the organisation, but it is significant for the process owner, considering the impacts on achieving the planned outputs of quality management processes. We can also define planning as (Robbins, and Coulter, 2006; Cholewicka-Goździk, 2016; Gębczyńska, and Wolniak, 2018; Horodecka, and Wolniak, 2015; Hoyle, 2009; Juszczak-Wiśniewska, and Ligarski, 2015; Juszczak-Wiśniewska, and Ligarski, 2016; Łagowski, and Żuchowski, 2016; Ligarski, 2013; Ligarski, 2014, Żemigała, 2017; Olkiewicz et al., 2019' Wolniak et al., 2019; Wolniak, 2019):

- the act or process of making or carrying out plans, specifically: the establishment of goals, policies and procedures for a social or economic unit,
- the process of deciding in detail how to do something before you actually start to do it,
- the process of setting goals, developing strategies and outlining tasks and schedules to accomplish the goals,
- business planning encompassing all the goals, strategies and actions that one envisions taking to ensure a business's survival, prosperity and growth.

When we plan for quality management systems, an organisation should consider the issues referring to the problem and determine the risks and opportunities that need to be addressed to (Natarajan, 2017; ISO 9001:2015; Łuczak, and Wolniak, 2016; Novakova et al., 2016; Pacana, 2014; Pacana et al., 2014, 2017; Pacana, and Stadnicka, 2006, 2017; Poksińska et al., 2002; Wolniak, and Sułkowski, 2015, 2016; Wolniak, and Hąbek, 2015; Wolniak, and Skotnicka-Zasadzień, 2010; Wolniak, 2013, 2014, 2016, 2017):

- give assurance that the quality management system can achieve its intended result(s),
- enhance desirable effects,
- prevent, or reduce, undesired effects,
- achieve improvement.

The aim of the paper is to analyse the problems connected with the planning of an organisation in the ISO 9001:2015 implementation process.

## 2. Basic concepts

An organisation, also according to ISO 9001:2015 principles, should plan (ISO 9001:2015):

- actions to address these risks and opportunities,
- how to:
  - integrate and implement the actions into its quality management system processes,
  - evaluate the effectiveness of these actions.

The requirements in the planning process in the ISO 9001:2015 system are (Natarajan, 2017; Hilson, 2001; Salvendy, 2001; Ścierski, 2011; Stamatis, 1995; Sułkowski, and Wolniak, 2016, 2018; Szczucka-Lasota, and Wolniak, 2018; Szkiel, 2016; Wolniak, 2011; Wolniak, and Sułkowski 2015):

- understanding risks and opportunities,
- determining risks and opportunities,
- planning the actions to address risks and opportunities,
- examples of planning the actions to address risks and opportunities, integrating the actions with quality management system processes and evaluating the effectiveness of the actions for three quality management system processes,
- risk is the probability and severity of failure to achieve the desired outputs (results) of processes. Probability of failure is the likelihood of risk occurrence and can be classified as: impossible, low, medium or high. Severity represent the potential impact of failure in achieving the desired outputs and can be classified as: minor, major, critical, catastrophic. Most risk management guidelines recognise at least four risk response

strategy types: avoid, transfer, mitigate and accept. All the general procedure for addressing risk and opportunities are presented in Figure 1.
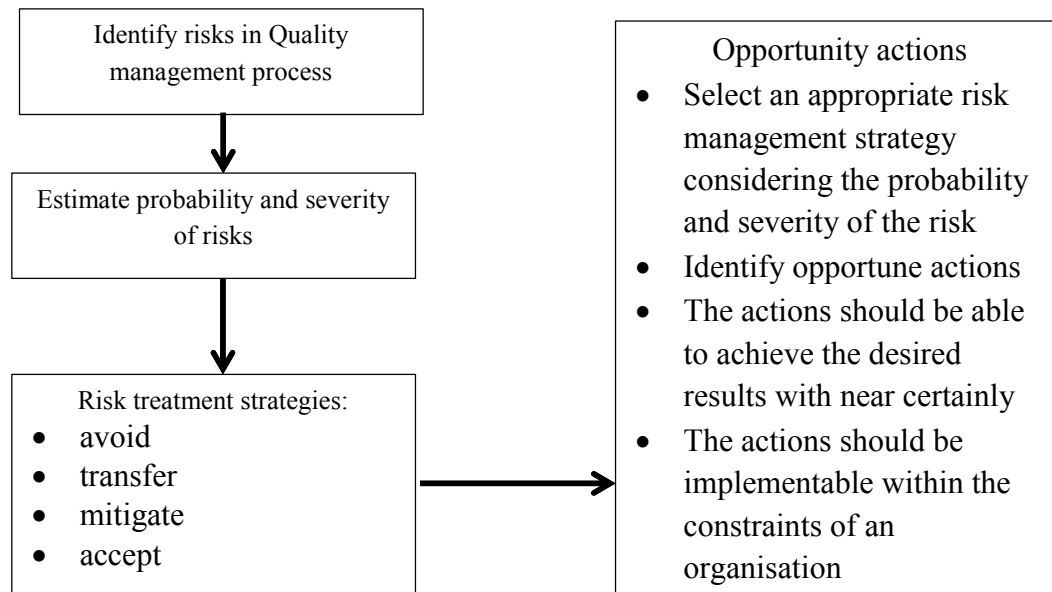
| Identify risks in Quality management process | Opportunity actions |
|---|---|
| ↓ | • Select an appropriate risk management strategy considering the probability and severity of the risk |
| Estimate probability and severity of risks | • Identify opportune actions |
| ↓ | • The actions should be able to achieve the desired results with near certainly |
| Risk treatment strategies:<br>• avoid<br>• transfer<br>• mitigate<br>• accept | • The actions should be implementable within the constraints of an organisation |

**Figure 1.** General procedure for addressing risks and opportunities. Source: (Natarajan, 2017).

## 3. Types of the risk

The difference between risk-based thinking and preventive action lies in the fact that in preventive action, a quality management system relies on interested parties (most likely employees) to detect and report potential risks and initiate a preventive action. The probability of achieving quality objectives improves because obstacles, interferences and interruptions are identified and removed in advance or opportunities initiate improvements. The objectives of risk-based thinking are as follows (Abuhav, 2017):
- Establishing a proactive approach of identification and elimination of errors in advance;
- Ensuring the quality management system can achieve its intended outcomes;
- Preventing or reducing undesired effects;
- Ensuring long-term normality, security and credibility of processes and business activities;
- Achieving improvement;
- Enhancing customer satisfaction.

The ISO 9001 standard specifically implies that it does not formally require a certain methodology for applying risk management, and an organisation can decide for itself whether and how to develop particular risk assessment methods. It can develop a more extensive risk

management methodology than required as long as the principles of that process are maintained. We could use the approach illustrated in Figure 2.



**Figure 2.** Risk management methodology. Source: (Abuhav, 2017).

The organisation must identify which risks are associated with interested parties, i.e. when, where and why their needs will not be met, and suggest ways and actions to avoid these situations or which expectations of interested parties might bring opportunities and whether developing these opportunities is feasible. The risks or opportunities associated with the expectation of interested parties are as follows (Abuhav, 2017):

- Owners and investors—risks associated with revenues and implementing strategies;
- Employees—risks associated with errors or nonconformities related to the operation of quality management systems;
- End users—risks associated with the specifications or requirements from the product due to technological, sociological, ecological, economic or environmental changes;
- Suppliers—risks associated with the performance and ability to supply goods and services according to specifications;
- Regulators—change of applicable regulations that might affect realisation processes;
- Auditors—change of standard requirements (e.g. revision of the ISO 9001 Standard);
- Employees—risks associated with safety during the realisation of a product.

To plan the conformity of a product with identification of the potential risk, an organisation should (Natarajan, 2017):

- Identify internal and external issues and the requirements of interested parties relevant to the risk;
- Identifying the causes of risks of the quality management system process;
- Identifying the actions arising from internal and external opportunities considering the risk response strategies associated with the opportunities;
- Integrating the finalised opportune actions with the documentation of the quality management system process;
- Monitoring the actions;
- Analysing data from monitoring.

Internal and external resources are utilised to identify actions to address opportunities for managing the risk associated with the process. In Tables 1 and 2 are some examples of opportunities from internal and external sources, respectively, with a possible response strategy.

All possible causes of the risk are associated with the acceptance of the enquiry. They should be identified and documented. In Table 3 is a description of the details of the risk in accepting a customer's enquiry – there are only primary causes included in table.

**Table 1.**
*Opportunities from internal sources with a risk response strategy*

| Actions arising from internal opportunity | Risk response strategy |
|---|---|
| Past internal records are examined to identify the opportunities that were successful in managing similar risks | Mitigating risk |
| Formation of an expert design team | Mitigating risk |
| Access to leading digital libraries around the world to use emerging technologies | Mitigating risk |

Source: own work based on: (Natarajan, 2017).

**Table 2.**
*Opportunities from external sources with a risk response strategy*

| Actions arising from external opportunity | Risk response strategy |
|---|---|
| Hiring related experts | Avoiding risk |
| Learning from competitors | Mitigating risk |
| Receiving the product as customer property | Transferring risk |

Source: own work based on: (Natarajan, 2017).

**Table 3.**
*Details of risk in accepting a customer enquiry*

| Risk | Primary causes of the risk | Severity of risk | Probability of risk |
|---|---|---|---|
| Inability to manufacture a large quantity per delivery schedule | Inadequate operators | Minor | Medium |
| | Inadequate external providers | Major | Medium |
| | Inadequate test equipment | Critical | Medium |

Source: own work based on: (Natarajan, 2017).

Examples of methods used for risk analysis are (Abuhav, 2017):

- FMEA—failure mode and effects analysis.
- Fishbone.
- FTA—fault tree analysis.
- ETA—event tree analysis.
- Design of experiments.
- Reasons for variance.
- Review for conflicting requirements.
- Pareto-analysis.

# 4. Quality objectives

In the organisation, we should plan the quality objectives and know how to achieve them. The organisation should establish quality objectives at the relevant functions, levels and processes needed for the quality management system (Wolniak, 2013, 2016, 2017, Wolniak,

and Skotnicka-Zasadzień, 20018, 2011, 2014). For each quality objective, the organisation should maintain documented information (Ząbek, 2016). The quality objectives should (ISO 9001:2015):

- be consistent with the quality policy,
- be measurable,
- take into account applicable requirements,
- be relevant to the conformity of products and services and the enhancement of customer satisfaction,
- be monitored,
- be communicated,
- be updated as appropriate.

The quality objectives should be derived from the quality policy and should be established at relevant functions (Purushothama, 2015):

- Quality policy documented → We, with innovative design and styles in textiles for apparels, are committed to quality and service on the foundation of human values, systems and teamwork to achieve customer satisfaction.
- Specific points in quality policy → innovative design and styles, quality, service, human values, systems, teamwork and customer satisfaction.
- Purpose of writing quality policy → Successful working of the organisation.
- Target to be achieved → Customer satisfaction.
- Product/Business → Textiles for apparel end use
- Commitment → Quality products and services
- Route → Innovation in design and style
- Foundation → Human values, teamwork and system

When we plan how to achieve a particular quality objective, the organisation shall determine (Abuhav, 2015):

- what will be done,
- what resources will be required,
- who will be responsible,
- when will it be completed,
- how the results will be evaluated.

When we are planning quality objectives within a firm, we should consider the following problems (Purushothama, 2015):

- Quality objectives should support decisions making – the data and information generated and gathered through the implementation of quality objectives allow different managerial levels in the organisation to make decisions regarding quality management systems.

- Quality objectives should be relevant to the organisation – quality objectives express the business expectations of the organisation concerning its business and operational performances.
- Quality objectives must be achievable – it does not do any good to define quality objectives that look good on the paper and may make a good impression in the audit, but which in fact no one can actually measure or reach.
- Quality objectives should not be exceeded – it is not recommended to define too many objectives, as this may cause frustration and dissatisfaction among employees rather than create positive results.
- Quality objectives should be practical – they must relate to the processes, activities and operations of the quality management systems.

There are many potential quality objectives within an organisation. They derive can derive from following factors (Table 4):

- Improved performance.
- Customer satisfaction.
- Quality products and services.
- Innovative designs and styles.
- Uplifting of human values.
- Improvement in systems.
- Working as one team.

**Table 4.**
*Examples of the objectives in organisations*

| Group | Examples |
|---|---|
| **Improved performance** | <ul><li>Increase in productivity at all levels</li><li>Increase in total sales turnover</li><li>Increase in net profits of the company</li><li>Increase in production per employee</li><li>Increase in sales turnover per euro spent in marketing</li><li>Increase in sales turnover per employee</li><li>Increase in sales turnover per capital invested</li><li>Increase in sales turnover per working capital involved</li><li>Increase in production per machine</li><li>Reduction in cycle time</li></ul> |
| **Customer satisfaction** | <ul><li>All products meet customer requirements</li><li>Zero complaints and increase in purchases by each customer</li><li>Products are provided to customers at competitive prices</li><li>Cost of manufacturing is less than that of competitors in the market</li><li>Customer gets the material on time and at the place he/she wants</li><li>On time delivery in full for all orders</li><li>Customer gets a positive and convincing response for his queries, feedback and complaints without delay</li><li>Customer refers the company to his friends and customers</li></ul> |

Cont. table 4.

| | |
|---|---|
| **Quality products and services** | • Zero rejection of the materials supplied to customers<br>• Reduction in internal rejections<br>• Reduction in wastes<br>• Increase in sales turnover per person in marketing<br>• Reduction in appraisal and field failure costs<br>• Zero stock of the final product packed. |
| **Innovative design and styles** | • Number of new designs prepared per year<br>• Number of designs approved as a percent of designs prepared and<br>• offered to customers<br>• Number of designs converted into orders<br>• Number of designs getting repeat orders<br>• Number of designs copied by our competitors |
| **Uplifting human values** | • Reduction in employee attrition rate<br>• Reduction in number of grievances by the employees<br>• Reduction in accidents<br>• Reduction in absenteeism<br>• Reduction in expenses for recruitment |
| **Improvement in systems** | • Reduction in the number of nonconformities in audits<br>• Reduction in the number of people in non-productive operations<br>• Reduction in cycle time for report preparation<br>• Reduction in inventories<br>• Reduction in non-moving items in stores and go down<br>• Reduction in response time for enquiries. |
| **Working as one team** | • Reduction in staff turnover<br>• Number of improvement projects undertaken in teams and implemented<br>• Reduction in average time for closing nonconformities<br>• Reduction in disputes between employes nd sections. |

Source: own work based on: (Purushothama, 2015).

Objectives connected with quality also serve the top management in the matter of leadership and commitment with respect to customer focus, where trends of data related to the quality objectives indicate the efficiency of resolving issues and problems related to customers. In Table 5, we have some aspect of customer satisfaction connecter with examples.

**Table 5.**
*Connections between quality objectives and customer satisfaction*

| Aspects of customer satisfaction | Example of an objective |
|---|---|
| Quality objectives should enhance the ability to solve the problems of customers as soon as possible. | Reducing reaction time to customer complaints.<br>Establishing plans to reduce customer complaints based on statistical analysis. |
| Understand and anticipate the needs and expectations of customers. | Scheduling an interaction with each customer at least once a year. |
| Quality objectives should increase the ability of the organisation to meet customer satisfaction in the long run. | Informing customers of the progress of their contract or order.<br>Improving the interface between the development and customers concerning their expectation from the product. |
| Quality objectives should motivate actions to eliminate situations where customer satisfaction is not achieved. | Increasing quality tests before delivering goods to customers. |
| The ability to ensure conformity of goods and services. | Handling nonconformities and corrective actions with the goal of achieving customer satisfaction. |

Cont table 5.

| | |
|---|---|
| Quality objectives should create the conditions for applying sufficient resources needed to achieve customer satisfaction. | Implementing a new system for a better communication of customer requirements throughout the supply chain. |
| Developing products that achieve customer satisfaction. | Improving the review processes of product characteristics. Performing a survey among customers for obtaining feedback and ideas for improvement in the next business year. |

Source: (Abuhav, 2017).

The realisation of the mentioned objectives needs to develop a link to the organisation's objectives. The steps to achieve this scope are as follows (Purushothama, 2015):

- Break the company objectives into departmental objectives;
- Break departmental objectives into sectional objectives;
- Break sectional objectives into individual objectives;
- Prepare an action plan to achieve section objectives and individual objectives;
- Prepare procedures and implement;
- Review implementation and take appropriate action;
- Revise procedures.

In order to implement and maintain quality objectives, an organisation should establish a system for monitoring and reporting the status of quality objectives. There is no explicit requirement for such a system, but during an audit, organisations are required to prove that all data and information regarding the quality objectives are available, organised and monitored. In the process of planning or describing such a system, organisations should consider the following aspects (Abuhav, 2017):

- Gathering data and information – the system must clearly indicate which type of data and information must be collected and processed. When the system refers to figures like turnovers, percentage of accepted offers, customer returns and errors in the production, it must be clear where this data and information are available.
- Tracking and monitoring – the system should refer to the relevant quality management system elements that must be monitored: processes, human resources, documentations and records.
- Observing – the system should ensure that activities for maintaining the quality objectives are performed, the objectives are measured, results are communicated to the appropriate persons and those persons invest the resources to review the results.
- Reviewing the results – the system must provide a view of trends indicating the business progress of the objectives and opportunities for improvement and include a comparison of periods.
- Reporting – the system should define the type of reports of the results of monitoring and measuring and should communicate them to the relevant persons in the organisation.
- Resources – the system should refer to the allocated resources needed for the achievement of the quality objectives: trainings, software, tools, etc.

When the organisation determines needs for changes to the quality management system, the changes shall be carried out in a planned manner. In this case, the organisation shall consider (ISO 9001:2015):

- the purpose of the changes and their potential consequences,
- the integrity of the quality management system,
- the availability of resources,
- the allocation or reallocation of responsibilities and authorities.

## 5. Conclusion

Changes in quality management systems need to be planned in an appropriate way. These changes may arise due to corrective actions, improvement actions, revising the scope of organisation, etc. The changes should be carried out in a planned manner described for establishing quality management systems. An organisation needs to consider the following problems before approving the changes to processes of quality management systems:

- The purpose of the changes and their potential consequences: The source (audit findings, corrective actions, etc.) and the purpose (reasons) of changes to the quality management systems processes are documented. The expected benefits of the changes are also recorded.
- The integrity of quality management systems: The proposed changes are examined and ensured that the changes comply with the requirements of the quality management systems of an organisation.
- The availability of resources: Most of the changes to production related processes would require resources, which might be simple fixtures, measuring devices, improving competence of personnel, etc. The availability of resources is ensured before effecting the changes to quality management system documents.
- The allocation or reallocation of responsibilities and authorities: Changes initiated by top management might require the allocation or reallocation of responsibilities and authorities for personnel. The changes are reflected appropriately in the related documents of quality management systems.

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