SUPPORT IN ISO 9001:2015

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Abstract: The aim of the paper is to carry out an analysis of support processes in an organisation that has implemented the ISO 9001:2015 system. According to ISO 9001:2015 requirements, an organisation shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of a quality management system. The organisation shall determinate and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes. The aim of the paper is to analyse the problems connected with the support of the organisation in the ISO 9001:2015 implementation process.

Keywords: quality management, ISO 9001:2015, ISO 9001, support, interested parties, needs and expectations, documentation.

1. Introduction

According to ISO 9001:2015 requirements, an organisation shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system. In this case, the organisation shall consider (ISO 9001:2015; Wolniak, 2013, 2016, 2017; Wolniak, and Skotnicka-Zasadzień, 2014):

- the capabilities of, and constraints on, existing internal resources,
- what needs to be obtained from external providers.

The following types of resources are considered within the quality management system (Abuhay, 2017):

- Human resources.
- Infrastructures.
- Process (work) environment.
- Tools and equipment.
- Information systems.

- Suppliers and partners.
- Natural resources.
- Financial resources.

The organisation shall determinate and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes (Wułkowski, and Wolniak, 2016; Szczucka-Lasota, and Wolniak, 2018; Szkiel, 2016; Wolniak, 2011; Horodecka, and Wolniak, 2015; Hoyle, 2009). Top management plans the requirements of personnel and provides them. Additional requirements are usually identified by process owners, and top management provides the resources after a review (Natarajan, 2017).

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

2. Basic concepts

The organisation shall to determinate and provide the persons necessary for the effective implementation of the quality management system within the particular organisation and to achieve conformity with production and services. The infrastructure of an organisation can include (ISO 9001:2015; Hilson, 2001; Gębczyńska, and Wolniak, 2018; Cholewicka-Gooździk, 2016; Chen et al., 2016; Pacana et al., 2014; Pacana, 2014; Olkiewicz et al., 2019, Novakova et al., 2016):

- buildings and associated utilities,
- equipment, including hardware and software,
- transportation resources,
- information and communication technology.

After determining the required infrastructure, the organisation needs to evaluate their suitability to the requirements of quality management systems. The goals of the evaluation process are (Abuhay, 2017):

- to ensure that the infrastructures are intact, sustainable and stable,
- to ensure that the infrastructures will support the organisation in achieving quality targets and plans,
- to verify that the infrastructures will not disturb the achievement of objectives or reduce the capability of processes,
- to identify areas and ranges for control,
- to determine which controls are needed,
- when needed, to implement improvements or to update infrastructures.

The top management is supposed to provide the required infrastructure; however, the users should justify their requirements (Wolniak, and Sułkowski, 2015, 2016; Wolniak, and Hąbek, 2015; Wolniak, and Skotnicka-Zasadzień, 2015; Wolniak, 2013, 2014, 2016, 2017). The infrastructure should help in achieving the organisation's objectives, enhancing customer satisfaction, enhancing stakeholder satisfaction, implementing quality management systems effectively and performing the right things correctly the first time.

The organisation should ensure that the resources provided (Purushothama, 2015):

- are suitable for the specific type of monitoring and measurement activities being undertaken,
- are maintained to ensure their continuing fitness for their purpose.

The organisation should also determinate, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services (Pacana et al., 2017; Pacana, and Stadnicka, 2006, 2017; Poksińska et al., 2002, Robbins, and Coulter, 2006; Salvendy, 2001; Ścierski, 2011; Stamatis, 1995; Sułkowski, and Wolniak, 2018). A suitable environment can be a combination of human and physical factors, such as (ISO 9001:2015):

- social (e.g. non-discriminatory, calm, non-confrontational),
- psychological (e.g. stress-reducing, burnout prevention, emotionally protective),
- physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).

The process environment is a very important support system to be given by the management to facilitate operations. The work environment may be divided into two parts, i.e. physical environment and psychological environment. The physical environment can be further divided into the environment required for the product and that required for the people working (Wolniak, 2017, 2019; Wolniak et al., 2019, Wolniak, and Skotnicka-Zasadzień, 2008, 2011).

3. Infrastructure

The determination of process environment conditions influences the characterisation of tools, infrastructures, equipment and human resources related to the realisation processes. These elements should be synchronised to provide optimal qualifications to the process environment (Abuhay, 2017):

- The process environment supports operations and activities related to the realisation processes.
- The process environment shall ensure the provision of appropriate conditions required for the conformity of products, services and customer satisfaction.

- Organisations will define, officially decide, make available, maintain and preserve from failure or decline the process environment necessary for its operations.
- Parameters that influence the process environment may include factors that affect the environment: temperature, recognition schemes, ergonomics and atmospheric composition. Such factors may be social, psychological or environmental.
- Besides the physical spaces or locations, social, psychological and physical conditions are considered as a process environment.

When analysing the environment, an organisation should (Abuhay, 2017):

- review all the environmental inputs and requirements, such as product, packaging requirements, human resource and risks,
- list all the related processes and activities,
- examine the flaws of the material throughout the realisation processes and inspect all the outputs of the processes,
- involve all the participants of the processes in order to cover all aspects and receive all the needed information,
- determine at each phase what the required conditions for the process environment are,
- plan and implement tools that will record the status of the conditions,
- control the conditions through analysis,
- maintain documented information of the process when found it necessary.

The process of infrastructure evaluation should consider six parameters described in Table 1.

Table 1.
Parameters of the infrastructure evaluation in a quality management system

Parameter	Characteristic
Suitability	The quality of having the properties that are right for a specific purpose. This parameter evaluates how appropriate an infrastructure is to its final purpose and how much it can support this purpose.
Security	This parameter evaluates the ability of an infrastructure to guarantee that an expected outcome will be met.
Reliability	The quality of being worthy of reliance or trust. This parameter evaluates whether an infrastructure is reliable while playing its role in the realisation process.
Maintainability	The capability of being kept in good condition. This parameter evaluates how well an infrastructure can be maintained.
Efficiency	The capability of the output to the input of any system. This parameter evaluates the results of an infrastructure with comparison to its objective.
Safety	The state of being certain that adverse effects will not be caused by using the infrastructures under defined conditions and controls the impact of the infrastructure on the work environment.

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

The organisation shall retain appropriate documented information as evidence of fitness for the purpose of the monitoring and measurement resources. The first problem is measurement of traceability. Traceability is defined as the property of a result of a measurement whereby it can be related to appropriate standards, generally national or international standards, through an unbroken chain of comparison (Juszczak-Wiśniewska, and Ligarski, 2015, 2016; Łagowski,

and Żuchowski, 2016; Ligarski, 2014; Łuczak, and Wolniak, 2016). This is an essential part of providing confidence in the validity of measurement results. The organisation shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose take appropriate action as necessary. To achieve this, measuring equipment shall be (ISO 9001:2015):

- calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information,
- identified in order to determine their status,
- safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

Measurement of traceability is ensured for the following categories of standards and resources of a particular organisation to provide confidence in the validity of measurement results:

- Mechanical measuring devices and equipment.
- Electronic equipment.
- Working and secondary standards.
- The instruments mandated by regulatory bodies, such as Occupational Safety and Health Administration.

The organisation is expected to analyse its needs for resources while considering certain organisational aspects. In other worlds, it should to determinate which resources they need in order to produce the product according to the expectations, which resources are available, how they can be deployed and what the limitation of its resources are. The realisation of these principles should help effectively determine the use of resources to support the organisation or service provider. In this case, an organisation should consider (Abuhay, 2017):

- Requirements: The resources are to support the organisation in meeting customer and regulatory requirements.
- Quality policy: A correlation between the resources and the quality policy is essential. In the quality policy, the nature of the organisation and its processes is determined, there is a commitment to meet customer as well as regulatory requirements, quality objectives (or principles for their determination) are set, and scope of activity is determined. It is then time to identify the necessary resources.
- Quality objectives: The defined resources must support the achievement of quality objectives.
- Realisation processes: Processes are a crucial constituent for realising goods or services. The processes determine the amount, extent and complexity of the resources.
- Improvement: The resources are to support activities necessary to achieve improvement of the quality management systems.

4. Knowledge

An organisation also needs to determine the level of knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge should be maintained and be made available to the extent necessary. Organisational knowledge can be based on (ISO 9001:2015):

- internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services),
- external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers).

The main internal sources of knowledge are (Natarajan, 2017):

- Capabilities and application of measuring resources: Understanding the capabilities and application of measuring resources enables one to use the resources efficiently and effectively for the production processes of products.
- Improving the competency of personnel: The competency of personnel is a source of organisational knowledge. Appropriate education and training could be organised for persons managing product design and production processes.
- Lessons learned: Knowledge sources exist in an organisation. Lessons learned from the root cause analysis of process and product failures and the successful management of risks in processes are examples of these sources. Problems solved by operators under suggestion award scheme should also be treated as knowledge sources.
- Conducting laboratory experiments is a method to generate knowledge power for an organisation.
- Intellectual property under transfer of technology: Technical expertise obtained from projects could be considered for implementation of other projects of an organisation.

In the case of the competences, an organisation shall (ISO 9001:2015):

- determine the necessary competence of the person(s) performing work under its control that affects the performance and effectiveness of the quality management system,
- ensure that these persons are competent on the basis of appropriate education, training or experience,
- where applicable, take actions to acquire the necessary competence and evaluate the effectiveness of the actions taken,
- retain appropriate documented information as evidence of competence.

In an organisation, different employees perform different tasks and activities to promote shared quality goals. For each level in each organisational unit, it is necessary to define the level of qualifications and skills that those persons need to perform their tasks. The main elements of job characteristic are described in Table 2.

Table 2.
Elements of job characteristics that should be defined and documented in a quality management system

Element	Characteristic
Education	The level of knowledge and education required for a role will be determined: engineer, technician, programmer, biologist and certified logistician. Some roles may not require any education or external certification at all. These definitions will be the preconditions for the hiring of personnel for specific roles.
Regulatory requirements	When a regulatory requirement demands a certain certification according to a law or a standard, it will be mentioned as a precondition for hiring a person for the job. The matter will be verified with evidence prior to hiring. This means that an auditor may ask to see different licenses or certifications of certain employees.
Knowledge	The knowledge that is required for the operation of activities, realising the product and meeting customer requirements.
Experience	The extent of experience and background in parameters of time as well as areas and scopes of activities will be defined.
Certification	The manufacturer will define a certification plan or process needed to introduce a person to a specific role: training about processes, procedures, work instructions or activities related to the job. The plan shall cover both operational tasks related to the realisation of the product or service as well as administrative and quality tasks.
Training	The training (external as well as internal) for the role will be planned. It is necessary to identify the critical points or events in a process which may affect the product and its integrity and to plan the training in accordance.

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

Very important issues of an organisation's activity are awareness and communication. According ISO 9001:2015 requirements, the organisation should ensure that persons performing under an organisation's control are aware of (ISO 9001:2015):

- the quality policy,
- relevant quality objectives,
- their contribution to the effectiveness of the quality management system, including the benefits of improved performance,
- the implications of not conforming with the requirements of the quality management system.

Awareness initiates identification, devotion and commitment to the goals of the organisation among personnel. By promoting awareness, the ISO 9001:2015 standard tries to avoid the following side effects (Abuhay, 2017):

- Not understanding the context of the organisation.
- Not knowing exactly who the interested parties are.
- Not understanding or knowing what the customer requirements really are.
- Delivering poor-quality products or services to the customer.
- Promising the customer what cannot be achieved.

- Ignoring or missing quality problems.
- Reacting to quality problems instead of avoiding them.

The internal and external communication should be relevant to the quality management system and includes (ISO 9001:2015):

- what it will communicate,
- when to communicate,
- with whom to communicate,
- how to communicate,
- who communicates.

Communication in the eyes of quality management means a process or activity for exchanging information between entities for the operation of the quality management systems. One of the major reasons for quality problems in any organisation is related to communication, and this may be miscommunication, inadequate communication, improper communication, communicating to a wrong person, communicating using the wrong medium, communicating at the wrong time, communicating in the wrong place, not reading the messages with a calm mind, not understanding the inner meaning of the communication, not competent to understand the language in which it was told or written, not understanding the context in which it was told, not understanding its importance while listening, and so on. This process of communication has a structure and direction and uses technology, tools, means or other instruments. Communication channels have important strategic goals, such as the following:

Ensuring that information and knowledge reaches the designated persons (Abuhay, 2017):

- boosting the processes in the organisation and contributing to their effectiveness,
- promoting the sharing of knowledge and information between entities or units that operate the quality management systems,
- promoting and conveying to employees the importance of meeting customer and regulatory requirements,
- helping identify problems and opportunities for improvement.

The quality management system within the organisation should be based on documented information. In this case, it includes (ISO 9001:2015):

- documented information required by this International Standard,
- documented information determined by the organisation as being necessary for the effectiveness of the quality management system.

Documented information relates to four kinds of documentations distinguished with different characteristics related to the context, maintenance and media (Abuhay, 2015; Locher, 2008; Kaoru, 1985; Mitra, 2016; Montgomery, 2009):

- Documented information needed to describe and document the quality management systems, e.g. quality policy.

- Documented information needed to document the quality processes of the quality management systems, e.g. form for management review or internal audit.
- Documented information needed for the operation of the quality management systems, e.g. work instructions, SOPs, process diagrams, etc.
- Evidence or processes or activities as records that are necessary to verify or validate results and to check and prove the effectiveness of the quality management systems, e.g. production charts for quality control or results of customer satisfaction surveys.

Quality management system documents are reviewed for their suitability and adequacy. The review requirements are especially as follows (Natarajan, 2017):

- Identification and description of the document.
- Complying with ISO 9001 requirements.
- Addressing the quality needs of internal and end customers (Sect. 1.3.1).
- Avoiding contradicting information.
- Guidance for proper use, as appropriate.
- Legibility of the documents.
- Updating related documents, as applicable.
- Appropriate information for external providers (purchasing), inspection production and preservation in product-related engineering documents.
- Version status.

The extend of documented information for a quality management system can differ from one organisation to another due to (ISO 9001:2015):

- the size of the organisation and its type of activities, processes, products and services,
- the complexity of processes and their interactions,
- the competence of persons.

Besides internal documentation, an organisation needs to use external documentation. Examples of external documented information can be (Abuhav, 2017):

- Information received from customers: drawings, packaging instructions, diagrams of production tools, quality requirements, design files and customer's approvals or agreements.
- Information received from suppliers: drawings, instructions for use.
- Regulations and standards.

In the process of creating and updating appropriate documents, an organisation should ensure appropriate (ISO 9001:2015):

- identification and description (e.g. a title, date, author, or reference number),
- format (e.g. language, software version, graphics) and media (e.g. paper, electronic),
- review and approval for suitability and adequacy.

5. Conclusion

The traditional and most common method to analyse the structure of documented information in an organisation is to arrange, classify, categorise and set levels to the types of documented information used in an organisation according to their characteristics and role in the quality management system. This can be presented in a documentation pyramid (Figure 1). The documentation pyramid describes the operational flow of documented information in an organisation and represents the levels for the types of documents that are usually used in quality management systems, from the planning of strategic stages to the daily work of performing activities and filling out forms.
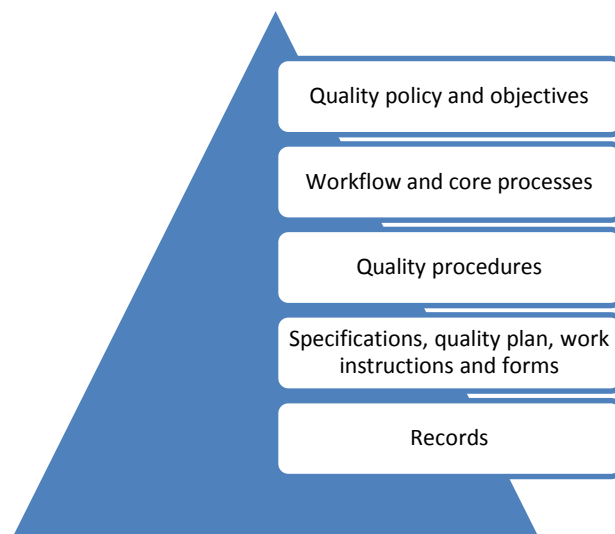
Figure 1. Documentation pyramid. Source: (Abuhav, 2017).

The next problem of maintaining a documented information system is related to control of the documented information. Control is needed to ensure (ISO 9001:2015):

- it is available and suitable for use, where and when it is needed,
- it is adequately protected (e.g. from loss of confidentiality, improper use or loss of integrity).

Procedures for controlling the documented information of quality management system processes are maintained. The control procedures are established to ensure (Natarajan, 2017):

- Availability and suitability of documents: The documents are available and suitable for use, where and when needed. The current revision of documents is made available to process owners to ensure the suitability of the documents.
- Protecting documents: Product-related documents might require protection from loss of integrity, improper use, etc. Appropriate arrangements, such as issuing the documents when required and returning the documents after processing, could be made by an organisation. Access to engineering documents is also controlled to ensure that the documents are available for authorised users.

Protection and preservation of records refers to the equipment and facilities that manage records and to the methods and techniques that are planned in order to protect records. Protection of records ensures that the information contained in the records is available and accurate for future reference and that the records must not be changed over time. For each type of record, organisations need to identify the risk and apply appropriate methods of protection and preservation. In this case, the firm should to consider following (Abuhay, 2017):

- Legibility: Protection of records shall support their legibility and ensure that the content in the records will remain clear and available for use over the life cycle of the record.

- Storage: It is necessary to ensure that storage of records is adequately in place according to the type of the record, e.g. organising folders in workstations, ensuring there is no confusion when filing, storing or archiving the records or in verifying the functionality of the data repository.

- Flow of information: It is necessary to ensure that records will reach their destination and will not be lost. This is important for the flawlessness of the workflow.

- Unauthorised access: It is necessary to ensure that no misuse of records is possible (through management of access and authorisation).

The documents should be available for the people to use. They should be kept in a specified location so that no one will waste his time and energy for searching them. Thus, it is necessary to mention their locations (Purushothama, 2015).

Documented information of an external origin determined by the organisation to be necessary for the planning and operation of the quality management system shall be identified as appropriate and be controlled. In the case of control of documents, the following activities are applicable (ISO 9001:2015):

- distribution, access, retrieval and use,

- storage and preservation, including preservation of legibility,

- control of changes (e.g. version control),

- retention and disposition.

The organisation retains documented information to demonstrate compliance to the quality procedure for creating, updating and controlling quality management system documents. The quality records are (Natarajan, 2017):

- Approved quality management system documents.

- Distribution or access list for the documents.

- Master list of internal documents.

- Change control information for updated documents.

- Master list of external documents with verification of version status.

- Retaining obsolete documents with suitable identification as specified in the process procedure.

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