

CONTEXT OF THE ORGANIZATION IN ISO 9001:2015

Radosław WOLNIAK

Silesian University of Technology, Faculty of Organization and Management, Institute of Economics and Informatics; rwolniak@polsl.pl, ORCID: 0000-0003-0317-9811

Abstract: The aim of the paper is to analyze the question connected with the context of the organization in the organization implemented ISO 9001:2015 system. In the paper we described the elements of the context of the organization and their influence on the activity of the firm, the needs and expectations of the interested parties and methods for monitoring the needs of the interested parties. The external and internal issues relevant to an organization are determined during management reviews. Top management assigns monitoring issues to appropriate process owners for monitoring. The process owner should monitor the issues and prepare appropriate reports indicating the methods and results of the whole monitoring process. If feasible, appropriate metrics are also advised for presenting the results.

Keywords: quality management, ISO 9001:2015, ISO 9001, context of the organization, interested parties, needs and expectations.

1. Introduction

First, an organization which wants to implement ISO 9001:2015 requirements should determine all external and internal issues that are relevant to its purpose and strategic direction and that affect the ability of the organization to achieve results within the framework of the implemented quality management system. To do this, the organization shall monitor and review all information concerning these external and internal problems.

Firstly, the organization should understand the needs and expectations of interested parties. To provide products and services that meet customer demand, the organization should implement statutory and regulatory requirements. All requirements of the ISO 9001:2015 standard are applicable to any kind of organization regardless of its type or size, as well as of the type of products and services it provides. The organization should monitor and review all the information collected about the interested parties and their requirements. To do this, the organization should determine:

- the interested parties relevant to the quality management system,
- the requirements of these interested parties that are relevant to the quality management system.

The aim of the paper is to analyze the problems connected with the context of the organization in the ISO 9001:2015 implementation process.

2. Basic concepts

Any organization is a combination of different business entities that relate and interact with each other as well as exchange information and materials. The context of the organization is an outline of the interactions and integrations of organizations (Chen, et al., 2016; Cholewicka-Goździk, 2016; Gębczyńska, and Wolniak, 2018; Hoyle, 2009). It is a set of functions, factors, processes, inputs, outputs, conditions and limitations that create the business environment of the organization. These problems have a significant impact on the ability of the organization to provide products and affect the goals and objectives (Juszczak-Wiśniewska, and Ligarski, 2015, 2016; Ligarski, 2013, 2014; Łuczak, and Wolniak, 2016). To do this, the organization should determine a business strategy and set the objectives of a functioning quality management system. Moreover, it should understand its every aspect (Pacana, et al., 2014, 2017; Pacana, and Stadnicka, 2006, 2017; Pacana, 2014). This understanding is the basis of a correct business strategy. Every area of expertise, sector, market, product family, or other business segmentation has its own relevant issues that affect the organizational context. External or internal issues may include:

The expectations of the interested parties:

- The main products that provide the most value to its interested parties.
- Processes and activities needed to meet the specifications and expectations of its interested parties.
- The influence of the business environment in which the organization is active.
- Availability of resources needed for the implementation.
- Competence of the human resources.
- Statutory and regulatory requirements.

3. Types of the interested parties and their expectations

The main types of interested parties of an organization are top management, shareholders, customers, suppliers, employees and their dependents, community and government (Figure 1).



Figure 1. Context of the organization. Source: Purushthama, 2015.

Interested parties differ from one another and thus have different needs and expectations. They perform their activities in the business environment in which the particular organization is active and which has an effect on the quality management systems. An interested party may be a person or another organization that can affect, be affected by or perceive themselves by the organization or its activities (Horodecka, and Wolniak, 2015; Łagowski, and Żuchowski, 2016, Novakova, et al. 2016; Poksińska, and Dahlgaard, 2002; Salvendy, 2001; Ścierański, 2011, Stamatis, 1995). Table 1 includes the analysis of the main influences of particular types of interested parties on our organization. After determination of the existing interested parties, the next step is to determine their expectations. The examples of possible expectations in accordance to types of the interested parties are presented in the Tables 2 and 3.

Table 1.*Examples of influences of the interested parties on the organization*

Factors	Examples
Customers	Expectations of the product, its intended use, and its characteristics. Changes in those expectations may influence the quality management systems and its activities.
Employees	Employees directly affect the quality management system and its processes and, thus, the quality of the product.
Suppliers and external providers	The quality of materials, components, or parts that must be integrated in the end product and their delivery by suppliers and external providers may directly influence the quality and conformity of the product.
Regulations	Regulations and statutory requirements may dictate processes and activities of the organization and thus affect the characteristics of a product.
Investors	The investors of the organization determine the availability of resources and thus may influence the quality and conformity of the product.
Competitors	Competitors may affect the profitability of the organization by delivering a product that meets customer needs and expectations better.
Other interested parties	Other interested parties and their influence on the quality and conformity of the product identified through PEST analysis.

Source: Abihav, 2017.

Table 2.*Needs and expectation of interested parties*

Factors	Examples
Customers	<ul style="list-style-type: none"> • Enhancement of customer satisfaction • Delivery of quality products, with a price and performance compliant with the specifications • Appropriate communication channels with the organization • Handling of property belonging to customers
Owners/ shareholders	<ul style="list-style-type: none"> • Increased revenue and market share • Sustained profitability • Flexible and fast responses to market opportunities • Evaluation of risks and opportunities
Employees of the organization	<ul style="list-style-type: none"> • Clear vision of the organization's future • Appropriate integration in the organization • A proper job definition • Good work environment • Work opportunities • Job security • Social conditions • Recognition and reward • Facilities for personnel in the organization • Developing and improving the competence of personnel (training)
Suppliers and partners	<ul style="list-style-type: none"> • Return on supply of goods or provision of services; appropriate communication channels between the organization and the supplier • Provision of resources such as information, knowledge, expertise, technology, processes, and training • Mutual benefits and continuity • Sticking to payment conditions • Handling of property belonging to external providers
Society in which the organization is active	<ul style="list-style-type: none"> • Environmental protection • Ethical behavior • Delivering products in accordance to the social, economic, ecological trends, and local cultural aspects
Regulators	<ul style="list-style-type: none"> • Compliance with statutory and regulatory requirements • Anticipating and reacting to expected changes in statutory and regulatory requirements • Understanding the labor market and its effect on the loyalty of people in the organization

Source: Abuhav, 2017.

Table 3.
Needs and expectations of stakeholders

Factors	Examples
<p style="text-align: center;">Top management</p>	<ul style="list-style-type: none"> • Increased rate of returns: The top management is the custodian of shareholders who have invested money and need returns. Higher returns entice investors to invest more. If an organization is not providing the expected returns, the investors may take out their shares and the organization cannot survive. • Increased turnover: The top management wants the industry/business to grow. Increased turnover helps the industry to grow by way of the reduced proportion of overheads for unit production. • Increased profits: The health of an organization is judged by the rate of profits earned. The profits build confidence not only for the management and employees, but also for the suppliers, community, customers, and other interested parties. No customer would like to stick to a supplier running in continuous loss as they would not be guaranteed consistent and timely deliveries of quality goods at all times. • Reduced rejections: Both internal and external rejections are a disease which, if not addressed immediately, may become chronic. The avoidance of loss due to poor quality can turn a loss-making organization to a profitable organization. • Reduced costs: Reduced costs help to increase profits as well as sustain in the business even in bad periods. Continual efforts to reduce the costs should be there in any organization. • Reduced inventory: Reduced inventory helps in reducing the interest burden and money tied up. In addition, the reduced inventory helps in organizing the existing floor area in a more useful and effective way. • Shorter cycle time: Shorter cycle time helps in quick turnover of money, reduces the interest burden on working capital, and finally helps in generating profits. • Reduced manpower: Normally, overstaffing leads to increased problems in the area of human relations, and it is easy to manage a small group. It is usually seen that employing more people than needed reduces efficiency, increases confusion, and leads to a number of other problems. • Lesser labor problems: Labor problems spoil the mental peace as it is more sensitive. Hence, the investors usually do not want to invest where labor problems are more significant. The customers also do not like to stick to a supplier struggling with more labor problems as the consistency in quality and delivery cannot be guaranteed by such suppliers.
<p style="text-align: center;">Employees demand</p>	<ul style="list-style-type: none"> • Increase in wages and bonus: There is no limit for this. The cost of living is increasing day by day, and wages and salaries need to be increased to compensate not only the increase in the cost of living but also the added experience and maturity that are improving the performance of the organization. • Increase in facilities: Employees depend on the organization. They want their family to be secured. They need facilities for the family and children, school, house, conveyance, hospital, etc., so that they can work in the organization with a peaceful mind and concentrate on quality and productivity. • Provision of an atmosphere so that families can stay together: In a number of cases, the newly married youngsters are leaving their family, going to a remote place to work. They go to their hometowns once a year. How can they be happy and concentrate on work? If a company provides an atmosphere for their families to stay together, they will be happy to work in that company. • Security in employment: Many of the employees are dependent only on their jobs, and hence security at work becomes a very important expectation. Employees like to work in an organization where security is there rather than in an organization which pays more but does not guarantee work for tomorrow.

Cont. table 3.

Employees demand	<ul style="list-style-type: none"> • Promotion opportunities: Everyone wants to grow. Promotion is an indicator of growth for a working person. If promotion opportunities are poor, people try to leave and go to other companies. Where the organizations have a policy of promoting the people within instead of bringing outsiders for higher positions, the attrition rate will be low. • Respect for job and people: All employees are human beings and expect to be recognized and respected. People are not working just for the money you pay, but for the respect they get by working in your organization.
Shareholders	<ul style="list-style-type: none"> • Increased dividends: The shareholders invest their personal savings into a business with the intention of earning. They would like to invest where they get higher dividends. • Higher market value for shares: Shareholders like to earn by selling their shares when the market value is good. Hence, they wish the market values of their shares to continuously increase. The market value of a company increases when it makes continuous profits and gives higher dividends. • Increase in facilities and privileges: Shareholders expect the facilities and the privileges given to them to increase continuously, as they have invested their money to run your business.
Customer expectations	<ul style="list-style-type: none"> • Desired products: The customer pays money to buy the product they require. We might have produced something fantastic but the customer will not purchase it unless it is useful and needed by them. They cannot buy just because it is made by you or me. Therefore, it is necessary to understand the exact requirement of the customer and deliver the products and services accordingly. • Timely delivery: All works are to be done in due time. The customer needs the materials for use in due time. There is no point in getting the material when it is not needed. It would be a waste if not available on time. The lack of material on time can become a threat to the running of the business itself. The customer might have to lay off the people due to the lack of work resulting from the unavailability of material. • No increase in prices (reduction is welcome): The customer has planned their activities considering a certain price (normally the last purchase prices) for the materials procured from you. If the prices increase in the meantime, all their calculations fail, and they have to face losses. Hence, no increase in price is accepted. • Prompt and quick service: The customer purchases materials to use them. If they encounter any problems while using the materials, their activity will be affected, and hence they will need our help, i.e., the service. We need to provide timely service. There are cases where there is no problem with the material but the user is does not know how to use it to get the best results, and in such cases, the customer asks for service and we need to provide it on time. • Smooth operation at the customer's premises: The materials are purchased for money to work smoothly at the customer's premises and not to create problems. • Compensation for the losses due to quality: Customer has purchased materials to run their business. Why should they suffer because of the quality problems in the materials supplied by us? They are right in demanding compensation, and it is the responsibility of the supplier to compensate the customer's losses resulting from the bad quality.
Vendors	<ul style="list-style-type: none"> • Please favor us with more orders: The vendors' business depends on the orders we give them. We are the customers for our vendors. They request us to place more orders so that they can maintain stability in the business as well as guarantee us consistent quality. • Our expenses have increased; please give a higher price: The cost of manufacturing increases due to various factors such as the increase in prices of raw materials, power, fuel, interest rates, wage structure, taxes, etc., which is beyond the control of the supplier. The supplier might try to reduce some of the cost but not all. Hence, they request us to pay a higher price for the materials supplied by them. • Request for timely payment: The supplier runs a business and needs money for that. Hence, they demand timely payments for the materials supplied by them.

Cont. table 3.

Government	<ul style="list-style-type: none"> • Increased revenues: The government has provided permission and facilities for us to run a business in their area. The government is supposed to provide various facilities to the community such as schools, roads, infrastructure, food, hospitals, etc., and funds are required for them. If the organization runs well and pays all the taxes on time, the government receives revenue. • Higher employment: One of the major responsibilities of any government is to ensure jobs for all their subjects. Hence, they expect the business units for which permissions are granted to enhance employment opportunities. • Employment for locals: The permission granted for our business to operate from here is to ensure job opportunities for the people in this area. You can bring people from outside but make sure that locals do not remain unemployed when they have the competence and are willing to perform that job. • Work stability: Any organization should have a stable working environment so that the government can work out the plans by projecting the figures depending on the trends. If the performance is fluctuating, no projections can be made as well as no decision can be taken. • Higher foreign exchange: The growth of a nation depends on its earnings from exporting its products and services. Hence, we need to export more and get foreign exchange to our government.
Public demand	<ul style="list-style-type: none"> • Clean environment: The communities around us do not want any pollution in the environment which can affect their lives. The industry should help in maintaining clean environment. Clean environment refers not only to air, water, noise, etc., it is also in the minds. The culture of the community should not be disturbed by the products, services, and the dealings of the organization. • No disturbances: The community wants to live peacefully and does not want any disturbances, such as strikes, traffic jams, economic imbalances, cultural imbalances, etc. A gradual improvement in economy is welcome. • Service to public: The public expects some service from the business being run in their area so that they can improve. Services such as helping in the development of schools, hospitals, roads, cultural activities, etc., are the normal expectations. • Help in running their business: A number of petty businesses, such as small hotels, shops, local conveyances like auto rickshaw/taxi, builders constructing houses with an intention of renting or selling them, and many others, depend indirectly on the organization. If the organization is running well, their businesses should also be running well.

Source: Purushothama, 2015.

4. Monitoring the needs

Interested parties are those which affect or have the potential to affect the organization's ability to consistently provide products that meet customers' requirements (Wolniak, 2011, 2013, 2014, 2016, 2017; Wolniak, and Hąbek, 2015; Wolniak, and Skotnicka-Zasadzień, 2010, 2015; Wolniak, and Sułkowski, 2015). The action planned by the organization achieve this include (Figure 2) (Natarajan, 2017):

- Determining the interested parties.
- Determining the needs and expectations of the interested parties.
- Monitoring and reviewing the needs and expectations of the parties.

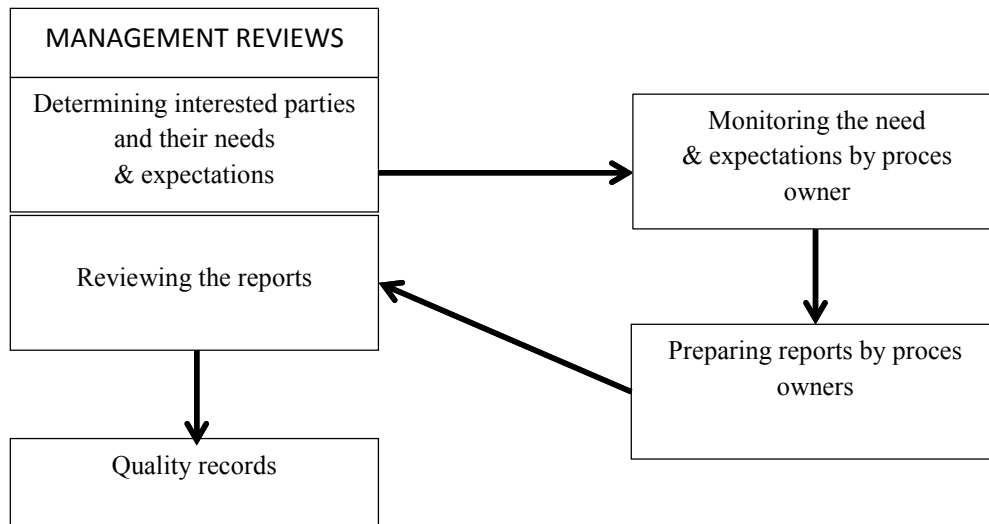


Figure. 2. Monitoring needs and expectation of interested parties. Source: Natarajan, 2017.

The scope of the organization's quality management system should be available and maintained as documented information. The scope of the implemented system shall state the types of products and services covered and provide justification for any requirements of the standard. While determining the boundaries and applicability of the quality management system, the organization should consider (ISO 9001:2015):

- the external and internal issues;
- the requirements of relevant interested parties;
- the products and services of the organization.

The first step in defining the organizational context can be an analysis of the whole business environment of the organization (Sułkowski, and Wolniak, 2018; Wolniak, and Sułkowski, 2015, 2016). In this process we should identify which internal and external environmental issues and interested parties are relevant to the organization. In this case we should identify the following factors (Table 4):

- political factors,
- economic factors,
- social factors,
- technological factors.

Table 4.
Factors influencing the organization

Factors	Examples
Political	<ul style="list-style-type: none"> • Ecological/environmental issues • Current legislation • Anticipated future legislation • International legislation (global influences) • Regulatory bodies and processes • Government policies, terms, and changes • Funding, grants, and initiatives • Market lobbying groups • Wars and conflicts
Economic	<ul style="list-style-type: none"> • National economies and trends • General taxation issues • Taxation of activities, products, services • Seasonality • Weather issues • Market and trade cycles • Specific sector factors • Customer/end user drivers • Interest and exchange rates • International trade and monetary issues
Social	<ul style="list-style-type: none"> • Lifestyle trends • Demographic trends • Consumer attitudes and opinions • Media views • Changes in laws that affect social behaviors • Image of the organization • Consumer buying patterns • Fashion and role models • Major events and influences • Buying access and trends • Ethnic/religious factors • Advertising and publicity • Ethical issues
Technological	<ul style="list-style-type: none"> • Competing technology development • Associated/dependent technologies • Replacement technology/solutions • Maturity of technology • Information and communications • Consumer buying mechanisms • Technology legislation • Innovation potential • Technology access, licensing, patents • Intellectual property issues • Global communication • Social media use • Maturity of organizations

Source: Own work on the basis of: (Abuhav, 2017).

The external and internal issues relevant to the organization are determined during management reviews. Top management assigns monitoring issues to appropriate process owners for monitoring. The process owner should monitor the issues and prepare appropriate reports indicating the methods and results of the whole monitoring process. If feasible,

appropriate metrics are also advised for presenting the results (Wolniak, 2016; Wolniak, and Skotnicka-Zasadzień, 2011, 2014). The reports are potential inputs for subsequent management reviews. The results of the analysis are evaluated in management reviews to decide the course of corrections (Ząbek, 2016; Żemigła, 2017). A quality manual is appropriate for documenting the procedure for understanding the organization and its context. The reports of process owners and the set of decisions of management reviews serve as the documented information (quality records), providing evidence for monitoring and reviewing the relevant issues. The procedure for monitoring and reviewing the external and internal issues is presented in Figure 3.

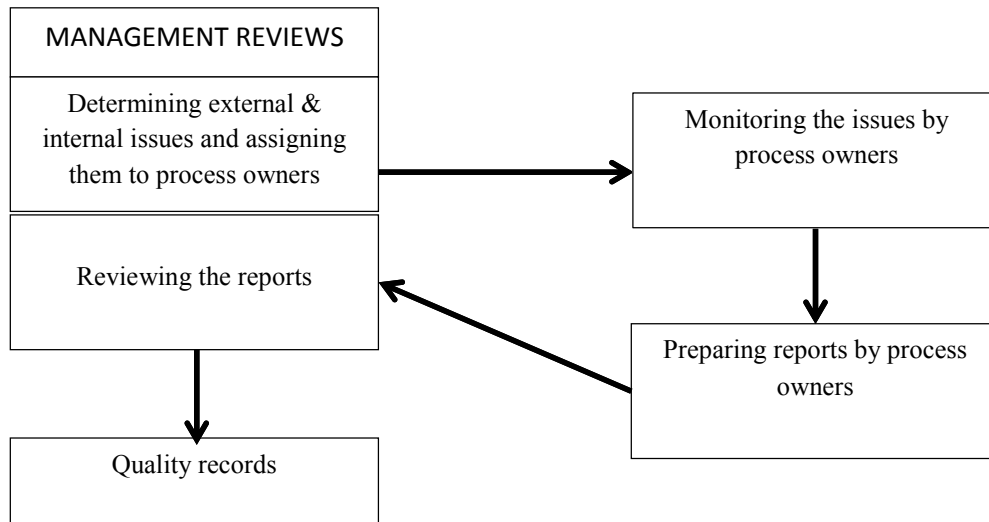


Figure 3. Monitoring external and internal issues. Source: Natarajan, 2017.

The organization shall establish, implement, maintain and continually improve the quality management system, including the processes needed and their interaction, in accordance with the requirements of the standard. To do this, the organization should conduct the following actions (ISO 9001:2015):

- determine the inputs required and the outputs expected from these processes,
- determine the sequence and interaction of these processes,
- determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes,
- determine the resources needed for these processes and ensure their availability,
- assign the responsibilities and authorities for these processes,
- address the risks and opportunities as determined in accordance with the requirements,
- evaluate these processes and implement any changes needed to ensure that the intended results of these processes are achieved,
- improve the processes and the quality management system,
- maintain the documented information to support the operation of its processes,
- keep the documented information to have confidence that the processes are being carried out as planned.

The important issue related to the implementation of quality management systems is that in order to deliver a compliant product or service and meet customer demand, a quality management system with the following specifications must be established and maintained (Abuhav, 2017; Sułkowski, and Wolniak, 2013; Szczucka-Lasota, and Wolniak, 2018; Szliel, 2016):

- It is based on the quality principles suggested in the ISO 9001 Standard.
- It is defined, planned, implemented, and controlled.
- It is customer-focused – the quality management systems should use methods to understand the present and future customer needs as well as develop processes to meet customer requirements and strive to exceed customer expectations.
- Its activities and processes address the needs and expectations of interested parties.
- Its resources are planned, allocated, and controlled.
- Its processes and activities are managed and whose interrelations are clear.
- It is constantly analyzed and controlled – data and information analysis is conducted and decisions are based on facts.
- It supports improvement through the collection of evidence and its analysis.
- It is fueled by top management leadership – it is through leadership that the purpose and strategic direction of the organization are established. Leadership shall create the environment for developing an appropriate quality policy in which employees can become fully involved and quality objectives can be achieved.
- People in the organization are aware of it.

The considerations for establishing the scope of the organization is illustrated in Figure 4. We can divide them into four main groups (Natarajan, 2017):

- Products offered: Broad categories of products offered by the organization are indicated.
- External and internal issues that would be monitored: Issues relevant to the quality management systems of the organization are included in the scope appropriately.
- Requirements of interested parties that would be monitored: The requirements of interested parties relevant to the quality management systems of the organization are addressed in the scope appropriately.
- The applicability of all requirements of ISO 9001: The requirements of ISO 9001 are examined whether they are all applicable for the organization or not. The exclusions to ISO 9001 are indicated with justifications.

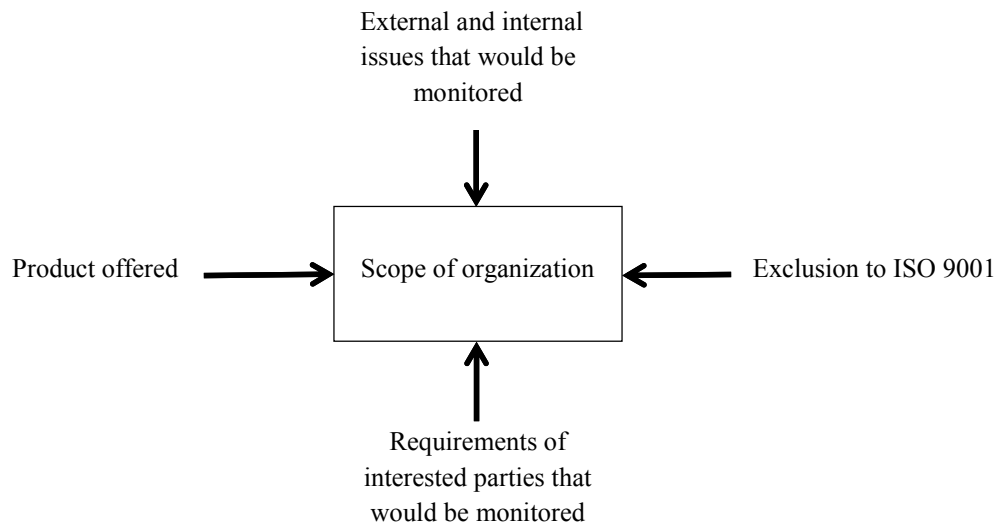


Figure 4. Monitoring the needs and expectations of interested parties. Source: Natarajan, 2017.

The scope of the quality management system will relate to the following issues (Abuhav, 2017).

- The products or services covered by quality management systems and delivered by the organization to its customers.
- All the applicable implementation activities that will be covered by the quality management systems: research and development, production, marketing, installation, service, and support.
- Locations of the organizational units that will be covered by the quality management systems (if applicable). Each location included in the scope must be audited separately.

5. Conclusion

On the basis of the analysis included in the paper it can be said that we can distinguish four main factors in the context of influencing the organization: political, economic, social and technological. Each of them has its own influence on the organization, its functioning and the whole ISO 9001:2015 system within. When the organization establishes the quality management system, it should to improve it in such way as to fulfill all the needs and expectation of the interested parties. The following four problems should be monitored: product offered, exclusions to ISO 9001, external and internal issues and the requirements of interested parties.

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