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Applying Theoretical-Methodological Tools for the Implementation of ISO 9001: 2015 Clause 4 Context of the Organization

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Nowadays, in order to satisfy the ISO 9001: 2015 requirements, organizations access to information from web sites, consultant guides, Internet forums, books, and courses, as a first approximation, however, the quality, reliability, validity, and accuracy of the information content in these is limited. The research topic of this study is the use of theoretical methodological tools, whose implementation supports the organizations in the fulfillment of requirement 4 of ISO 9001: 2015, adapting it to their particular needs, minimizing rework in the documentation, increasing the motivation of the personnel involved and promoting well-being within the work environment. Some theoretical methodological tools were implemented in the case of Engineering laboratories of the Faculty of Higher Studies Aragón, that support and complement the teaching-learning process in the theoretical-practical subjects of the curricula of the engineering bachelor's degrees, providing students with practical training in the use of equipment, devices, and tools, as well as extracurricular courses. In the study participated the stakeholders of laboratories. From the results, it was observed that the time for the documentation of the quality management system was reduced using the theoretical tools proposed in this study. In conclusion, this study will thus be useful as a starting point in using formal tools for the implementation of ISO 9001: 2015 standard.

Keywords: quality management system, ISO 9001, internal analysis, external analysis, methodology, stakeholders

Introduction

As Dale, Van der Wiele, and Van Iwaarden (2007) explain: the purpose of a Quality Management System (QMS) is to establish a framework to ensure that every time a process is developed, the same information is used and the same methods are applied, tools and controls, consistently. In this direction, ISO 9000, is a family of international standards inherent to QMS, created to support organizations of any nature to standardize their processes, measure their performance, promote the achievement of objectives, provide their customers with products and services that meet their needs, as well as promote continuous improvement in a consistent manner,

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which can enable them to be competitive globally. ISO 9001, firstly released in 1987, is the standard from the ISO 9000 family that establishes the criteria of the QMS. The structure of ISO 9001 indicates the minimum requirements necessary for the design and implementation of a QMS. It focuses on all the elements of quality management that an organization must have in order to manage and improve the quality of their products and/or services.

The 2015 version of ISO 9001 consists of 10 requirements according to ISO (2015): Requirement 1 Scope; Requirement 2 Normative references; Requirement 3 Terms and definitions; Requirement 4 Context of the organization; Requirement 5 Leadership; Requirement 6 Planning; Requirement 7 Support; Requirement 8 Operation; Requirement 9 Performance evaluation; Requirement 10 Improvement. The last few years have witnessed how ISO 9001 QMS has been used by organizations to improve their performance (Santos, Costa, & Leal, 2012; Martínez-Costa, Choi, & Martínez, 2009). It has been shown that companies have implemented an ISO 9001 QMS, and they also have obtained a long time increment in their investment and improvements in productivity and competitiveness. Derived from the last version of ISO 9001 released in 2015, organizations are forced to update or implement a QMS. In order to satisfy the ISO 9001: 2015 requirements, organizations access to the information from IAF (International Accreditation Forum Guides) and ISO Guidelines, however they are not aware of it. Additionally, information from web sites, consultant guides, Internet forums, books, and courses, etc., can serve as a first approximation or best practices. However the quality, reliability, validity, or accuracy of the information presented is limited. Little attention has been paid to the use of theoretical tools that indicate the way in which the implementation of ISO 9001: 2015 should be carried out. Therefore, organizations are immersed in the problem of interpreting empirically the ISO 9001: 2015 requirements. In fact, standard does not establish the application of theoretical tools or methodologies for its implementation. Although much has been learned empirically about the implementation of ISO 9001 over the last 30 years, many important issues remain unresolved as the use of methodological tools to guarantee an successful implementation, otherwise organizations will incur on expenses, failures, confusion and loss of time. The purpose of the present paper is to apply the theoretical methodological tools, whose implementation supports the organizations in the fulfillment of requirement 4 of ISO 9001: 2015, adapting it to their particular needs, minimizing rework in the documentation, increasing the motivation of the personnel involved, and promoting well-being within the work environment.

This study is divided into three main sections. Firstly, the literature review is provided, followed by the research methodology that includes the theoretical-methodological tools for the implementation of ISO 9001: 2015 Requirement 4 Context of the Organization, then the research results from the implementation of the ISO 9001: 2015 Requirement 4 in a case of study are presented, and finally the conclusions are outlined.

Literature Review

The majority of ISO 9001 certification research studies conducted so far are supported by surveys; analysis of financial indicators; case studies; interviews; literature review; and statistical data analysis (Sampaio, Saravia, & Guimarães Rodrigues, 2009). For instance, Mo and Chan (1997) investigate the factors influencing the process of ISO 9000 certification for small and medium-sized manufacturers and identify the critical issues inhibiting its implementation. Poksinska, Dahlgaard, and Antoni (2006) evaluate results from a survey on ISO 9000 certified companies in Swedish industry. The predominant reasons identified for seeking certification were the desire to improve corporate image and quality. The study underlines the need for management

commitment and participation. The benefits that the companies gain from the standard showed dependence on the motivation which initiated the drive for the certification. More recently, Ochieng, Muturi, and Njihia (2015) carried out a study to establish the effect of ISO 9001 implementation on the performance of organizations in Kenya. Results of the survey revealed that ISO 9001 certification influenced return on net assets of the organization thereby influencing their performance. The finding of the study provided justification for adoption of ISO 9001 standard in organizations in all key sectors of the Kenyan economy for sustained quality management practices.

This study is of relevance, a lot of organizations through the world need to adopt the ISO 9001: 2015 to their QMS, but they do not know the existing formal tools that can be used so their implementation cost is not optimized. Since the adoption of ISO certification in organization over a decade ago, no study has been carried out that suggests the use of theoretical frameworks to ensure compliance with the requirements. This study will thus be useful as a starting point in using formal tools for the implementation of ISO 9001: 2015 standard.

Research Methodology

The structure of ISO 9001: 2015 Requirement 4 describes the minimum requirements necessary for the development of an SGC. It focuses on all elements of quality management that an organization must have in order to have an effective system that allows it to manage and improve the quality of its products and/or services, but does not establish a methodology to follow. However, from the literature it was found that a useful tool is association of the systemic approach and the theoretical-methodological tools.

Theoretical Methodological Tool to Implement Sub-requirement 4.1 of ISO 9001: 2015

Audit, diagnosis, and mission. In order to describe briefly the organization and its historical context, it needs to take into account the following aspects: identification data (name or business name, location, sector to which it belongs); organizational structure; organizations with which it interacts; date of establishment, founders, budget; products or services offered; the organization's mission and vision. On the one hand, Fuentes (1994) proposed that when establishing the mission, it is necessary to consider at least one of the following points: (1) Field of action: it is the axis of the business and therefore of the mission, including what products or services are offered, what type of clients are targeted, and in what geographical area is involved; (2) Basis of success: What distinguishes an organization to be preferred by customers?; (3) The philosophy of the firm: principles and values of the organization, as well as the contribution and responsibility towards society. It also tells us what the organization is committed to its employees and what is expected of them; (4) Fundamental achievements: position of the organization in the middle; (5) Emblem: symbolic figure the motto. On the other hand, the vision of an organization allows us to visualize the aspirations of the organization. According to Fuentes (1994), several of the following challenges could be considered when the vision of an organization is stated. For instance, the expansion and/or strengthening of business, new products, customers, or markets, boosting competitive capabilities, the internal or external integration, principles and values to be enhanced, commitment for those involved, and the big goal, the most significant results expected.

Internal analysis. As discussed by Valdés (2005), the internal analysis of an organization can be obtained from the identification ofgoods and services offered by the organization as well as its characteristics and how they are controlled; the internal customer and their requirements; the competition and its characteristics; the functions, responsibilities, scope, functioning, regulations, and work distribution; the competence of the

personnel with respect to the process that operates, since of these benefits can be released many strengths; the infrastructure as for example, the equipment and facilities and by consensus to define whether they are adequate, sufficient or need to update. It is important to note that ISO 9000: 2015 defines the competence of staff as the ability to apply knowledge and skills, in order to achieve the expected results. Also, ISO 9000: 2015 defines infrastructure as the system of facilities, equipment, and services necessary for the operation of the organization. In order to define infrastructure strengths and weaknesses, it is recommended to make an inventory with respect to buildings and associated services, equipment, machines, measurement devices, information and communication technologies; the organization should seek a consensus mechanism to determine the pertinence, adequacy, and sufficiency of the infrastructure.

External analysis. For organizations, by external it is considered everything that surrounds the organization but goes out of its control. It should include aspects such as economic, political, social, cultural, technological, scientific, labor, market, etc. To carry out this analysis and given that both the organization and its product are different from any other, a working group should be formed and the first step will be to define what the organization understands for each of these aspects from its perspective. Once defined and identified by the organization, the most relevant news of these concepts should be given to the task of investigating in current sources such as magazines, periodicals, research papers, etc. To determine the impact of these environments on the organization, it is necessary to analyze what situations pose a threat to the organization and what an opportunity.

Matrix SWOT. Based on the external analysis, there is already a fairly strong picture regarding Strengths and Weaknesses (internal analysis) and Opportunities and Threats (external analysis). On the one hand, Valdés (2005) makes the point to start with those that with the highest degree help the organization to achieve its mission and in the last place the least contribution. On the other hand, Ponce (2007) points out listing only those considered by the organization as a key.

Generic lines of action. The SWOT cross-impact matrix is useful to determine the actions called generic action lines or strategies (Valdés, 2005; Ponce, 2007). FO strategies should apply the internal forces of the organization to take advantage of external opportunities. OD strategies overcome the weaknesses of the organization taking advantage of external opportunities. FA strategies let the organization's forces to minimize threats external. DA strategies are defensive tactics that seek to reduce internal weaknesses and avoid the threats of the environment.

Management Tool Used to Implement ISO 9001: 2015 Sub-requirement 4.2

Relevant stakeholders are all those people who add value to the company or are affected by the activities of the company. They should therefore be considered as customers, owners, suppliers, trade unions, (regulators), partners, society (as recipients of knowledgeable students), competitors, pressure groups, etc. For instance, all those interested parties could be affected by the decisions taken by the organization or the scope of the GSC. To determine the relevant stakeholders of the quality management system will be necessary to link them with the processes of the system with which they interact and their importance within it, it is suggested for their proper identification that the organization asks the following questions:

Can your activities affect the service/product? Can your activities disrupt the process? The organizational chart is suggested as a good source of information for stakeholder determination.

Theoretical-Methodological Tool to Implement Sub-requirement 4.3 of ISO 9001: 2015

Sub-requirement 4.3 of ISO 9001 states that the scope of the quality management system should describe the types of products and services provided by the organization (extension), the limits should clearly indicate processes, facilities, departments and/or divisions to which the QMS will be applied. If any ISO 9001: 2015 requirement needs to be applied to the organization, it should be indicated (applicability) together with the justification of why it does not apply. The theoretical methodological tool that is proposed to be used to achieve this sub-requirement is the Rummler-Brache superstructure model (Rummler & Brache, 2013). In the model the organization is presented as a system that transforms inputs into a service, which is delivered to its client, it must be considered that the system is in a social, economic, and political scenario. According to the Rummler-Brache methodology (Rummler & Brache, 2013) one should identify the processes, the stages of each process through SIPOC (Suppliers, Inputs, Processes, Outputs, and Customers), the necessary environment elements, the functional elements, and the relationships between elements. The model includes workflows (processes) that allow us to see the relationships between the areas. A SIPOC diagram is usually drawn to map a process at a high level (Pyzdek, 2003). Also, SIPOC allows the implementation of the process approach as it describes the stages of a process from its inputs. This diagram identifies the inputs (I) necessary for the process to be executed, who is the supplier (S) of those inputs, who is the client (C) of that process, the process activities (P) and once executed, what is the expected result (O).

Theoretical-Methodological Tool to Implement Sub-requirement 4.4 of ISO 9001: 2015

The ISO 9001: 2015 standard emphasizes the approach to processes and asks to identify the inputs and the outputs of the processes as well as the determination of criteria and methods necessary to assure the effective operation and the control of the same ones. The process map is a graphic diagram, which represents the different processes that the organization uses to operate and perform its functions and which offers a common view of the management system of an organization. For this, the organization analyzes the different activities that it performs and identifies its processes, which it classifies according to its purpose in ISO/TC 176/SC 2 N544R3. The different processes are distinguished as following: process for the management of the organization, process for the management of resources, process of realization, and the process for measurement, analysis, and improvement.

Research Results

Implementation of ISO 9001: 2015 Sub-requirement 4.1

Diagnosis and mission of the Engineering laboratories of the Faculty of Higher Studies Aragón. Name of Organization: Faculty of Higher Studies Aragón (FES Aragón). The Engineering laboratories support the curricular subjects of each of the Engineering careers offered at the Faculty and were created to meet the needs of practical academic activity demanded by their curricula, as well as the additional preparation required by the labor market to which its graduates are oriented (Quality Manual, FES Aragón). At the Laboratory of Design and Manufacturing (L1), practices are given to complement the training of students in the management of different equipment and techniques of metal-mechanic manufacture and other types of materials such as conventional cutting and cutting machines, welding, forging, milling, and casting. In this laboratory attends to the students of the Race of Mechanical Engineering and Industrial Engineering. At the Laboratory of Thermal and Fluids (L2), the student performs various activities that allow him to corroborate and complement the

knowledge acquired in the theoretical class of the subjects related to it. In this Laboratory the practices of Thermodynamics, Thermo Fluids, Thermal Machines, and Physicochemistry are taught. In this laboratory the practices are given for the students of the Career of Mechanical Engineering, Electrical and Electronics Engineering, and Industrial Engineering. At the Laboratory of Electrical-Electronics (L3) only the areas Electricity and Magnetism, Analysis of Electrical Circuits, Measurement and Instrumentation, Control, Digital Communications, Communication Systems and Filtering and Modulation are within the scope of the QMS. The laboratory has the purpose of preparing students in a practical way, in the areas of electricity and electronics for the solution of engineering problems. In this laboratory, students are given practical training in Computer Engineering, Electrical and Electronics Engineering, Mechanical Engineering, and Industrial Engineering. At the Laboratory of Civil Engineering (L4) practices are given to complement the training of the student in the management of different equipment and techniques of the construction industry: soil and rock tests, materials technology, hydraulic tests, planimetry, altimetry, etc. In this laboratory practices are given for the students of the Civil Engineering Career. Finally, the CAE504 center is a physical space belonging to the Computer Engineering Career, created to meet the practical activity needs of the career and support the teaching-learning process of students with courses that complement their professional training.

The L1, L2, L3, L4 and CAE504 Engineering Laboratories support and complement the teaching-learning process in the theoretical-practical subjects of the curricula of the engineering bachelor's degrees, providing students with practical training in the use of equipment, devices, and tools, as well as extracurricular courses, which allows them to solve the present and/or future problems and needs of the country, both in the national and international context. In the year 2035, the laboratories are intended to be an institutional reference point offering quality services through efficient management of their processes under ISO 9001: 2015, supported by teachers with a sense of belonging to the Faculty, contributing to the integral formation of innovative engineers and with high social responsibility.

Internal analysis of the Engineering laboratories of the Faculty of Higher Studies Aragón. The engineering laboratories of FES Aragón have identified three services, one for L1, L2, L3, L4 engineering laboratories and two for the CAE504 center. On the one hand, the engineering laboratories offer the support service for the execution of the practices of each one of the careers that they attend respectively. On the other hand, the CAE504 center supports the Computational Engineering career programming the curricular classes. Also, the CAE504 performs the management of extracurricular courses offering students during the inter-semester a series of courses that help complement their curricular learning.

External analysis of the Engineering laboratories of the Faculty of Higher Studies Aragón. To carry out this analysis a working group was formed to define what the organization understands for each of these aspects from its perspective. Economic, political, and social aspects were considered. Economic aspects: factors that influence the allocation, distribution, and operation of the budget allocated to the division. For instance, Federal budget assigned to the Faculty of Higher Studies Aragón, exchange of dollar, Mexican economic situation, increment of student population, etc. Political aspects: factors related to the national and international political environment that affects the activities, operation, and prestige of the Faculty of Higher Studies Aragón. For instance, governmental elections at federal, state, and municipal levels, decisions-making by politicians affect the Faculty of Higher Studies Aragón, legislative reforms, etc. Social Aspects: factors such as social segregation, economic means, security, and coexistence that influence the provision of the service, social manifestations, insecurity, etc.

Matrix FODA of the Engineering laboratories of the Faculty of Higher Studies Aragón. The strengths and weaknesses (internal analysis) and opportunities and threats (external analysis) are listed below. Those that with the highest degree help the Engineering Laboratories of the Faculty of Higher Studies Aragón to achieve its mission and in the last place the least contribution.

Internal analysis. Strengths: adequate human resources to attend to laboratory practices, sufficient infrastructure to attend students, commitment of stakeholders, and planning and control of inputs. Weaknesses: the equipment of some laboratories is not sufficient to carry out the practices, technical equipment is not up to date, some manuals missing in laboratories, some students and teachers do not use the internship manuals.

External analysis. Opportunities: generation of extraordinary economic resources, extra training in quality systems, certification ISO 9001: 2015. Threats: student mobility, national economy, increase in number of students, low budget, loss of collaboration agreements.

Implementation of ISO 9001: 2015 Sub-requirement 4.2

Table 1 shows the relevant stakeholders of the Engineering Laboratories of the Faculty of Higher Studies Aragón and the processes in which they are involved. The student population attending the classes at the laboratories, were distinguished mainly from professors, the Head of the Division, the Department of Quality Verification, the Technical Secretary, the Management Secretary, and the Purchasing Department.

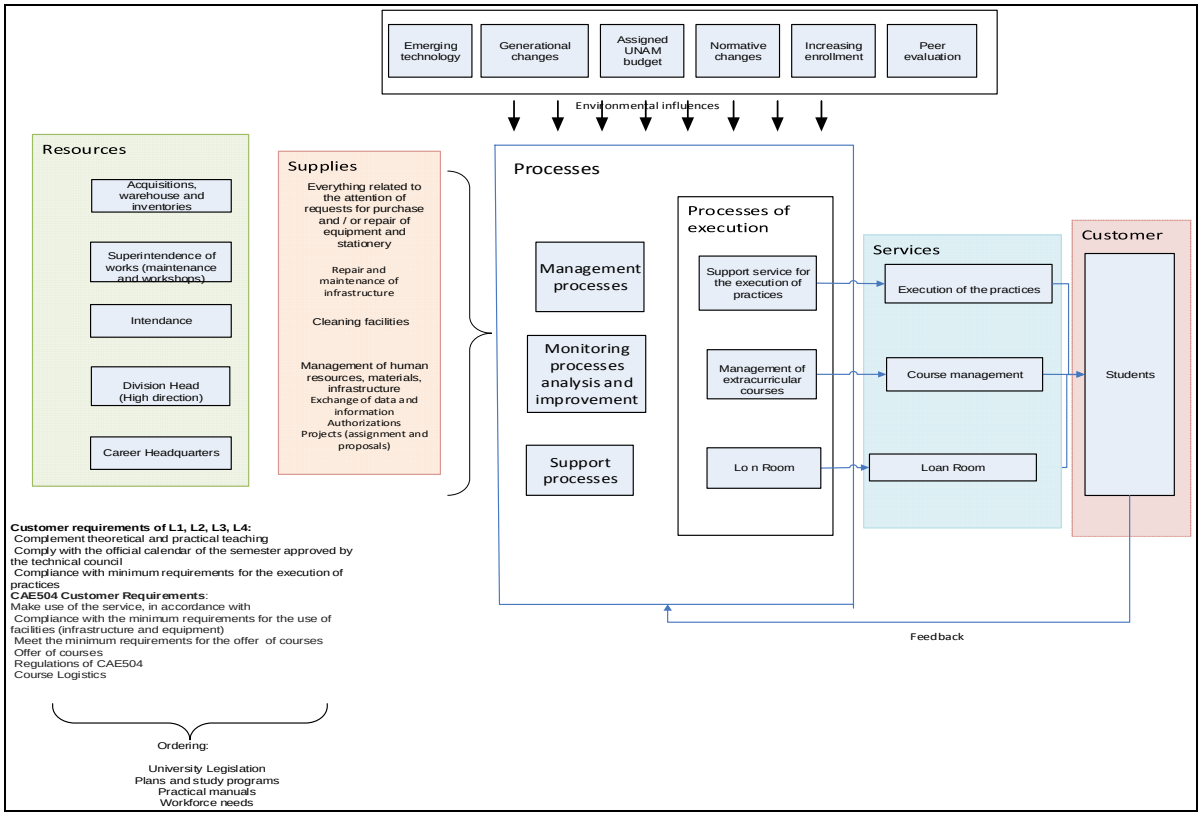

Figure 1. Interaction among process of the engineering laboratories, FES Aragón.

Implementation of ISO 9001: 2015 Sub-requirement 4.3

To implement the sub-requirement 4.3 of ISO 9001: 2015 at the Engineering Laboratories of the Faculty of Higher Studies Aragón, the theoretical methodological tool proposed by Rummler and Brache (2013) was

used. As seen in Figure 1, the laboratories are presented as a system that transforms inputs into a service, which it delivers to students. The processes, the stages of each process through SIPOC, the necessary environment elements, the functional elements, and the relationships between elements, were identified. The model includes workflows (processes) that allow us to see the relationships between the areas.

Table 1

Main Stakeholders of the Engineering Laboratories, FES Aragón

Stakeholder	Process
Student	Management/support/analysis and improvement
Laboratory professor	Management/support/analysis and improvement
Head of the division	Management/monitoring/analysis and improvement
Department of quality verification	Management/support/analysis and improvement
Technical secretary	Management/support
Management secretary	Management
Purchasing department	Support

Implementation of ISO 9001: 2015 Sub-requirement 4.4

In order to identify the inputs and the outputs of the processes of the Engineering Laboratories, FES Aragón as well as the determination of criteria and methods necessary to assure the effective operation and the control of the same ones, a processes map illustrated by Figure 2 was designed.

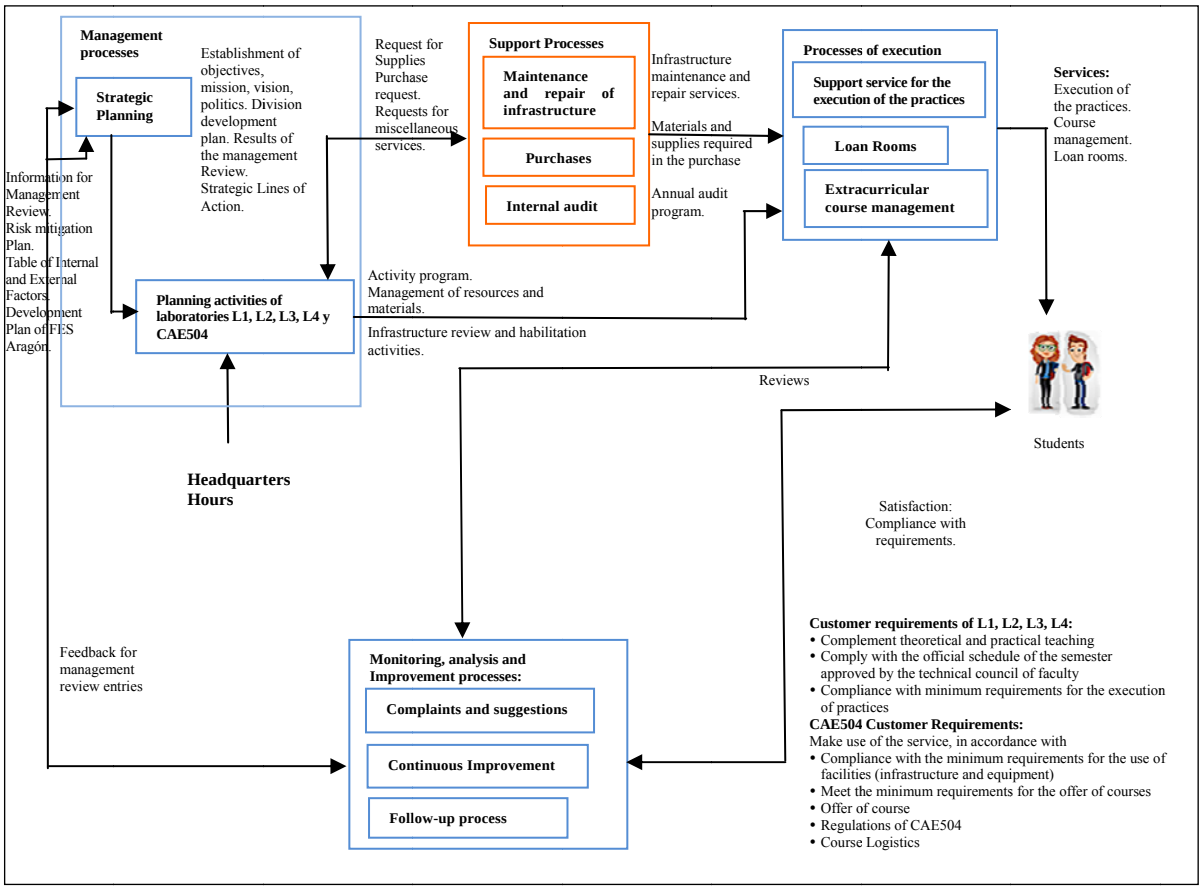

Figure 2. Processes map of the engineering laboratories, FES Aragón.

Conclusion

The main contribution of this study was the application of theoretical methodological and management tools to implement the Requirement 4 Context of organization of ISO 9001: 2015 standard in the Engineering Laboratories of the Faculty of Higher Studies Aragón. Each tool provided an overview of laboratories, with their internal and external interactions, as well as going into the organization to the subsystems themselves, resulting in a very complete process analysis. The theoretical methodological and management tools facilitated the implementation of the Requirement 4 Context of organization of ISO 9001: 2015, the implementation time was minimized, the frustrations of stakeholders were eliminated, and the work was done just once. In conclusion, this study will thus be useful as a starting point in using formal tools for the implementation of ISO 9001: 2015 standard.

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