A Novel Implementation Framework for ISO 9001: 2015

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Abstract

This study proposes an alternative implementation method for ISO 9001:2015 by using knowledge transfer best practice as basis for the development of an implementation framework. ISO 9001 is by far the most widely implemented ISO management system with an implementation base of 1.1 million accreditations worldwide, and benefits of ISO 9001 accreditation are well researched. Despite this, implementation of the standard is at times superficial. It has been shown that diagrams assist with learning in preparation for a biology test. Though the environments are very different, organizational learning and therefore the ability to implement ISO 9001 requirements, might also be more effective if information is presented in a diagram or flowchart form. This principle was applied in the development of an alternative implementation framework in the form of an interactive and editable flow chart. This approach promotes the sustainable integration of requirements into existing operations. The benefits of certification and barriers to implementation of ISO 9001 are well established. However, there is a gap in literature on implementation methods for ISO 9001. This study will be a valuable contribution to the ISO 9001 body of knowledge. Companies seeking or maintaining ISO 9001:2015 accreditations would find this model useful.

1. Introduction

The International Organization of Standardization (ISO) 9001 management standard is the most widely implemented ISO management system with an implementation base of 1.1 million accreditations across the world (Figure 1). The next largest implementation base being ISO 14 001, is standing at a quarter of ISO 9001's implementation base (The ISO Survey of Management System Standard Certifications, 2016).

Two factors can be attributed for this wide implementation base:

1) Increasingly ISO 9001 is becoming a pre-requisite for doing business in both the private and public sector (McAdam & Canning, 2001).
2) In addition, ISO 9001 is generic in nature and therefore applicable to all industries.

This is no different for ISO 9001 accreditations within South Africa. The number of accreditations in South Africa (SA) have steadily increased over the years as can be seen in Figure 2. When last measured in 2016 the number of ISO 9001 accreditation was standing at 4761 accreditations across all industries (The ISO Survey of Management System Standard Certifications, 2016).

The advantages of ISO 9001 accreditation are well established (Rusjan & Alič, 2010). However, researchers have also found numerous barriers to implementation, such as senior management's understanding and attitude towards ISO 9001 (Yeung et al. 2003), and cases of superficial implementation (Zeng et al., 2007).

Although benefits and barriers to implementation are well researched, there exists gaps in the literature as to how to address these barriers. The aim of this research is therefore to put forward an alternative implementation framework to promote internalization of ISO 9001:2015 requirements for sustainable implementation. Knowledge transfer best practice will be utilized to assist with the development of this framework. The framework was developed for a South African State Owned Enterprise (SOE), however it is generic in nature and can be applied to any environment.

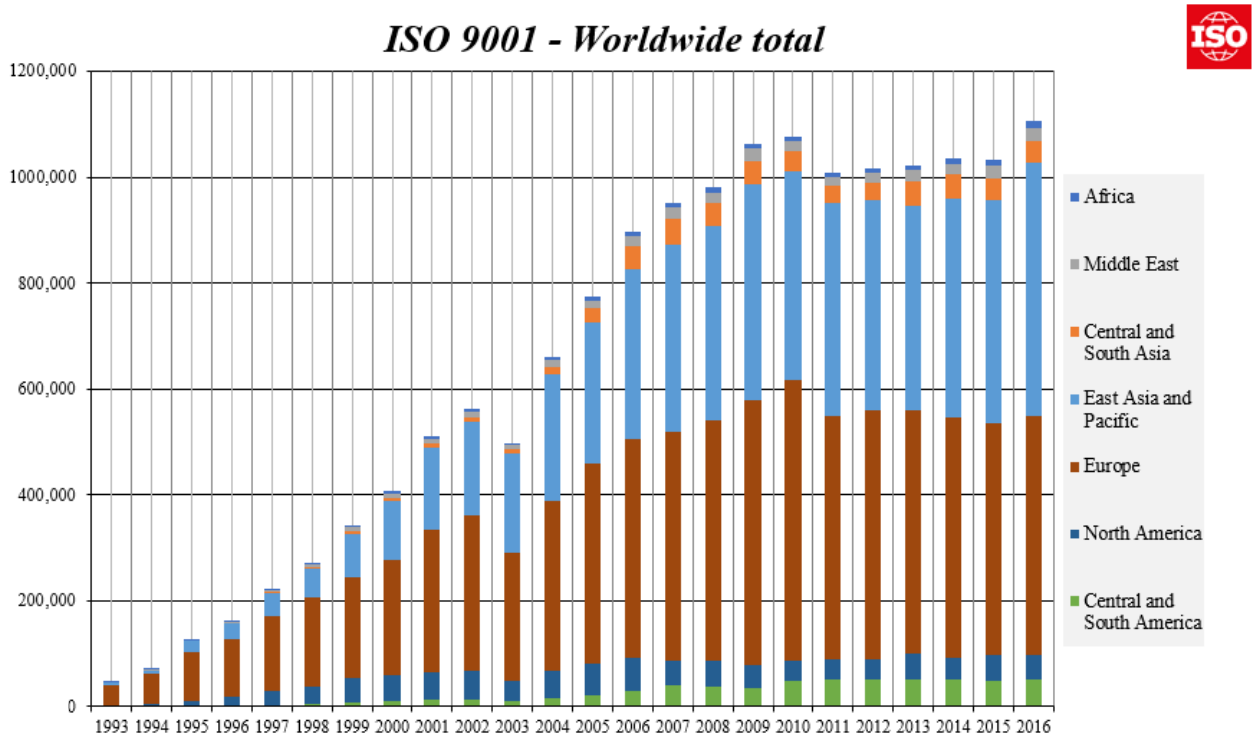

Figure 1: Number of ISO 9001 accreditations worldwide (The ISO Survey of Management System Standard Certifications 2016)

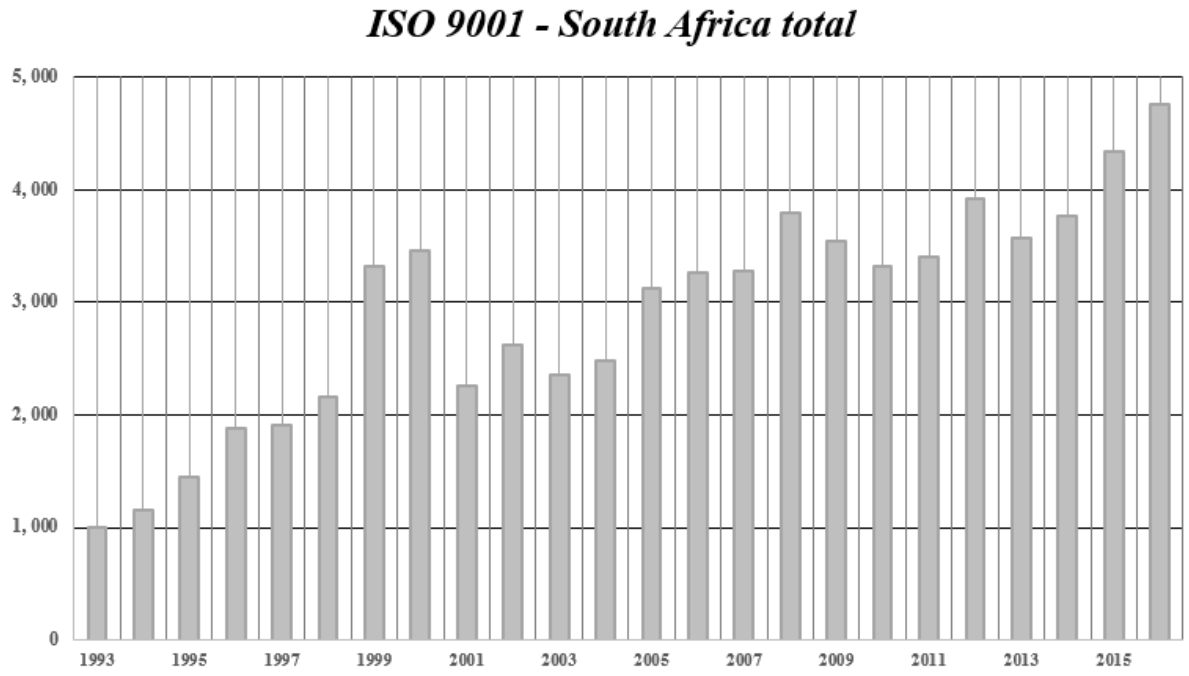

Figure 2: Number of ISO 9001 accreditations in South Africa (The ISO Survey of Management System Standard Certifications, 2016)

2. ISO 9001 in South Africa and the State Owned Enterprise context

When compared to other BRICS countries (Brazil, Russian Federation, India and China), South Africa (SA) has a similar index score in terms of "number of citizens per accreditation" as Brazil (Table 1). Also note that even though SA has a comparable "total number of accreditations" as the Russian Federation, SA has a much higher adoption rate. In terms of the BRICS countries SA has a mid to high adoption of the standard. Notwithstanding this high adoption rate, there is limited published research in existence with regards to ISO 9001 in both the South African public and private sector.

Table 1: BRICS citizens per accreditations

Country	Total number of ISO 9001 accreditations in 2016 [1]	Population total for 2016 [2]	Number of citizens per accreditation
China	350 631	1 403 500 365	4 003
Brazil	20 908	207 652 865	9 932
South Africa	4 761	56 015 473	11 765
Russian federation	5 083	143 964 513	28 323
India	37 052	1 324 171 354	35 738

[1] The ISO Survey of Management System Standard Certifications (2016)

[2] World bank (2016)

Apart from a studies by Smith (2013) and Turner et al. (2000), there is not much published research on ISO 9001 implementation within the South African context, let alone State Owned Enterprises (SOEs).

Smith (2013) investigated quality management performance at Eskom's Nuclear Power Station with a specific focus on the audit monitoring program. Internal auditing is part of the requirements of ISO 9001. Eskom is a South African State Owned power utility. The study involved looking at the effective use of the data generated by the audit monitoring program. It found that the data was being underutilized, and that by including theming and additional severity metrics during analysis of audit results, this information can be better utilized by leadership in providing high level strategic direction. Findings by Smith (2013) suggest that more value might be derived from ISO 9001 accreditations at SOEs. This is consistent with the aims of this study.

Turner et al. (2000) did a study on ISO 9000 accreditations among South African Agricultural businesses. It was found that firm size was the most significant variable distinguishing between businesses that acquired an ISO 9000 certification and businesses opting to for an alternative quality related accreditation. This study represents the sum of peer reviewed published research on ISO 9001 in the South African context. In light of this, there is still immense scope for more research to be conducted on ISO 9001 in both the South African public and private sector. This is especially relevant considering the growth in accreditation numbers in South Africa.

3. Implementation considerations

The advantages of ISO 9001 accreditation are well established. Rusjan & Alič (2010) found the following benefits upon doing a review of empirical research done up to 2010:

- Reduction of potential negative effects as a result of non-conformances identified
- Reduction in operational costs as a result of continuous improvement of operations
- Increased revenue due to improved quality of products and the assurance of better quality due to certification
- Performance enhancement from improved efficiency leading to better profitability and return on investment

Yeung, Lee & Chan (2003) showed through an empirical study that "attitudes to implementation" and "confidence of understanding", both among senior executives, are the most influential factors to successful implementation of ISO 9001. It is therefore critical to take leadership's "understanding" and "attitude" into account during the development of an ISO 9001 implementation initiative.

Sampaio et al. (2012) found that depending on their motivation for certification, quality managers had difficulty quantifying the financial benefit gained by companies as a result of an ISO 9001 certification. If their motivation was internal, that is to say that they were seeking certification in an effort to improve their outputs, then quality managers

were unable to quantify the benefit gained. If the source of motivation was external, for example if the organization requires certification in order to qualify for tenders, then the benefit was easy to quantify since their customer base and turnover increased specifically due to obtaining accreditation.

Zeng et al. (2007) found that 63% out of 125 Chinese companies' Quality Management System (QMS) was perfunctorily implemented. The most pertinent barrier as reported by 42% of the companies surveyed was "Short-sighted goal(s) for 'getting certified'". The motivation for seeking certification therefore remains external to the company. Even though initial benefit is easier to quantify it may lead to a QMS that is superficially implemented and that does not in actual fact contribute to the performance of the organization. Note that state owned entities made up 37% of the sample size for this study. This was the largest group amongst the ownership type category.

There are countless factors influencing a company's performance. For organizations fostering an internal motivation for seeking accreditation, it is extremely difficult to isolate how any one improvement initiative impacts performance. This is consistent with findings by Sampaio et al. (2012) discussed earlier. It is not to say that accreditation does not hold benefits for an organization, but merely that benefit from accreditation are difficult to quantify.

Biazzo (2005) investigated what he calls "ceremonial conformity" in the Veneto region of Italy. He found evidence of auditors merely assessing whether a company's documented processes complies with requirements on a superficial level, rather than checking whether they are an effectively capturing organizational best practice. This approach does not add value to the organization being audited nor the customers they serve.

In addition Lee & Palmer (1999) found that implementing and maintaining an ISO 9001 accreditation demands considerable effort and there are many challenges involved. The study found that for large companies, the most pertinent challenges are:

- Monitoring employees everyday adherence the standards requirements
- Quantity of paperwork
- The organizations documented processes do not reflect employee's actual activities

Since implementing and maintaining an ISO 9001 accreditation takes considerable effort it follows that organizations would naturally want to maximise on the benefits gained from this effort. Allur et al. (2014) found that this could be achieved through proper internalization of the standard's requirements. They found that a higher level of internalization of ISO 9001 requirements yield greater benefits for organizations. Furthermore they assert that companies should implement ISO 9001 with the aim of improving everyday operations. This is as opposed to doing the minimum mainly for compliance reasons which also requires considerable effort.

This does raise the question as to how this internalization can be achieved. It is clear that a considerable further benefit can be derived if organizations turn their motivation inward and seek to implement ISO 9001 in a way that creates real quality improvement and assurance. However it is unclear how this can be done practically. Work by Ainsworth & Loizou (2003) potentially provides a clue. They found that in preparation for a biology test, learning is more effective when information is presented in diagrams. Though the environments are very different, one may speculate that organizational learning and therefore ability to implement ISO 9001 requirements, might also be more effective if information is presented in a diagram or flowchart form. A diagrammatic or flowchart type implementation framework can possibly assist by promoting better internalization of requirements into existing operations.

Studies on implementation methods for ISO 9001 could not be found in literature. This is possibly because the implementation methods are mostly generic and therefore not distinguished and defined in literature. Rather, the benefits of certification (Rusjan & Alič, 2010) and barriers to implementation (Zeng et al., 2007) of ISO 9001 implementation are studied, though a means of overcoming these barriers could not be found in the literature. This study endeavours to contribute to filling the gap by putting forward a novel implementation framework.

4. ISO 9001:2015 Implementation framework

4.1. Aims

A novel implementation method is proposed where the requirements for ISO 9001:2015 are presented in flowchart format, that is editable for leadership to populate with information from their own environments. This is as opposed to traditional implementation methods where requirements are presented in a checklist format. In the checklist, an interpretation of the standard's requirements is listed. Departments are assessed to determine their level of compliance and gaps are addressed through an action plan

Superficially implemented QMS have been found to be a major issue among Chinese companies (Zeng et al., 2007) with 63% of implementations assessed found to be superficial. As previously discussed, research by Ainsworth & Loizou (2003) found that knowledge transfer is more effective when information is presented in a diagram form as opposed to in paragraph form. Knowledge transfer by means of the common checklist implementation method is consistent with presenting information in a paragraph form. It may be asserted that the checklist implementation method is not the best practice for communicating ISO 9001:2015 requirements since it presents requirements in a way that is foreign and disconnected from the existing operations. This can potentially lead to superficial implementation of ISO 9001 requirements. By using the concept as proposed by Ainsworth & Loizou, the framework will communiate ISO 9001:2015 requirements more effectively by presenting these requirements in a flowchart format.

Recent research by Allur et al. (2014) finds substantial evidence that greater benefits are derived from an ISO 9001 accreditation if there is a higher level of internalization of the standards requirements. In contrast to the checklist implementation method that creates a situation where the QMS is external to the operations of an organization, the proposed implementation framework will promote internalization by placing the operations of an organization at the centre of the QMS. Subsequently, the aim is to lead managers through the requirements of ISO 9001:2015 on exactly how these requirements relate to their environment. The concepts as discussed above was utilized in the development of the proposed implementation framework.

4.2. Target audience

Yeung et al. (2003) found that the most significant factor for the development of a QMS is senior management's confidence in understanding of the ISO 9001 standard. For this reason it is important to take leadership's perspective into account in the development this framework. However note that this finding pertains to the development of a QMS and not the implementation as such. In addition it was found that despite senior management's understanding of requirements being a critical factor for the development of a QMS, it does not necessarily lead to improved performance of the organization. It can be argued that even though senior management's understanding of ISO 9001 will assist with the development of a QMS, it will have little effect on performance if the QMS is not effectively integrated into the operations of the organization. This is consistent with research by Allur et al., (2014) as discussed earlier, which found that higher levels of internalization leads to greater benefits derived from an ISO 9001 accreditation.

Therefore, with the aim set on improving internalization of the ISO 9001 requirements, the target audience chosen for this implementation tool is first line management. First line managers interact with staff on a daily basis and are intimately involved with the operations of various departments. Employee buy-in and involvement is paramount during implementation and for the maintenance of a QMS (Cheng & Rao Tummala, 1998). In addition Anholon et al. (2018) investigated difficulties in the implementation of ISO 9001 and found the following difficulties associated with employees:

- Resistance to adoption among employees.
- Lack of comprehension of how ISO 9001 can improve the operations of an organization.
- Training on quality principles not rolled out to all employees

With regards to these difficulties, first line managers are the main influencers at this level of staff and are therefore a natural choice as a target audience.

4.3. Scope

Generic requirements of management systems are often implemented independently in each department of an organization. In this context, generic requirements refer to the requirements of the standard that are universally applicable across the entire organization. This is in contrast to requirements that are only applicable to support service departments such as human resources, finance and procurement.

This approach is necessary to ensure compliance across big enterprises, but it means that implementation of the new system runs concurrently in each department. Consequently, the total man hours spent overall quickly accumulates due to the multiplication effect.

In view of this, it follows that one would want to maximise on the value realised from the time spent on implementation in each department. The scope of this study is therefore limited to the implementation of generic requirements of ISO 9001:2015.

4.4. Framework development

4.4.1. The process approach

The process approach (as depicted in Figure 3) is a common model adopted among several ISO management system standards, including:

- ISO 9001 – Quality management system standards
- ISO 14001 – Environmental management system standards
- OHSAS 18001 – Health and Safety management system standard, and
- ISO 27001 – Information security management system standard

It is a methodology for modelling a company's operations in a simple and effective way (ISO 9001 Quality management systems, 2015). It is universal in nature and can be applied to any organization regardless of size, type or complexity. In essence it sets out the organization's activities in an organised manner.

Since the process approach is central to the ISO 9001:2015 standard and it is already in flow chart form, it is the obvious place to start for the development of an implementation framework.

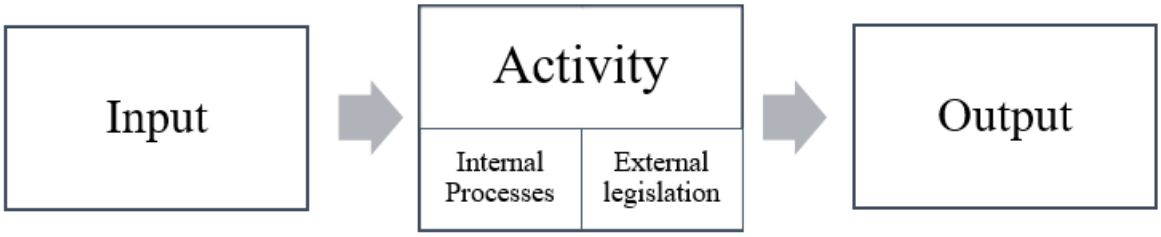

Figure 3: The process approach

Inputs are regarded as the info, energy or matter that triggers or mandates work within a department. These triggers should be supplemented by customer and or organizational needs and specifications. Customer needs are especially pertinent in design environments. Inputs are then linked to outputs via activities. An activity is the route that the input, in the form of info, energy or matter, takes to get to the output. The standard requires that activities are guided by one or more internal governing document and/or external legislation where applicable as illustrated in Figure 3.

Subsequently the identified generic requirements, as discussed in section 4.3 were placed in a flowchart centred around the process approach. This is depicted in Figure 4. In doing so, the operations of an organization is conceptually as well as physically placed at the centre of the framework, with sign posts as to exactly where ISO 9001 requirements apply. In the framework, numbers signify the order that the compiler will follow when populating the framework and arrows signify the relationship between these steps.

4.4.2. Customer focus

The 2015 revision of the ISO 9001 standard puts emphasis on fostering a customer focus (ISO 9001 Quality management systems, 2015). Consequently it was decided to identify customers and their needs early within the flow of the framework. For large organizations, where the end customer is far downstream from the output interface of a department, it can be difficult to adopt a customer focus. Because of the lack of end customer proximity, it is easy to lose to track of customer needs and turn the department's focus inward. This is evidenced by the well-known "silo" effect many organizations have difficulties with.

In addition, for large organizations products or services are realised through a complex interaction between departments. In this way, departments are internal customers of one another. Due to the complexity of this interaction it can be difficult to identify internal customers. For this reason, to assist departments to foster a customer focus, it will be immensely helpful towards implementers of ISO 9001, if a systematic methodology can be developed to identify customers and their needs,

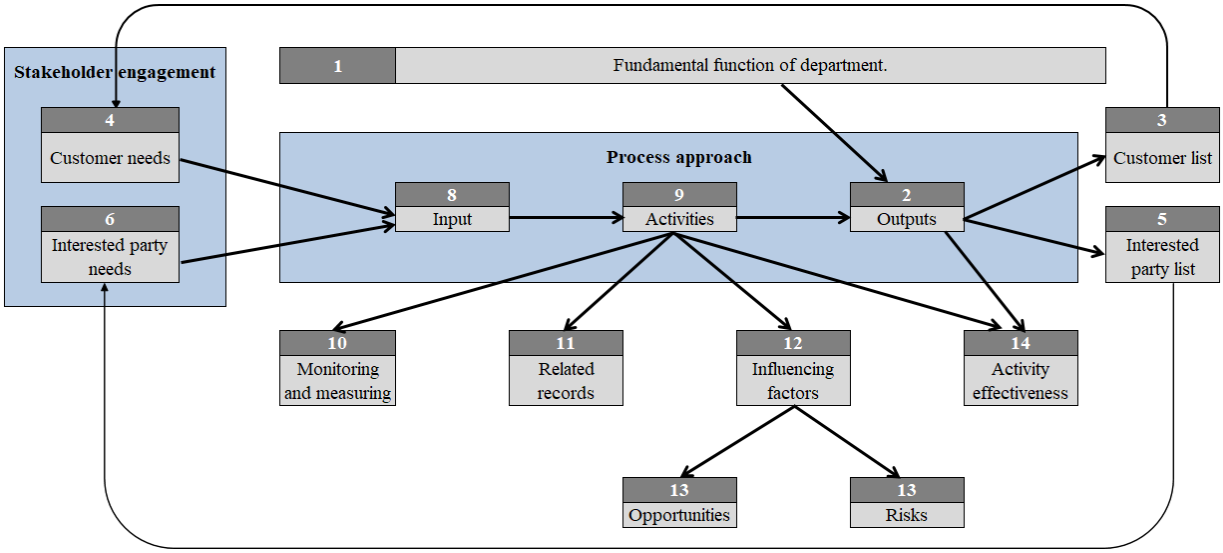

Figure 4: ISO 9001:2015 implementation framework

To be able to get to the customer needs in a systematic way, the fundamental function of the department is first identified in step 1 (Figure 4). The fundamental function identification assists in helping the manager to focus their efforts on their core business. This function is then broken up into high level outputs as illustrated in Figure 5. From this point it is a simple task to identify the receivers or customers of these outputs. This will probably consist of a combination of internal and external customers depending on how close that department is to the external client interface. One output might also have more than one customer associated with it. Through this process customers are accurately and systematically identified.

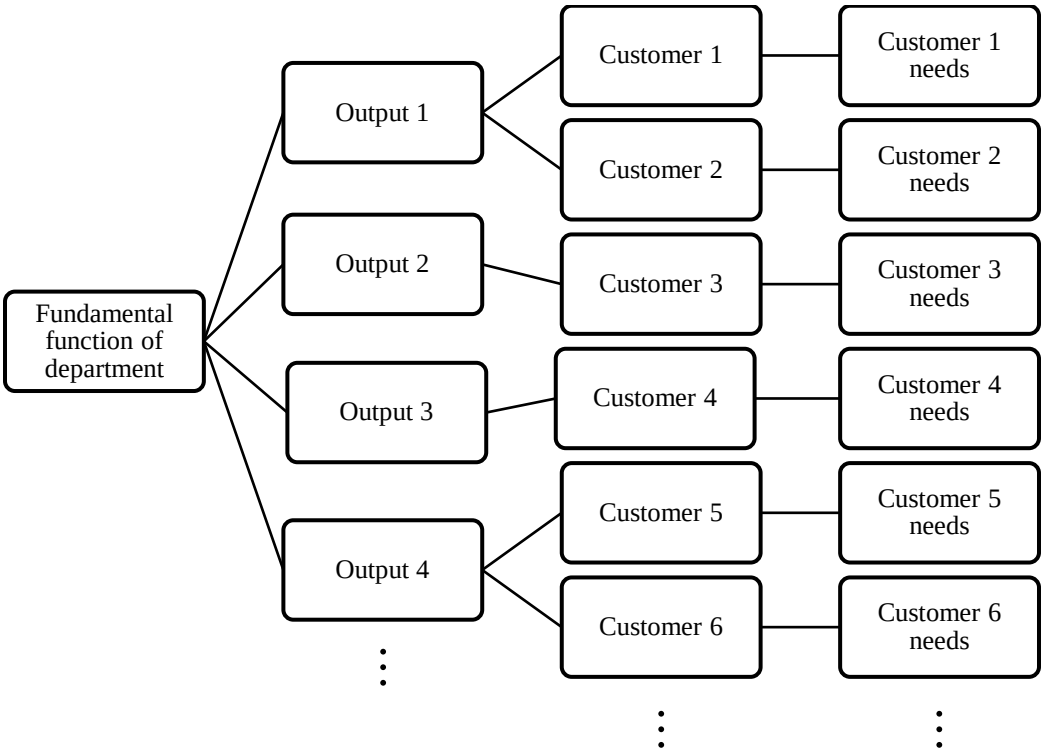

Figure 5: Customer need identification methodology

Interested parties are those entities that that have an interest in the operations of a department. According to the standard, interested parties include customers but also consists of those entities that are not the direct receivers of the output of a department. These entities might have an interest or are influenced further down the line by the output and level of quality at which the output is delivered to the direct customer.

For the purpose of the framework, since customers have already been identified and taken into account in step 3 (Figure 4), the interested party list in this case excludes direct customers. Compliance is still achieved since customers have at this stage already been identified taken into account and does not need to be duplicated in the interested party list.

Subsequent to creating a customer and interested party list, the needs of these entities are identified specifically with regards to the output involved. The methodology followed to identify customer needs is illustrated in Figure 5. The same methodology is followed for identifying interested party needs. However instead of identifying the needs of the direct receivers of the outputs, the compiler reflects on what are the needs of the non-direct interested parties. If it is practical or if the company processes requires it, the customer and interested party needs already identified, should be confirmed as accurate by those entities.

It is important to take interested party needs into account for the following reasons: By taking customer needs into account, one is ensuring that the direct interfaces between departments operate as planned. By taking interested party needs into account, one is acknowledging the entire life time of the product or service provided by a department in the complex interaction of an organization's operations. In essence by taking interested party needs into account one is creating assurance that the entire workflow operates as planned, and not only the direct interfaces between departments.

For the purpose of the framework, together the customers and interested parties are seen as a department's stakeholders. As part of maintaining a customer focus, stakeholders need to be engaged to determine their level of satisfaction with the product or service provided. The framework allows for the interaction between a department and its stakeholders to be effectively and accurately documented. Since the stakeholder needs have been identified in a focused way, stakeholder can be engaged on their specific needs and any subsequent issues identified can also be addresses in a focused way. This is as opposed to the more commonly used generalised customer satisfaction form. Since issues can be accurately pinpointed resources are optimally utilized to address and correct these issues.

4.4.3. Requirements relating to activities

As part of the process approach a list of activities are identified for a specific department. Many of the standard's requirements are operational and therefore apply to the activities of department. Through the framework, the relation between the ISO 9001:2015 requirements and a departments activities are effectively presented and explained to the compiler.

The first of these relate to monitoring and measurement systems, as illustrated in step 10 in Figure 4. The standard requires that organizations have monitoring and measurement programs so as to ensure conformity of products or services to a set of requirements. This ranges from non-physical measurements, such as key performance indexes to full gauge Repeatability and Reproducibility (R&R) studies. The reason for including this in the scope of quality management, yet again relates to customer satisfaction. Customers have certain requirements for the products or services they procured. These requirement are usually translated into a set of specifications. An organization cannot be sure whether it is truly meeting those customer specifications if measurements are not being taken. Monitoring and measurement programs ensures an acceptable level of confidence that customer needs are being met. In addition it follows that where physical measurement are being taken, the measurement equipment used should be calibrated to ensure measurements are true within an acceptable tolerance. For quality assurance it is therefore essential that where measurement traceability is required, equipment is calibrated according to national or international calibration standards.

The standard requires that organizations keep records of the execution of its processes, which in essence are the activities of that organization. Recall that as part of the process approach, internal governing processes and external legislation that guide activities are identified. The motivation for keeping records of activities is to have confidence that the processes of the companies are being followed and that legislation is being adhered to as planned.

Figure 6: Monitoring and measurement flowchart

ISO 9001:2015 also requires that an organization determines those influencing factors, internal and external to the organization, which affects its ability to deliver products and services as planned. Through the framework, the influencing factors are identified by reflecting on what factors affect a department ability to carry out its activities, be it positive or negative factors. Subsequently the positive influencing factors are translated into opportunities whereas the negative influencing factors are translated into risks. The standard then requires that action be taken to realise opportunities and to address risk.

If activities are not achieving their intended outcome, then these activities are ineffective. In these cases, effort and resources may go into the activity, yet little or no value is being realized from it. To address this issue, the standard requires that the current practice with regards to the execution of an activity, be evaluated to determine whether these activities are effective. The framework facilitates this process by leading the compiler to reflect on the current activity execution practice and identify areas that are ineffective in achieving planned outcomes. Once these issues have been identified, actions can be put in place to address these issues.

The implementation framework proposed in this paper, provides a systematic methodology to identify and address the aspects covered in this section, namely:

- Monitoring and measuring,
- Related records
- Influencing factors
- Activity effectiveness.

This is as opposed to the common checklist method where implementers of the standards would as an example, merely be required to keep related records. The requirement in this format is loose standing and does not specifically link to the operations of a department. Because of this it can be difficult to implement if one is not well acquainted with ISO 9001:2015. In contrast the methodology provided by the framework leads the compiler on exactly on how keeping records relate to the operations of a department and which records need to be kept. By means of the proposed implementation framework, ISO 9001:2015 can be effectively and efficiently implemented.

5. Conclusion

In conclusion, ISO 9001 is by far the most widely implemented management system standard from the ISO series. Certification has been shown to be advantageous across many industries (Rusjan & Alič 2010). Despite this, there are challenges involved in implementing a sustainable QMS that is well integrated into an organization's operations. This is supported by studies that show that:

- The motivation for seeking accreditation determines the organization's ability to quantify the benefits gained from accreditation (Yeung et al. 2003),
- Superficial implementation of the standard is common among certified companies (Zeng et al., 2007).
- There is evidence of "ceremonial conformity" in the audits of the QMS (Biazzo 2005).

Despite the barriers being well research, no research could be found on how to address these challenges. Because of the wide implementation base and the lack of a means to address the known challenges pertaining to ISO 9001 implementation, finding a more effective means of integrating ISO 9001 into the operations of an organization in a sustainable way, will have major benefits across many industries.

From a South African point of view, there is still a lack of literature on ISO 9001 within both the public and private sector. This is despite a growing number of ISO 9001 accreditations. This study is therefore particularly add value to this context.

This study proposes an alternative implementation method for ISO 9001:2015 by using knowledge transfer best practice as basis for the development of an implementation framework. In addition it promotes internalization by

means of the incorporation of the process approach as the centre point for the framework. The process approach effectively models the operations of a departments. Subsequently, the framework was then set up to lead the compiler through the ISO 9001:2015 requirements, by placing the generic requirements of the standards around the process approach in relation to how they pertain to that department's operations. In this way, ISO 9001:2015 requirements is effectively communicated and can subsequently sustainably be implemented.

The proposed implementation framework stands to be of benefit to organizations that are seeking ISO 9001 accreditation or that are already maintaining an accreditation. In addition it will contribute to the current body of knowledge by assisting in closing the gaps in literature on overcoming barriers to sustainable ISO 9001 implementation.

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Biographies

Jolanda Becker is a Primary Plant Maintenance Engineer at Eskom Distribution division and holds a degree in Mechanical Engineering obtained at the University of Stellenbosch. She has been employed by Eskom since 2012 as part of the Distribution division where she gained practical experience through exposure to a wide array of environments. She completed secondments to Rotek Industries and Koeberg Nuclear Power Station where she focused

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Wynand van Dyk is an Adjunct Associate Professor at the Industrial Engineering department of the University of Stellenbosch. He is a chemical engineer by trait, with over 20 years of experience in the mining industry. He held various positions in the Platinum Group Metal, Diamond & Consulting fields, including Senior Manager for a Base Metal refinery and Senior Technical Manager at Lonmin Platinum. He is founding director with Arete Consultants and specialises in process optimization, risk management, metallurgical accounting systems, 6 sigma strategic alignment and project management. As risk management strategy consultant to Managers and Executives of various international mining houses, and project manager for the recently completed Elandsfontein Phosphate Mine, he brings practical expertise in transforming safety and operational risk management aspirations into reality.