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Quality Management Systems

A Selective Presentation of Case-studies Showcasing Its Evolution

Edited by Leo D. Kounis



QUALITY MANAGEMENT SYSTEMS - A SELECTIVE PRESENTATION OF CASE-STUDIES SHOWCASING ITS EVOLUTION

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Meet the editor



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Preface

The terms *quality, quality control* and *quality management* are interrelated and not new. Indeed, the aforementioned words were known—and as such practised to a certain extent—by ancient civilisations. Performed research suggests that in order to construct monumental structures—such as the Great Pyramid of Giza, the Parthenon in Athens or the Temple of Apollo Epicurius at Bassae—and high-precision machinery such as the Antikythera mechanism, a systematic and well-monitored system for assuring quality had to be in place.

Ancient Greek philosophers, in particular Plato and Aristotle, introduced the term *quality* (*poiotes*) so as to categorise between different levels and forms of observed or ideal qualities, albeit as an attribute.

The Roman Empire further capitalised on the fundamentals of philosophy and engineering to create a state-of-the-art construction system, which included among others bridges, roads, dams, reservoirs and aqueducts. One may regard these engineering milestones as the forerunners of a more detailed *quality control* and *management* framework. The latter would re-emerge in the 1920s, when statistical theory was applied to control the quality of the manufactured goods.

The Industrial Revolution called for large teams being responsible for a certain stage of the manufacture of a product, which was now mass produced. Frederick W. Taylor and Henry Ford identified the systems' shortcomings and introduced standardisation of design and processes alike.

Inspections were deemed as safeguarding build quality. The former included measuring, examining and testing products to a specific set of limits. This principle worked fine for as long as companies were small. As soon as the latter expanded, diversified and grown quality-specific bottlenecks were identified that soon morphed into problems.

The advent of World War II forced companies to implement to a larger extent statistical control methods and techniques, which are credited to the work of W. Edwards Deming and Walter Shewhart.

Joseph Juran placed an emphasis on "managing for quality". This comprised of the following key aspects:

- Quality planning
- · Quality control
- Quality improvement

A. Feigenbaum coined the term total quality management (TQM) during the first International Conference on Quality Management in 1969. However, Kaoru Ishikawa stressed the importance of getting all personnel involved in TQM from the workers to the head management.

The application of quality technique tools and management by Japanese companies resulted in qualitative products—predominantly electronics and automobiles—that started to successfully flood export markets. By early to mid-1980s, though, Western companies and, in particular, American ones started to adhere to stricter total quality management guidelines.

It is worth noting at this point that the introduction of the Malcolm Baldrige National Quality Award (MBNQA) may be regarded as an immediate outcome of the joined efforts of the US Government in setting and refining quality-specific standards. Europe would soon follow path with the European Quality Award, currently referred to as European Foundation for Quality Management (EFQM) Excellence Award.

In the meantime, manufacturing industries and service provider organisations were improving their in-house quality-specific manuals so as to remain competitive and increase their market share. Towards the end of the twentieth century, the term TQM started to fall out of favour. At the start of the twenty-first century, the term *quality management system* (QMS) was introduced by K. Croucher and incorporated the ideas of transparency and sustainability.

Indeed, the ISO 19011 audit standard addresses quality and sustainability issues and their seamless incorporation into companies.

It can be thus stated that a quality management system is a set of business-specific processes and procedures aimed at continuously satisfying customer/end-user requirements. This is further enhanced by quality standards, of which the ISO 9000:2015 is the most widely used one. A multitude of similar and market-specific standards was created. Of particular notion are the ISO 14000, the ISO/TS 16949 and the ISO 13485 set of standards. The latter is applicable to medical device manufacturers and is harmonised with the European Union Medical Device Directive 93/42/EEC, the US Food and Drug Administration (FDA) and Code of Federal Regulations (21 CFR 820).

The FDA has identified seven core subsystems of a quality system, which include the following controls:

- Management
- Design
- Production and process
- Corrective and preventive actions
- Material
- Records, documents and change
- Facilities and equipment

This book presents eight chapters discussing quality management systems pertaining to engineering and technology, health and education.

The first chapter provides an overview of the most widely used quality management standards and elaborates on their implications and use by companies and organisations. It continues by comparing major quality standards and introduces an integration model based on a holistic approach that is aimed at fostering sustainable development.

In a highly competitive market, academic institutions and research centres aim to deliver excellent education. In doing so, a plethora of metaphors is being used so as to convince the potential candidate. However, this paper argues that not that much is known about the quality management model implied to generate such excellence. It therefore introduces a multidisciplinary approach by elaborating on a meta-synthesis methodology proposing hybridisation of quality models per se.

Quality management systems may equally be regarded as a system of interacting elements that although market-driven—is also sector-specific. Indeed, a large number of manuscripts invariably discuss the impetus of such implications in higher education. With a growing number of universities offering open and distance earning schemes (ODLS), this chapter explores the relationship between QMS and ODLS, acknowledging the works of M. Heideggerl and L. P. Althusser.

It thus discusses the constructs of the philosophical being and becoming and their influence in shaping the epistemological and ontological dimensions of quality management systems and their use as effective management tools.

The impact of financial crises has been well studied and documented. Staff shortages coupled with cuts to budgets for social care in conjunction with an ageing population of inferior quality levels have inadvertently affected countries' health systems. These include but are not limited to Greece, Spain, Cyprus and the United Kingdom. This paper showcases the development of a novel TQM model aimed at improving patient care. This was facilitated by integrating contemporary organisational theories with total quality management.

The fifth chapter elaborates on the ISO 9001:2015 quality standard and focuses on process management issues, which form one of the standard's core requirements. In order to effectively address this issue, business process management (BPM) in conjunction with the integration of business informatics and information technology (IT) is studied taking into consideration the effects of quality management on ISO 9001-specific requirements.

Other areas subject to a wide range of quality standards are agriculture and food safety. Proper quality control measures are adamant to safeguard public health on the one hand, whilst facilitating effective "hand-shaking" and synergies between producers' quality management practices and government-related activities on the other. The entire cultivation, production, storage and distribution chain ought to be seamless, so as to avoid potential contamination. A set of applied quality management technique tools is herein discussed.

The cumulative sum (CUSUM) control chart is a widely used quality technique tool that is used for monitoring change. The latter applies to automation and sensor device technology. Usually, two symmetrical CUSUM charts are used in order to detect two-sided mean shifts. However, predicting the actual magnitude of a mean shift is regarded as difficult. This paper introduces and discusses the adaptive CUSUM that exploits the steady-state condition in order to improve the zero-state performance.

Control charts form a vast family and are another quality technique tool that is used to establish if a process is within specified tolerances, i.e., limits. This final book chapter highlights their various applications on selected industrial case studies. The effects of information technology are equally highlighted. Current and future potential developments are presented.

This book exhibits selected topics elaborating on various applications of quality management systems, which may be used as a platform for further research.

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Integrated Management Systems and Sustainable Development

Burhan Başaran

Additional information is available at the end of the chapter

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Abstract

Management system standards, optional for organizations, have started to be considered as a strategic tool for organizations seeking institutional success and adopting innovative approaches. Establishing and managing these standards independently for the same organization yield some difficulties for organizations. It would rather be a more rational solution to provide a holistic view to all standards, which is to integrate them all. As integrated management systems can be shaped according to the needs of the organization, they involve different management system standards. Therefore, there is no common model defined for said integrated standards. These systems offer organizations a management philosophy for the processes to be successfully managed and to achieve desired results. When the emerging management philosophy is internalized by management and employees, a corporate culture is formed. The effects of integrated management systems on the sustainable development of the organization can be categorized as management, people, market, production, environmental and occupational health and safety totaling in six categories. Integrated management systems provide organizations with a management philosophy that enables processes to be successfully managed and to achieve desired results. Despite the advantages of integrated management systems for organizations, they may also have some drawbacks.

Keywords: integrated management systems, sustainable development, ISO 9001, ISO 14001, OHSAS 18001

1. Introduction

Organizations that have to sell more each day and aspire to maintain or increase their current market share need to adapt laws such as occupational health and safety and consumer protection. Changing expectations of consumers and other stakeholders should also be



considered. Moreover, they have to be flexible in their upcoming competition-based strategies so as to adapt to these changes. This adaptation plays a vital role for organizations. Within the scope of new competition-based strategy, organizations need to observe the developments taking place in their milieu, evaluate the current information, and by making best use of its resources so as to maintain sustainable development. In addition, the quality of products and services offered by businesses today is no longer adequate alone. Owing to the increased environmental awareness, current technological processes, procedures, and policies focus on improving and optimizing tools and techniques to minimize the effect on the environment. Indeed, management system standards (MSSs) are regarded as a strategic tool in order to effectively deal with processes such as governance, personnel, and occupational health and safety [1–3].

There are two major milestones in the emergence of MSSs. First, there is the industrial revolution that facilitated mass production and thereby reduced cost. The latter is the World War II that caused a change in the perspective of industrialization and qualified staff of the states involved. In the aftermath of the war, new balances emerged in the world affecting quality development and the necessity of establishing certain standards [4].

MSSs are published by the International Standards of Organization (ISO). ISO was founded in 1947 with its main headquarters in Genova, Switzerland. It is an independent organization hosting members from 163 states. From 1947 up till now, ISO have published 21,623 international standards covering nearly all aspects of technology and trade [5].

There are a total of 57 MSSs currently in effect, developed by ISO for different coverage and areas of use [6]. Some of these standards (e.g., ISO 9001, ISO 14001, ISO 45001, ISO 27001) are applicable for all sectors. Apart from these, there are also sector-specific standards such as ISO 22000 for companies producing food, food equipment, and food packaging; ISO 13485 for companies producing medical devices; and ISO 16949 for automotive and subsidiary industry sectors.

The establishment of management system standards is optional for organizations. However, MSS has become a mandatory practice for organizations that want to keep-up with the developments in the world and gain prestige in trade [7, 8]. Various studies state that MSSs make positive contributions to the innovative performance of organizations when implemented constantly, systematically, and in the long run, it is also a vital tool for sustainable development. As a result, standards are becoming more and more important today [9–11].

Establishing and managing MSS in organizations independently of each other lead to some difficulties in organizations and do not yield the desired synergistic effect [12]. Instead, it would be a more rational solution to gather different MSS under a single roof and to provide a holistic view to all standards, which is to integrate them all. Today, integrated management systems are considered as a practical and a useful method for the future [13–15].

The purpose of this study is as such:

to share the necessary knowledge to improve the effectiveness of the integrated management systems,

- to demonstrate its impact on sustainable development, and
- to lead the relevant stakeholders in choosing the best option

2. Literature review

2.1. Integrated management systems (IMS)

Before dwelling on the content of IMS, it is necessary to explain the concept of integration. Integration refers to "completion" and "aggregation" [16]. However, the term integration should not be confused with "combination" and "compliance" in terms of MSSs.

Compliance refers to parallel management system standards prepared for the same discipline despite showing great differences in terms of structure and content [17]. With regards to the term combination, it is the creation of a new system by adding different management systems to each other. According to the British Standards Institute (BSI), there is a four-step process in MSSs-integrated practice that goes from combination to integration [18].

- 1. Different management systems are implemented independently of each other in the same organization and in the same time frame (combination)
- 2. The organization prepares for integration by identifying common elements of different management systems after implementation
- 3. The organization eliminates the differences and removes the contradictions among different management systems. It adds new elements to the initial common elements. This step is about the combination of the systems
- 4. The organization creates a new meta-system that integrates all identified common elements

Integration, in terms of management systems, refers to owning each MSS content per se, which is prepared for certain disciplines. Being so, integrated management systems can be defined as a set of systems that are planned, applied and continuously revised, and improved in order to meet jointly multiple MSSs and other systems to which they have to comply [19–21]. In order for a company to conduct its operations systematically, it must comply with laws, MSSs, and customer conditions. It is therefore better to use the concept of integration of systems instead of integration of standards.

There are different views of integration in organizations [22–24].

- No integration: Each system exists with its own identity in the institution
- Partial integration: It refers to the harmonization of certain elements of each integrated system. It is projected at the middle management level that systems should be constructed according to business functions and be independent. It is assumed that systems should generally be compatible with each other, but this compatibility will not be 100%

• Full integration: Each integrated system loses its identity and a single multi-purpose metasystem emerges. It is assumed that systems will form a complete integration at executive and operational level

As IMSs can be shaped according to the needs of an organization, they are capable of including different management system standards. Therefore, there are still debates about IMS. However, literature review on IMSs show that ISO 9001 (QMS), ISO 14001(EMS), and OHSAS 18001(OHS) standards are the most researched standards [25–29]. It is possible to make different integrations by adding ISO 9001-ISO 14001, ISO 9001-OHSAS 18001, ISO 14001-OHSAS 18001, ISO 9001-ISO 14001-OHSAS 18001, or other standards that are specific to the sector. In other words, there is no limit to MSSs integration. An exemplary model of IMS is shown in **Figure 1**.

ISO 9001 quality management system: ISO 9001 defines the requirements for enhancing customer satisfaction by meeting the requirements of an organization's customers and legal liabilities. The general provisions of the standard are organizational chart, duties, authority and liabilities, efficient use of resources, interrelationship of the processes, product or service design and development works, customer satisfaction, internal audit, continuous improvement, and documentation. The main purpose of the system is to prevent errors or defects that may occur either in the final product or service, or reduce them to the acceptable levels via interim controls. Its final revision was made in 2015 [31, 32].

There are many studies highlighting the benefits of ISO 9001 for organizations. From an overall perspective to these studies, the advantages can be divided into two categories. Internal benefits include cultural change in employees, organized action, management efficiency, better documentation, increase in production efficiency, and reduction of costs.

External benefits include customer satisfaction and loyalty, increase in market share of the business, readiness for official audits, strengthening the organizational image, and increase in competitive power [33–35].

ISO 14001 environmental management system: At present, with resources being gradually depleted in an irreversible process, it is the author's view that all elements making-up the environment are under threat. It is now accepted by the whole world that the threat is not local or regional, but global. In both written and visual media, there are a lot of environment-oriented

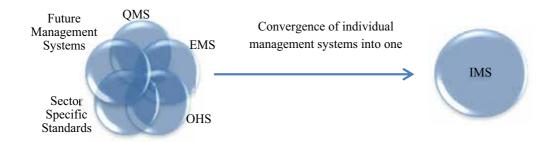


Figure 1. ISO 9001, ISO 14001, OHSAS 18001 IMS [30].

news and information. Today's consumers not only demand maximum benefits from the product or service they purchase but also seek applications that do not harm the environment or at least cause damage at minimum level. Therefore, a number of states prepared various regulations to reduce the harm to the environment. Many organizations review their activities regarding the environment. In order for these revisions to yield success, they need to be handled systematically. ISO 14001 is an international standard that methodically exposes the conditions that must be fulfilled by performing risk analyses for every hazard at every stage from the design to the consumption processes of the products or services. Its final revision was made in 2015 [36-38].

OHSAS 18001 occupational health and safety management system: Each year nearly 2.3 million workers have occupational diseases and more than 6000 workers lose their lives [39]. Organizations are more and more interested in occupational health and safety practices due to legal regulations, economic policies, and most importantly the safety of the employees. ISO 18001 is an international standard that assesses potential hazards that may arise during the conduct of business for an employee via risk analyses; its main purpose is to create a better working environment and protect the health of employees. Based on OHSAS 18001, ISO published the ISO 45001 [40, 41].

The main reason for placing an emphasis on these three standards in studies conducted on IMSs is that human health, environmental dimension, and quality have become an integral part of today's life. All three standards can be implemented in all the sectors regardless of activity type, size, and the number of employees of organizations. In addition, these standards cover different geographical, cultural, and social conditions [42].

ISO publishes the documentation statistics on ISO management systems on a regular basis (**Table 1**) [43].

The most common standards with the highest number of documentation globally are ISO 9001 and ISO 14001. They are followed by ISO 22000. The number of documentation increases in line with the increase in importance attached to management system standards. By observing Table 1, it can be stated that the reason why most studies are devoted to ISO 9001 and ISO 14001 among other integrated management systems is again evident in the number of certification.

Year	2010	2011	2012	2013	2014	2015	Total
ISO 9001	1,076,525	1,009,845	1,017,279	1,022,877	1,036,321	1,034,180	6,197,027
ISO 14001	239,880	243,393	260,852	273,861	296,736	319,496	1,634,218
ISO/IEC 27001	15,626	17,355	19,620	21,604	23,005	27,536	124,746
ISO 50001	_	459	2236	4826	6765	11,985	26,271
ISO 22000	18,580	19,351	23,278	24,215	27,690	32,061	145,175

Table 1. MSSs number of documentation by years.

2.2. IMS models

ISO did not publish an integrated management standard. However, based on performed research, 37 out of 57 that are currently in use can be applied in an integrated manner in terms of structure, content, terms, and definitions. There are common elements that facilitate MSS integration.

IMS can change according to the fields of activity, needs, mission, and visions of organizations. It is the author's view that this change is continuous in par with changing conditions. There are still various views regarding IMSs implementation. Hence, there is no common model defined. The most accepted models for IMSs in literature are listed below:

2.2.1. IMS model based on system approach

This model also has a system that uses all the resources in line with the same goals and objectives, so that the processes are compatible with each other. This system approaches each problem from a holistic point of view. This methodology helps to harmonize various functions of different MSSs. The integration in system approach can occur in different forms such as ISO 9001-based integration, ISO 14001-based integration, and ISO 9001-ISO 14001-based integration [44].

2.2.2. Management systems evolution model

This model makes an overall assessment of changes experienced by management systems in time, and creates a new model by assessing different integration models together. Management systems evolution model involves three phases namely standardization, rationalization, and integration. Renfrew and Muir [45] consider ISO 9001 as an initial point in terms of IMSs. Other sector-based cases were implemented later on. The next phase is the IMS matrix. The latter refers to the identification of similar elements among different MSSs. The fourth phase is the integration of procedures and processes. While it is possible to create integrated procedure for standards, it is rather difficult to attain this for processes. The next phase is QUENSH, which is the abbreviation of QU for quality, EN for environment, and SH for safety and health. Finally, a single management standard is formed (Figure 2).

2.2.3. IMS matrix

This model table shows the overlapping of elements. Its main purpose is to illustrate that different MSSs can be integrated [46]. **Table 2** shows an IMS matrix sample [47, 48].

There are different views in IMS matrix regarding the compatibility of elements between one another and their implementation by organizations. According to one point of view, there is a strong connection between ISO 9001 and ISO 14001, and it is possible to implement an IMS matrix in integration [49]. Another view suggests that standards have special functions pertaining to themselves, and problems are likely during an integration process based on IMS Matrix. [50].

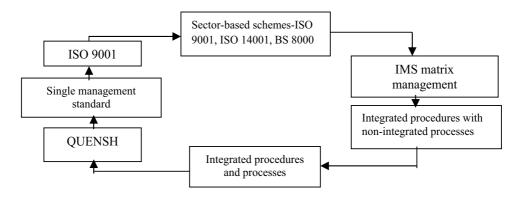


Figure 2. Management systems evolution model of Renfrew and Muir [45].

Based on the findings thus far, it may be stated that the similarities between MSSs, especially among the quality management standards, are considerably higher than the differences. It is the author's view that an IMS matrix is important as it shows how compatible or incompatible the different MSSs are in integration.

2.2.4. European Foundation for Quality Management (EFQM) excellence model

The EFQM excellence model was prepared by the European Foundation for Quality Management in 1988 to enhance competitive aspects of European organizations. EFQM excellence model was developed in such a way that it can be employed as a quality system by all kinds of organizations regardless of differences in sector and capacity. The philosophy of this model is based on self-assessment by organizations themselves. This method enables organizations to identify their current situation and to develop new strategies to enhance processes. EFQM includes nine criteria, five of which are enablers, and the remaining four are results. These criteria are leadership, strategy, people, partnerships and resources, processes, products and services, people results, customer results, society results, and key performance results. There are 32 sub-headings under these criteria [51, 52] (Figure 3).

It is worth mentioning at this point that the EFQM excellence model was not developed for management systems integration. However, the criteria suggested by EFQM overlap to a great extent with MSSs. Therefore, integration is possible with reference to EFQM criteria.

2.2.5. ISO Guide 72

ISO Guide 72 defines all MSSs common elements and proposes a certain rational order for IMSs. Thus, it is possible to develop, review, compare, and revise many standards, while increasing in-between standard compatibility. Table 3 shows common elements defined for MSSs in ISO Guide 72 standard [53].

Each of the MSSs is revised according to changing conjunctures and conditions. As the compatibility among standards is taken into account for the aforementioned revisions, one might expect an increasing number of similar standards in the future in terms of structure and

ISO 9001:2015 Standard number ISO 14001:2015		ISO 14001:2015	Standard number
Scope	1	Scope	1
Normative references	2	Normative references	2
Terms and definitions	3	Terms and definitions	3
Context of the organization	4	Context of the organization	4
Understanding the organization and its context	4.1	Understanding the organization and its context	4.1
Understanding the needs and expectations of interested parties	4.2	Understanding the needs and expectations of interested parties	4.2
Determining the scope of the quality management system	4.3	Determining the scope of the quality management system	4.3
Quality management system and its processes	4.4	Environmental management systems	4.4
Leadership	5	Leadership	5
Planning	6	Planning	6
Actions to address risks and opportunities	6.1	Actions to address risks and opportunities	6.1
Quality objectives and planning to achieve them	6.2	Environmental objectives and planning to achieve them	6.2
Support	7	Support	7
Resources	7.1	Resources	7.1
Competence	7.2	Competence	7.2
Awareness	7.3	Awareness	7.3
Communication	7.4	Communication	7.4
Documented information	7.5	Documented information	7.5
Operation	8	Operation	8
Operational planning and control	8.1	Operational planning and control	8.1
Performance evaluation	9	Performance evaluation	9
Improvement	10	Improvement	10

Table 2. IMS matrix sample.

content. Hence, it is the author's view that implementation of different integration types will be even more easier in the future.

2.2.6. ISO 9001-based integration model

The history of ISO 9001 standard is older than the other standards. In addition, it is acknowledged that at present, companies initially establish this standard as it is applicable to all sectors. This is the most common model for IMSs establishment. System approach model, management

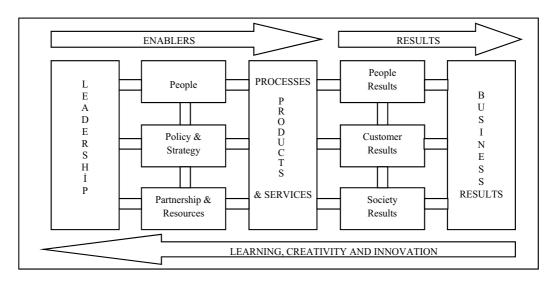


Figure 3. EFQM excellence model [52].

Main subjects that are common to all MSSs	Common elements 1.1. Policy and principles		
1. Policy			
2. Planning	2.1. Identification of needs, requirements and analysis of critical		
	issues		
	2.2. Selection of significant issues to be addressed		
	2.3. Setting of objectives and targets		
	2.4. Identification of resources		
	2.5. Identification of organizational structure, roles,		
	responsibilities and authorities		
	2.6. Planning of operational processes		
	2.7. Contingency preparedness for foreseeable events		
3. Implementation and operation	3.1. Operational control		
•	3.2. Management of human resources		
	3.3. Management of other resources		
	3.4. Documentation and its control		
	3.5. Communication		
	3.6. Relationship with suppliers and contractors		
4. Performance assessment	4.1. Monitoring and measuring		
	4.2. Analyzing and handling nonconformities		
	4.3. System audits		
5. Improvement	5.1. Corrective action		
-	5.2. Preventive action		
	5.3. Continual improvement		
6. Management review	6.1. Management review		

Table 3. Common elements of ISO MSSs.

systems evolution model, IMS matrix model, and ISO Guide 72, all comply with ISO 9001based integration. In this integration system, ISO 9001 is established initially, and other systems are integrated following its implementation. This model is based on process approach [54].

2.2.7. ISO 14001-based integration model

In this integration system, ISO 14001 is established initially, and other systems are integrated following its realization. It is the author's view that this is rarely implemented, as it is generally preferred by companies whose products or services are expected to yield severe harms to environmental conditions. It is possible to benefit from the IMS matrix in this model. The main objective of this model is continuous improvement as it is the case in the PDCA cycle [55].

2.2.8. Co-establishment of ISO 9001 and ISO 14001 followed by the integration of others

Initially, ISO 9001 and ISO 14001 standards are co-established as an integrated management system, and other systems are included in the integration later on [56].

2.2.9. Integration based on integrated procedures or integrated processes

The main purpose of this model is to prepare common documentation for each standard to be integrated. The main approach is continuous improvement. Firstly, common documents are determined for each standard. This mainly results in the full integration of procedures and the partial integration of processes. This is because each standard has its own processes. Then, the other documentation is integrated into the system. An IMS matrix can be utilized for this integration model. Moreover, this model is one of the phases of management systems evolution model [57].

2.2.10. Single management standard

IMSs yield more benefits to the organization than it would benefit from the implementation of separate standards. Therefore, some countries have published a single management standard for integration. Single management standard was prepared with reference to organizations that are already implementing two or more standards.

Britain-PAS 99: This is the first integrated management standard in the world, being prepared with reference to six general conditions of ISO Guide 72. PAS 99 is designed to provide a general framework for organizations in the act of integrating their systems. Therefore, PAS 99 standard does not provide the benefit that a single organization requires from a management system [58, 59].

Denmark DS 8001: Within the scope of IMSs development, the Danish motto is "Single business, single management". Danish Standards Foundation published DS 8001 to help organizations with two or more management systems transit to integrated management systems. DS 8001 involves ISO 9001, ISO 14001 standards and approaches specific to the EFQM model. The first section of the standard explains characteristics of a good management. The second section deals with common elements that should exist within a management system, while the third section includes terms that facilitate comprehension of the system [60].

Spain-AENOR: The Spanish Association for Standardization and Certification (AENOR) published an integrated management system standard based on the ISO 9001 and ISO 14001. This was the outcome of a number of studies that were initiated due to demands from companies. Two types of models, partial integration and full integration, are suggested in this standard [61].

Model	Scope	Model characteristics	Purpose	Limitations
The system approach	The requirements in the standards	An IMS based on both the PDCA circle and the process approach.	To avoid the problems regarding to different underlying models	Ignores culture
IMS Matriksi	The standards themselves	Harmonization of the elements in the standards	Show combinability Aligned not integrated	
ISO Guide 72	The common elements	The integration of common elements	Avoid duplication	Aligned not integrated
Integrated documentation	The documentation	One management handbook for all systems	Simplify and reduce documentation	Aligned not integrated
EFQM	Total quality management	Includes strategic and cultural management	Business excellence	Do not address the ISO certification requirements
ISO 9001-based IMS	The requirements in the standards	An IMS based on the process approach	An IMS based on the process approach	Ignores culture
ISO 14001-based IMS	The requirements in the standards	An IMS based on the PDCA circle	An IMS based on the PDCA circle	Ignores culture
The single management standard	The standards themselves	Based on only one common standard	One company, one system	ISO not exists, potentially inflexible, must be regularly updated

Table 4. Comparison of IMS models [57].

2.3. Comparison of IMS models

It is worth noting at this point that all standards are of equal importance. This is because each model has its own gains and drawbacks. The approaches of models toward the scope and integration are different from one another.

Moreover, some researchers [62] argue that the culture specific to any given society should be taken into account for integrated management systems or each system to be implemented. Hence, the need for developing new integration models still exists. Table 4 shows comparison of IMS models.

3. Results and analysis

3.1. The advantages of integrated management systems and their contribution to sustainable development

The rapid increase in production, and consequently, consumption has made the concept of sustainability even more important today. Sustainability is a three-dimensional concept involving environmental, economic, and social issues.

Sustainable development for organizations can be defined as the ability to efficiently manage risks associated with economic, environmental, and social factors in order to create long-term value in organizations. By resolving the aforementioned risks from a holistic point of view, namely dealing with these risks via IMSs, it is possible to create positive contributions to performances and sustainable developments of organizations. In addition to benefits to organizations, it is revealed in many studies that IMSs have many gains that are closely relevant to sustainable development. Advantages influential on sustainable development can be summed up in six themes [63–72].

Management results:

- The image of the company was positively affected and it gained international prestige
- It improved management of relationships with suppliers and subcontractors
- A holistic perspective was offered to the events
- A transparent management approach emerged
- It saved time and costs by joint internal/external audits
- It facilitated the interrelationship of activities and co-ordination
- It attributed efficiency to internal and external communication
- It made risks easier to control
- It was beneficial for a clearer and explicit definition of liabilities and authorities
- It ensured efficient use of resources
- It facilitated strategic planning and decision making for executives
- Bureaucracy and procedures decreased while documentation got simplified
- The time and cost of implementing the systems decreased
- Incompatibility among ISO 9001, ISO 14001, and 18001 reduced
- Internal innovation increased
- An easier and more efficient management system was achieved
- Supplying capital became easier
- A continuous improvement process started
- The organization gains flexibility and speed for change

People results:

- Employee motivation and awareness increased
- Employees participated in system works at the highest level
- Employees adopted the system more

- Employees have more loyalty toward the organization
- Newly-employed staff adapted to the system more rapidly and easily

Production results:

- Productivity increased
- Scraps and wastes are reduced
- There is a considerable drop in error rate during process
- There is a cutback of production time
- Delivery process of productions is improved
- Costs decreased and profit increased
- Minimization in customer audits

Market results:

- There is an increase in customer demand
- There is a decrease in customer complaints
- There is an raise in customer satisfaction
- There is an amplification in quality perception of customers toward the organization
- Competitive power improved
- Market share and profitability grew

Environmental results:

- Complying with legal liabilities toward environment became easier
- The number of environmental damages decreased

Occupational health and safety results

- Adherence to legal requirements in terms of occupational health and safety became easier
- There is a decrease in the number of work-related accidents

3.2. IMSs drawbacks and difficulties of implementation

Though IMSs offer many advantages, it may also have disadvantages for organizations. These are as follows: [73–75].

- Focusing less on one or more than one of the standards constituting IMS
- Documentation and the management thereof become more complicated compared to previous actions

- Paper work and management associated costs increase
- Human resources were not used effectively

There are also certain difficulties in implementing IMS. These include, but are not limited to:

- Inadequacy of resources
- · Lack of information
- · Corporate culture
- Difficulties in focusing on different fields
- Constantly changing regulations and standards
- Lack of qualified staff
- · Conflicts among employees and
- Difficulties in making changes.

In addition, some studies revealed that some administrators who work in organizations are opposed to IMS applications because they think that their expertise areas will lose their importance and that in integrated management systems, their positions will no longer be needed [76, 77].

4. Discussion and conclusion

From the agricultural age to the age of industry and finally to the age of information, all organizations operating in the public and private sector need new approaches to meet customer expectations, while differentiating from their competitors and succeeding in the market. Moreover, approaches that can meet the expectations of all stakeholders have gained importance. It is neither possible for an organization operating in a competitive market to ignore common values such as environment, social responsibility, and human resources, which should be protected as they may be regarded as a company's assets. Indeed, for a company to succeed in today's antagonistic marketplace, management systems standards and integrated management systems may be regarded as providing a holistic view of these standards. They are considered as an important tool for solving aforementioned problems and ambiguities.

Integrated management systems provide organizations with a management philosophy that enables processes to be successfully managed and achieve desired results. When the emerging management philosophy is internalized by executives and other employees, it has a positive impact on sustainable development as well as providing many benefits to the organization. Performed literature research indicates that integrated management systems have a constructive effect on management, employees, production, environment, market, occupational health and safety processes. However, these studies also highlight certain negative impacts that integrated management systems hold. Yet, if an assessment was made between the two, positive

effects of integrated management systems would outweigh the negative ones. Integrated management systems focus on medium- and long-term goals of companies rather than the improvement in short-term indicators and form a corporate culture to this end.

Different approaches to integrated management systems are still underway. However, studies focus on creating a common IMS model for all sectors in general. Instead, it is believed that creating a sector-specific IMS model will be more rational. Moreover, it is thought that this work may provide stakeholders with a building platform so as to broaden their interest in integrated management systems.

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Quality Management Systems in Education

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Additional information is available at the end of the chapter

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Abstract

This chapter stretches the characterisation of quality management systems and models that is abundant in literature by assessing the capability of the most common of the systems and models. Multiple data gathering and processing techniques were used within the context of a constant comparative approach in which data, theories and cases were plugged into each other. Based on the performed research, obtained outcomes suggest the presence of numerous opportunities and benefits in using quality management systems. Based on the findings, further work needs to be done to create the conceptual, managerial and behavioural competences that should facilitate the embedment of the quality management models into the daily lives of education institutions. A critique of quality management through the lenses of the disciplines of team learning, systems thinking, shared vision and mental modelling and of the Six Sigma, roadmaps should engender a new approach to improving quality in education. It should be of interest to explore the potentials of hybridising quality management models in education.

Keywords: quality management systems, Six Sigma roadmaps, creative tension, systems thinking, mental

1. Introduction

Quality management systems (QMSs) abound in literature with much of it focusing on describing them and the contexts of their inceptions. Performed research indicates that a number of scholars have described social imageries of World Class Universities (WCU), Better Schools Programs (BSP), Star Schools Projects (SSP) and other versions of the imageries of types of best-performing education institutions. Literature has however, reported on numerous ingredients for high quality performance but remained ambivalent about whether there is a singular methodology of accomplishing high-level customer satisfaction in education. This chapter uses a synthetic-evaluative approach to critique the capability of the various QMSs used in education. It also explores how institutional quality performance can be bettered by paying attention to the



context in which the model is adopted. The next section starts by dissecting the concept of QMS, detailing the three constituent elements: quality, management and system. Understanding each component of a QMS in its individuality should help in building a picture of how a QMS can be at the service of a student-focused and market-oriented education delivery system. The chapter presents a comparative structural analysis of the various quality management models and critically analyses the meanings and implications in each category.

2. Quality management systems

There are three perspectives to QMS which will be discussed below so as to appreciate the scope of what a QMS should sound like in its philosophical perspective, methodological outlay and performativity implications. The perspectives are quality, management and system. Each acts as a gear engaging with the others and yet powered each by an overarching question about its purpose in a QMS infrastructure.

- **a.** Quality—What is the institution's conception of quality and the methodology of doing 'quality'?
- **b.** Management—Is the institution's strategy plan on quality integrated and aligned with its vision of quality?
- **c.** System—How does the institution's strategy, culture, structure, rewards, behaviour, etc. support its own model of quality?

A QMS is as useful as its ability to serve as a coherent framework for systematically integrating, aligning and focusing institutional and business processes. The focusing of business processes should help the institution in accomplishing its network of objectives and infrastructure of goals effectively and efficiently. Effectiveness and efficiency of processes ensure maximisation of customer satisfaction. Such a scope of QMS has intriguing implications on the structure of the organisation, its culture, knowledge management practices and customs. It has further implications on the technological co-efficiency of the organisation at all levels of the processes deployed across the institution.

2.1. Quality

Literature variably refers to quality as 'slippery', 'mobile', 'elastic' and 'elusive' [1]. Notwithstanding, the chapter conceives quality as referring to an expression of satisfaction with the constitution, form and performance of a good based on the beholders' conditionality of time and space. The value or worthy a person assigns to a good can appreciate or depreciate dependent on time and environment or space in which one finds himself. Nonetheless, quality is generally perceived as a representation of complex mix-and-match of qualities and variables embodied in products and services. The functional relationship has been captured by [2] in Eq. (1).

$$EduQuali = \sum_{j=i}^{k} (P_{ij} = E_{ij})$$
 (1)

where EduQUAL is perceived education quality of student 'i', k is the number of education attributes/items, P is perception of student 'i' with respect to performance of an attribute 'j' of institution, E is the education quality expectations of student 'i' for an attribute 'j'.

It should be noted that customers do not always assign the same importance to any characteristic or feature permanently. The ever increase in the numbers and peculiarity of substitute and complimentary products/services and even features complicates the Education system's comprehension of the package of features that would best meet customer needs and wants. Thus, the measure of quality education depends on the skill with which the various stakeholder voices are integrated, processed and escalated into features of the institution and its related deliverables such as courses and programs. Such features include, but are not limited to:

- **a.** institutional structure,
- **b.** institutional facilities,
- c. program and course content,
- **d.** delivery modes and
- e. instructional interaction at the student-teacher interface.

Defining quality in terms of the integration of different 'voices' disarms higher education institutions (HEIs) of the prerogative to define quality in their 'own terms' and the quality assurance agencies from single-handedly imposing the yardsticks of quality assurance (QA) [3].

2.2. Management

Management has been focused through the lenses of a planning process, provision of leadership, staffing, organising, monitoring and controlling, all with the aim of achieving effectiveness and efficiency across the institution. Good management is about boundary spanning and gluing people of same and different dispositions around the institution's vision, mission and operations. The proclivity for turf-warring, group-think and de-generation into clinches is high in multi-stakeholder and multi-layered institutions [4]. In such contexts, management needs to be good at dealing with political game-playing and the emergence of power-seeking mates. It therefore must be effective and efficient on two main strategies: encouraging and resourcing favourable ideas and actions and weeding elements of negative monolithic politics. Balancing the two strategies creates the space for maturation of quality management infrastructures. QMSs are more effective and efficient in the hands of experts and those willing to become better by de-learning, (re)learning and supporting alternatives to their own proposals as long as such alternatives are more sound and productive [5]. The personal quality of allowing personal positions to be contested and fecund by others (constructive vulnerability) is a critical success factor in consulting for and co-creating institutional values, missions and visions [6]. This disposition to defencelessly and proactively feel at ease with 'constructive vulnerability' however takes long to develop. There are some 14 Best Practice Principles (BPPs) that [7] argue that they smoothen the management for quality in institutions:

- **a.** Being disciplined: this BPP refers to the application of a strong systems perspective in all structural, functional and behavioural aspects of the institution. The systems perspective must be vision-driven and buttressed by policy and standards.
- **b.** Being time-based: this BPP means the institution values time as a competitive tool and resource of critical developmental value. Therefore time should not be wasted, for instance, in pursuing non-value creating ideas and activities.
- **c.** Being up-front: a BPP that expresses employees' high moral probity in their valuing of honesty, humility and sincerity in all their interactions and relations.
- d. Creating customer value: a BPP expressing the strength of the institution's mental model of customer needs and wants, and how management, products and services delivery should be derived therefrom. The implication is that management, teachers and everyone in the institution must treat the other as their customer and understand what the other treats as value at their role level.
- **e.** Creating strategic capabilities: a BPP that expresses how institution-business capabilities are defined, understood and shared as key determinants of continuous improvement (CI) and customer satisfaction performance plans.
- **f.** Embracing change: this BPP defines the institution's disposition to evolve and generate new ideas and built resources for continually pursuing customer satisfaction performance. The implication is that individuals, teams and roles need to be open, vulnerable and malleable in order to change from within their hearts and souls.
- **g.** Ensuring integration of effort: a BPP expressing the institution's focus on value creation, management and delivery over functional needs and hierarchies.
- h. Establishing a learning culture: this BPP expresses the robustness of the institution's developmental orientation as focusing on knowledge and skills updating through a shared customer satisfaction performance-driven knowledge management infrastructure.
- **i.** Gaining alignment: a BPP that seeks vertical and horizontal congruence among strategy plan, key performance indicators and critical success factors.
- **j.** Having the desire to be out front: a BPP that describes the institution's structural, functional and behavioural disposition to live well above and ahead of industry-business standards, norms and practices.
- **k.** Linking the micro to the macro: a BPP, an expression of how employees manage their personal mastery in the understanding of how their individual efforts contribute to the wholesome business success.
- 1. Measuring, reporting and learning; a BPP that exhorts institutional sectors to measure, report on performance so that teams learn and better perceive the institution's atlas of improvement.
- **m.** Resourcing for the medium-term measures the institution's ability to excel at accomplishing short-term objectives and turning them into resources for medium- and long-term goals.
- n. Supporting distributed leadership: in this BPP employees take up roles with commitments to make careful decisions that fecund their own and others operational effectiveness and efficiency.

Good as they are, these BPPs need to be in vinculum with quality excellence principles upon which education is premised. In fact the BPPs must help in creating a context for optimisation of policies, procedures and standards used to deliver high quality education in institutions.

2.3. System

A system is an organised, purposive structure consisting of interdependent components that perpetually, but variably influence one another. Education and QM infrastructures are both deliberate purpose-driven systems. Any education is bestowed with a number of goals and objectives just as any quality management model is charged with a number of goals and objectives. A QMS applied to education should consist of a corpus of integrated, aligned, complex elements that relate in some sophisticated way. Educational systems consist of personal or human elements and impersonal or non-human components like buildings, machines, etc. While the 'hard elements' dealing exclusively with impersonal categories of systems are easy to measure, the personal issues or soft elements of a system (sociological, behavioural and relational aspects) are somewhat not measureable in simple quantitative terms. Because of this shortcoming, whatever standards are assigned in attempting to measure them will remain subjective, relative and therefore highly prone to contestations. Elements of a system can be further dichotomised into either quantitative or qualitative. The critical issue is that a systems perspective sees education as a collection of institutional-business processes focused on achieving quality policy and quality objectives designed to meet customer requirements and needs.

3. Making a quality management system serve education

A meta-synthetic analysis of research in both the private and public sectors indicate that the generic focus of QMSs is on the planning, directing, organising, monitoring and controlling of the education provision system or processes. At the input stages, the focus is on the selection of input factors of the highest quality. At the throughput stages, the focus is on the correct match-and-mixes that will provide the highest quality processes aligned with producing the correct and accurate outputs and outcomes. The throughputs routes and their inherent transformative activities must show concerns on wastage, increasing business opportunities, effectiveness and efficiency. At the output stages, the focus is on outputting products and services that satisfy and delights the customer. A clear institutional paradigm on quality education should determine the quality of inputs selected and how they get transformed in ways that approximates hypothesised quality as close to perceived quality as possible.

It is the author's view that the route to high quality education should be designed down from the institution's vision which must be explicitly clear on quality objectives and metrics. Subjecting educational outputs to the scrutiny and validation of the customers helps in setting and sharing meaning and standards against which to design a corpus of criteria for success. Modern industry-based QMSs like Six Sigma, Total Quality Management and quality function deployment among others have, since the 1980s, become widely used in education. The success of such adoptions depends partly on the ability of protagonists to make the focus of the QMS overlap with the focus of their education. Examining the alignment of the assumptions of a quality model with the key performance indicators in education would tell whether a

model suits the expected array of results. The quality management model must embody the sub-systemic issues that matter to quality education. Thus, an encompassing QMS must be hinged on a system-based mental model in which individuals accept responsibility to learn with others and to partake in a shared vision about how to create, manage and deliver quality. Models previously used in education are now stunted as they focus on small-scale aspects of the education system:

- a. The four-level model and the goal-free evaluation model both focus on measurement.
- **b.** The behavioural objectives approach focus on results.
- **c.** The responsive evaluation model, the consumer-oriented approach and the empowerment evaluation model focus on the customer.
- **d.** The organisational learning model focus on knowledge management while.
- **e.** The participatory/collaborative approach focus on partnerships.

The author acknowledges that there is something of each model or approach in every other model but what matters is a clear mental model of how they integrate and sustain the effort for quality education. Because educational institutions are complex interactions of sub-systems, a model that improves a singular part of the entity will not accomplish the goal of overall institutional quality performance. The meaning and implications in managing the various aspects of educational delivery will be discussed in much greater profundity in the following sections.

3.1. Management of educational assessment: meaning and implications

There is need for a focused strategic approach to choosing assessment methods and in implementing them. This is because the mix-and-match of assessment techniques should respond to the age, curriculum contexts and teacher qualities among other factors. The assessment methods need to be the most appropriate and be accurately operationalized. An array of assessment methods, exemplified below, can be used on the same students, same programme and within same or staggered periods. An educational institution's assessment methodology should encompass direct and indirect strategies, techniques, tools and instruments for the collection of information that strategists use to measure the level, scope and depth of learning experienced by the student. The concurrent use of multiple data gathering and processing techniques in assessment of teaching and learning improves the quality of information assessors will gather from the students and other sources. The triangulation approach strengthens the relevance, validity and reliability of strategies derived from such data. Among direct assessment methods are:

- a. Capstone course (projects)
- b. Certification exam
- c. Comprehensive test
- **d.** Embedded techniques
- e. Entrance interviews, etc.

Among the indirect assessment methods are:

- a. Focus group
- b. Institutional data
- c. Reflective student essays
- d. SWOT analysis
- e. Syllabus review
- f. Surveys (course evaluation, graduate, alumni and employer).

Assessment that asks students to demonstrate (direct) is as critical as those asking them to reflect (indirect) on their learning.

3.2. Management of quality control and quality assurance infrastructure: meaning and implications

Managing of the educational quality assurance infrastructure encompasses seeking the best fit among the various assessment methods and the rest of the activities that in their own ways determine quality of educational outputs and outcomes. Educational QA (quality assurance) has various activities, including assessments and quality controls (QCs) that are designed to track and resolve deficiencies, optimise inputs and processes to ensure that emergent customer needs and requirements are met continually. While QC (quality control) tends to focus on comparing inputs, throughputs and outputs against some scheme of criteria and specifications, quality assurance goes a little further in recognising that customer needs are complex, diverse and mobile [8]. Thus, in a fast-pacing world the need for focusing on quality assuring than QC is imperative. Because of globalisation, changes in resources types, processes and skillsets are giving rise to floods of styles and fashions. New Business Models have become more invasive in HEIs (higher education institutions) than in primary and secondary education institutions.

3.3. Management of resources/inputs: meaning and implications

The relation among inputs, processes and outcomes is not uncommon in educational management literature. The generic perception is that it is needful to ensure that the quality of inputs is as high as we would like the quality of outputs to be. Two assumptions come into play in this instance:

- **a.** The quality or how well the processes will work out will be determined by the quality of the resources input into the transforming processes.
- **b.** Assuming the input resources are favourable, the quality of outputs will be determined by the appropriateness and quality of the transforming operations.

But further to these assumptions is the need to ensure that the recruitment and selection of the inputs is subordinated to the framework of customer satisfaction performance. It basically means that the inputs and outlay of processes must be built from an analysis of the demands,

needs and wants of the student, industry-commerce and society. A framework by which output requirements can inform input requirements through the Six Sigma Roadmap can be referred to as 'designing down'. Among the touted inputs are:

- **a.** Quality of teachers often defined by their level of certification rather than by their ability to make their students acquire and perform particular skills;
- **b.** Quality of the buildings often rated by the imagery in them than their appropriateness as facilitators to a process of learning and transformation and
- **c.** Quality of students often perceived through lenses of some assessment system that is little aligned to what the student will develop along the institutional experience.

In essence the inputs in both quantity and quality must be derived from the 'voice of customer' and institutional vision on quality than anything else.

3.4. Management of educational processes: meaning and implications

Management of educational throughputs is a complex program because it calls for vertical alignment as well as horizontal integration of modes of thinking as of action. There is need to link the Strategy Plan from top-level goals to shop-flow operations and across the sectors and departments of the institution. It is therefore of paramount importance that strategists, managers and those at the operational-technical level appreciate the criticality of connecting every micro-activity with the bigger (macro-) picture of the institution. Linking the micro- to the macro- is a critical success factor in strategy implementation as it keeps every action looped with the strategy's objectives and goals. The positions of classroom practitioner, level head, head of department and upward have different job descriptions and assumed person competences that are, often in principle, 'proven' to facilitate good learning in the institution. These assumptions are combined to an array of standing and emergent policy regime that is meant to support or positively exploit the human skills. The delivery of high quality education may be constrained by inconsistencies in the policies and in their implementations.

3.5. Management of outputs: meaning and implications

'Management of outputs' may sound a rather inappropriate terminology for how the institution deals with the results of the learning-teaching processes. Educational outputs include the extant, the near and medium range results of an instructional experience. This includes the reflections undertaken by the teacher after encounters with the students and these focus on the reactions and responses of the learners. There is a need to differentiate educational outputs from educational outcomes. Educational outputs are more of the immediate and fairly near-term results of the education delivery system. Outcomes of an educational system and experience are rather difficult to winnow and claim in an exclusive fashion. Outcomes are a much delayed feature and their manifestation embodies the influence of other learning from society and the environment that the individual brushed with since the last instructional relationship. Outcomes reflect the deeper learning that resulted in the transformation of behaviour. It is important that the institutional process in the classroom does not limit itself to impacting content. It must as well focus on developing critical thinking skills, systems thinking and personal mastery. This transformative approach has implications on subject didactics and

school pedagogy [9]. The next section compares six quality management models, evaluating their biases and thus, assesses their capability of improving quality of educational delivery.

4. Comparative analysis of quality management systems

A comparative analysis of QMSs should help in assessing and evaluating why and how QM models fail or survive their brush with the gang aft agley of operational reality. A structural analysis of seven mostly used QMSs are ISO—International Standards Organisation; EFQM—European Foundation for Quality Management; MBNQA—Malcolm Baldrige National Quality Award; SQAF—Singapore Quality Award Framework; CFfBE—Canadian Framework For Business Excellence; ABEF—Australian Business Excellence Framework and TQM—Total Quality Management) show that (strategic) planning and a focus on both internal and external customers are of paramount importance (100% presence in the models).

Leadership, process management and business results came second with 83% presence among the seven models. Knowledge management, partnerships and information rate at 33% presence across the seven models. Measurement, policy, improvement, innovation and resources stand at 17% presence among the seven models. The five focus areas in Section 3 are in fact categories of the models shown in **Table 1**. In summary, the nine quality management models under Section 3 call on the education delivery system to respond to the needs of the student and the market of future employers (including self); the robustness of the metrics for success; the empowerment of the learner and the teacher to determine what constitutes a real learning chain or environment and the growth through collaborated engagement of the society, the institution and the student. The failure of most QMSs ubiquitous in education is based on their miniaturisation of education and focusing on small-scale issues of education [10]. Sections 4.1–4.11 will explain how the new public management (NPM) embrace these quality management models as categories within them.

4.1. Leadership in quality management systems

The content and processes of leadership at any institution is determined by the balance of interaction between top management and the led or followership, and the stage in evolution of the institution. Literature is awash with castigations of top-down, hierarchical and authoritarian leadership styles [11, 12]. Despite the castigations, these styles of leadership will continue to find relevance at various stages of institutional development. These styles may be used where resistance is anticipated and where quick fixes are required. Thus, a QMS while it may not exhort the use of such styles as a permanent mode of interaction between the leaders and their followership it should not repudiate their service to high quality performance at any level of the institution, at some (rare) occasions/time. Except for radical business process redesign (BPR), most quality models tend to encourage a mixture of bottom-up and top-down management system, with many authors arguing that a team-based structure would greatly favour success of most QMSs. Most strategic plans view education as an ongoing program of multiple subprograms and projects with each having multiple activities and objectives. Therefore, a QMS would work better if everyone was fully committed to work with and recognise the value of everyone else. Leaders, managers and strategists in QMS should facilitate in defining and

	Leadership	Strategic Custo planning focus	dership Strategic Customer Process	nent	Business results	Business Knowledge Improvement Measurement Partnerships Information Policy Innovation Resources Number of results management	Improvement	Measurement	Partnerships	Information	Policy	Innovation	Resources	Number of categories
ABEF	×	×	×	×	×	×	×			×		×		60
CFfBE	×	×	×	×	×				×					90
EQFM	×	×	×	×	×				×		×		×	80
ISO	×	×	×	×	×	×	×	×						80
MBNQA	×	×	×	×	×	×		×						20
SQAF	×	×	×	×	×					×				90
TQM	×	×	×			×	×							05
	100%	100%	100%	%68	%68	22%	43%	29%	29%	29%	14%	14%	14%	

Table 1. Comparing QMS models by their key categories.

clarifying the different project priorities; inspire sufficient collaboration and participation; manage and catalyse change and deal with conflict. The transformation towards locally based, distributed or participative leadership is important [13, 14]. Inclusion of institutional members in modelling decisions multiplies their power to act on those decisions.

4.2. Strategic planning in QMSs

Strategic planning is a disciplined effort to produce fundamental decisions and actions that shape and guide what an institution is, what it does, where it wants to be and how it intents getting there. A strategic plan must clarify the 'what', 'why' and 'how' of the institution's life. The fundamental output of strategic planning is a strategy plan which is a documentation of what the institution is, what is undesirable about it and what it wants to be in some specific time. It also shows how it will traverse from current to the desired and why each of the 'how' is the best option as well as why the change is deemed desirable. The outcome of good strategic planning and implementation is institutional survival, growth and sustainability. Institutional growth may not always be measured in financial terms as there are many non-financial pursuits of the institution. Any desirable change, for instance, profound understanding of stakeholder requirements, substantial reduction in the frequency and content of customer complains can be interpreted as growth. Scholars [15] refer to five fundamental disciplines that form the bedrock of profound change:

- a. systems thinking
- **b.** mental model
- c. shared vision
- **d.** personal mastery and
- e. team learning.

Framing strategy planning and implementation on the five disciplines improves the breadth and depth of understanding of related key performance indicators and critical success factors. With such understanding, the institution will be able to continually narrow its risk envelop [16]. The following sections focus on the meanings and implications of the five disciplines as relating to education.

4.2.1. Systems thinking in QMSs

Systems thinking in education are a mental tool of understanding how sub-components of a whole influence one another so that resolving problems within one part of education should neither negatively impact the performance of other areas nor create unforeseen consequences. Generating and maturing a systemic and complete vision of education or the institution can be enriched and perfected by use of such techniques as causal loop diagrams, links and loops, stock and flow modelling, archetypes and computer models among others. These tools help the institution examine and exchange hypotheses about institutional performativity. There is very little inclusion in masters' level curriculum of what managers and technicians will require

on the ground [17] and little taught in education are the core elements of Senge et al.'s five disciplines [18]. These are shown in **Figure 1**.

The five CSFs for cross-stakeholder engagement are co-creating a vision, learning together to co-create projects and programs and self-governance impact QM in a significant way. However, most education managers develop and diffuse systems thinking skills through casual experiences far late in their careers. Management that focus on quick fixes and quick results are less likely to sustain a quality culture. Notwithstanding, most management show high disposition to bring change by dealing with rules, work processes, information flows, physical facilities, material flows, control mechanisms and reward systems. Systems thinking create the vocabulary and language that help members see events, patterns of behaviour, systems and mental models in strong vinculum.

4.2.2. Mental model in QMSs

Mental model refer to the images, assumptions and stories which people carry in their minds about themselves, other people, institutions and every aspect of their environment. Because people are differently attracted by different details of any one system, they are bound to pay unequal attention to same issues. Consequently, they will have different intensities of emotions about the same components of a system. To have a complete picture of the ever-changing world, people need to be more reflexive and truthful about how they feel about what surrounds them. Reflecting and perpetually enriching and updating perceptions of the world and how these influence people behaviourally and psychologically improves humans' chances of taking correct developmental decisions. Mental models and attitudes are the make, maintain

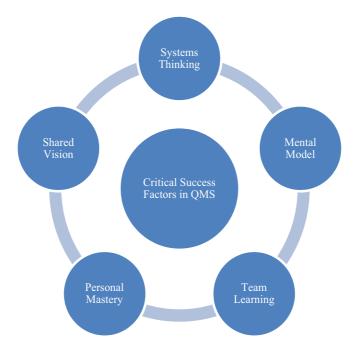


Figure 1. The five critical success factors in a quality management system.

and break of QMSs in education because they shape people's actions, reactions and responses to others, policy, rules and regulations. Institution-wide tendencies to fragment and compete 'for no sake' are not unusual [19]. Some of the factors likely to impede the institution's quality performance include therefore the inability to deal with divided staff that goes to 'war' over every small issues, the lack of skill to engage those at cross purpose as well as failure to diagnose beyond symptoms of conflict and dysfunction in institutions.

4.2.3. Personal mastery in QMSs

Personal mastery means the capability of learning to expand individual, team or institutional capacity to create own strategic capabilities in pursuance of personal, team and institutional goals. The individual is the basic unity of structure and function in the deployment of quality. It is therefore important that individuals in the institution appreciate the gaps in their behaviour, knowledge and skills so that they can map out an atlas of personal developments and improvement. The tools of personal mastery help to measure and analyse the gap between where one stands and where one want to be. Once people have a correct and accurately detailed picture of the scope of the gap people get to the thresholds of a creative tension. The creative tension now becomes the motivator for improvement. The power to resolve the creative tension arises from the relationship among the different elements of the institutional context. Institutions thus, need a workforce and strategists that help one another clarify and understand the current reality and chemistry of the creative tension. Creative tension means the felt gaps among components of a system and the gap between the current and the desired futures. Figure 2 depicts the creative tension as a dynamic system of the context, the desired future and the pathway thereto.

Personal mastery relates to quality management in that if people are able to reflex truthfully they should be able to tell themselves how they are causing poor quality performance. They too should be able to say how they can contribute to quality education.

4.2.4. Team learning in QMSs

Lest people confuse team learning with team building, the latter's focus is about improving communication and team members' skills. Team learning is about how the organisation can

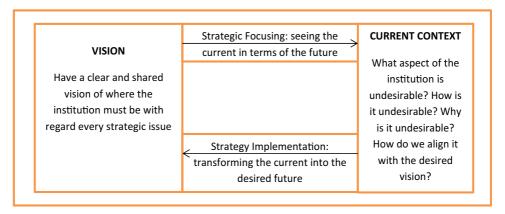


Figure 2. Creative tension: understanding the current in terms of the future and mapping how to get there.

work with internals and externals to create and share a coherent and relevant vision, think strategically on even the minor issues and build a mental model of a continuously improving institution. The crux of the discipline of team learning is to help teams re-create themselves in ways that sustain and self-reinforce gained strategic capabilities. In most pedestrian level it may seem that 'stakeholders' in education are at cross-goals. In reality, quality assurance agencies, industry, students and governments have as top of their agenda—high quality education. Applying the Six Sigma roadmaps should help stakeholders appreciate that working in some co-ordinated manner creates the strategic capacity of thinking, learning and acting in synergy. In a team, each needs the other to accomplish a result. The intricate relationship among the disciplines and each of them and the whole to strategic thinking and the strategic planning process itself cannot be overemphasised. The assumption of the model depicted at **Figure 1** is more complex than the schematic representation is.

The manner in which individuals conduct themselves in relationship to others and their contexts (personal mastery) determines their disposition to learn and grow themselves and others (team learning). The more they interact and converse about their experiences and the more they understand their contexts and the broader universe. The more people comprehend their contexts and incorporate such understanding systematically in their decisions the more they improve the quality of their universe and incorporate such understanding in their decisions (systems thinking). Profound personal mastery and a disposition for team learning and systems thinking help build strong and informed mental models that help people accomplish enlightened strategies of accomplishing win-more-win-more outcomes (shared vision). It benefits institutions to think and adopt strategic planning for quality education guided by the five disciplines. Much of the failure with the adoption of quality assurance measures are not in the models but in the incapability of conceptualising how workforce and stakeholders can draw up vectors of learning and improvement within the five disciplines. As long as this incapability persists, it is the author's view that there will not be improvements in the quality of education and institutions providing it.

4.2.5. Shared vision in QMSs

Sharing a vision about quality and its management into daily institutional practices is about connecting with the rest of the workforce and stakeholders, understanding what they are doing now that is constraining or improving quality of education. Open deliberations help people be truthful about their contexts and helps too in people talking frankly about what futures they desire and how much they are willing to give to achieve that future. The Six Sigma roadmaps shown in **Figure 3** is one such strategy of putting together different voices in building shared visions.

4.3. Process management: meaning and implications

Process management is the set of methodological and management practices used in ensuring that business and institutional activities accomplish their allotted performance targets. Information technology (IT) enhances process management and continuous improvement thus turning processes into assets. Indeed the basis of quality assurance is in assuring that processes are optimised without compromising their focus, effectiveness and efficiency in pursuing

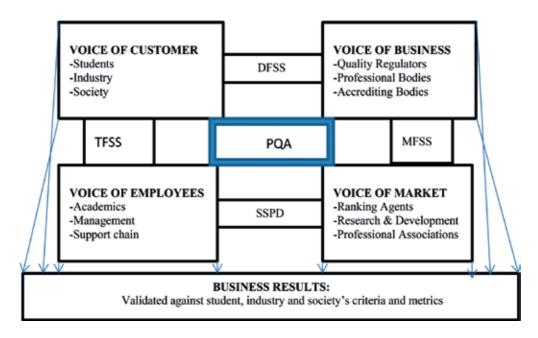


Figure 3. The combination of voices for program quality assurance.

customer satisfaction performance. Quality can only be assured with appropriateness of processes. Business process management systems can benefit the quality effort in a number of ways including pinpointing interface noise. Interface noise cause quality to decline. The Six Sigma roadmaps (Figure 3) in various ways improve quality of products and services by:

- Firstly, focusing institutional design and processes (DFSS) on operational target goals and objectives.
- b. Secondly, by aligning and integrating system-system, system-person and person-person processes (SSPD).
- Thirdly, by using technology in optimising utilisation of core and complementary resources (TFSS).
- Fourthly, by working only on value-creating processes (MFSS).

Processes that may have detrimental effects on value or do not add any are a liability to the institution. Setting-up a process improvement infrastructure should start from interviewing and surveying people throughout the institution to find out what they do, how they do it and why they like or dislike the experience. This however, needs honed skilful discussion competences on the part of management and the workforce. Well-developed competences in skilful discussion help to mine truth from behind workforce's fears, mistrust and doubts. People are more prone to hiding information and data when they are in fear, mistrust and doubtful. In times of poor quality performance, the temptation for corporate isomorphism or adoption of radical process and structural redesign or the use of consultants to fix the messy is high.

It is the author's view that neither of these strategies is likely to embed a permanent and relevant solution to poor institutional quality performance. In fact the institution may suffer a duplication of activities, clogging of interfaces and exhaustion of workforce on valueless activities. This leads to overall decline in amount and quality of processes that directly create customer value. District offices and schools complain of too much work which would be greatly reduced were processes that created that work aligned, integrated and right-sized. Time saved can be re-arranged to encourage focus, concentration and intensive work or even afford workers 'free' or unstructured time. Quality of work depends somewhat on the amount of such unstructured time people spend ruminating about their roles and the assignment in their charge.

4.4. Customer focus: meaning and implications

In education the many customers to an institution may be allotted into one of the four categories below:

- **a.** Voice of Customer (students, society and industry).
- b. Voice of Business (quality regulator, accrediting agents, professional agents).
- c. Voice of Employee (academics, supply chain staff, non-pedagogic staff).
- **d.** Voice of Market (ranking agents, professional bodies, Research & Development).

Figure 3 illustrates the interaction of the four voices and they ultimately confluence into business results as measured by yardstick of student, society and industry satisfaction. In the ultimate instance, the Voice of Market, Voice of Business and Voice of Employee must focus on meeting requirements in Voice of Customer (students, society and industry) as in Figure 3. A focus on the customer should translate into a robust market-oriented philosophy or mental model and a pragmatic methodology of hearing, understanding, learning and responding to the four voices. Profiling and understanding the customer has a strong impact on how well the institution will develop and refine their processes, mission, values and consider development of their own vision sketch. A mental model of customer requirements informs the whole framework of training, skilling and refining of the institution's vectors for continuous improvement (CI). Vector of CI is meant a specification of how much and what direction a process, skill or competency needs to be improved so as to meet a customer requirement. The amount of change may be quantitative or qualitative. The direction of improvement may be negative (removal or reduction) or positive (addition or innovation). These three types of improvement vectors can be operated singly or may be executed within the same program. The important thing is that they are driven from the 'voice of the customer' and validated through a Six Sigma roadmaps approach.

The validation should be based on the impact the skills will make in DFSS, SSPD, TFSS and MFSS. Most institutions have strong and vociferous claims of customer-orientation yet the features of their product /service are determined by the institution or some other organ rather than derived from the voice of their customer [20]. In their isolation, these voices will not lead to much long-lasting change towards customer-focusing. To avoid reactivity to multiple and fragmented customer demands the voices can be combined, forming four Six Sigma Roadmaps as illustrated in **Figure 3**. Most institutions receive or do provide training and some sorts of skilling on customer care. The value of such budgets become questionable if the trainers, the content and

the purpose is alien to the contexts of the four Six Sigma roadmaps. Customer-focused training and skilling must be premised on creating strategic capabilities in the form of substitute quality characteristic (SQC) or technical competences (TC) and target values (TV). These three terms are meant conceptual, managerial, behavioural or practical capabilities that close the gap between P_i (intended performance) and P_o (observed performance) as illustrated in Eq. (2)

$$SQC_{gap} = P_{intended} - P_{observed}$$
 (2)

Note that the terms target value can be applied to non-human resources like tools and machines while the terms SQC and TC are often used in Ref. to human performance competences. In the ultimate instance, the strategic concern is for all the voices to feed into the needs and wants of the student, society and industry-and-commerce. This point is further illustrated in the comparative analysis of the structure of the different QMSs. In **Table 2**, it is shown that business results are measured in terms of customer satisfaction performance, wherein the customer is students, society and the institution. There are many techniques used to gather information and data from education's customers. These include interviews, student evaluation of teaching effectiveness (SETE) forms, observation schedules, records of complains, training needs analysis, learning needs analysis, etc. The data and information can be processed by use of brainstorming, tree diagrams, Kano diagrams, etc. Research has shown that copious amounts of data are collected by institutions but very little is done to process the data and make it influence hiring, procurement, budgeting and other management decisions [21]. Least done is the process of making the customers validate the information extracted from the data. Representatives from within the four voices can be used too in constructing and contenting the different data gathering instruments. Representatives from within the four voices can further be used to validate the list of needs and wants.

4.5. (Continuous) Improvement

Strategic planning must identify the improvement vectors within the disciplines of systems thinking; team learning; personal mastery; mental model and shared vision. With improvements

Focus of results Ficalora and Cohen [21]	Six Sigma customers Matorera [1]	EFQM-based results	Short-hand expected results Matorera [3]
Voice of customer	Student Society Industry	Customer results	Offered Quality supersedes expected Quality: $Q_o > Q_e$ therefore $Q_p > 1$ meaning positive CSP
Voice of employee	Academics Support staff Management	People results	Work-life balance, effective and efficient systems and institution
Voice of business	Quality regulator Accrediting agent Professional agent	Business results	The teachers, course outlines, courses, programs and the institution meet a threshold of criteria on quality as the constituents define it
Voice of market	Ranking agent Professional bodies Research & Development	Society results	The teachers, course outlines, courses, programs and the institution outsmarts the generic criteria of quality & creates unique competitive competences

Table 2. Relations among the different voices, EFQM and expected business results.

in these disciplines, there come earnest improvements in the institution's breadth and depth of the strategy plan. Improving skills in the five disciplines should increase relevance of the Change-Project Management schedule and appropriateness of the Framework of Implementation Strategies as well as comprehensiveness of the Strategy for Risk Management as shown in **Figure 4**.

The basis of continuous improvement is a creative tension that correctly and accurately details the undesirability of the current institutional context(s) and the aspired future state(s) (**Figure 2**). The creative tension itself sets the atlas of institutional change. Expert strategists, through intrainspection (personal mastery), systems thinking, team learning and sharing visions of their institutions build mental models of what their customers really desire. Based on these mental models, the institution must be able to precisely define the desirable behaviour change indicators (BCIs), key performance indicators (KPIs) and critical success factors (CSFs) that improve quality performance of individuals, teams and the institution as a whole. Different institutions adopt different strategies of doing strategic planning. The third strand of the strategy focus wheel (SFW) is Change-Project Management which is supported by five BPPs (Best Practice Principles):

- a. Being time-based
- **b.** Creating customer value
- c. Creating strategic capabilities

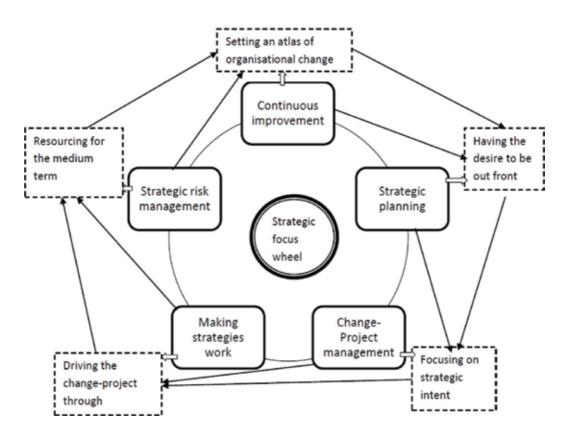


Figure 4. Strategy focus wheel applied to QMSs [3].

- d. Gaining alignment
- **e.** Linking the micro to the macro.

In this stage, special emphasis is brought on assessing the environment to identify strengths, weaknesses, opportunities and challenges; identifying and framing strategic issues; formulating strategies to manage the strategic issues; reviewing and adopting the Strategy Plan. It is logical that in seeking to manage quality, institutional members, at all cost, work from institutional contexts otherwise the strategies will not respond to the institution's quality necessities. One of the shortfalls is coming up with SWOT analyses as being an end unto itself. In quality management, a SWOT analysis is just but a tool for designing a set of strategic plans that should use institutional resources to deal with institutional challenges. The prime focus of the SWOT analysis should be to help the institution see how on a cost–benefit analysis the institution can utilise opportunities and its strengths to mitigate threats and weaknesses and drive change and projects through. Making strategies work is directed at driving change-projects through and hinges on the functionality of the seven BPPs:

- a. Being disciplined
- b. Being up-front
- c. Embracing change
- d. Ensuring integration of effort
- e. Establishing a learning culture
- f. Measuring, reporting and learning
- g. Supporting distributed leadership

Done well, the main gains to the QMS would be an effective implementation process, and the establishing of an effective organisational vision for the future. While both radical and revisionist BPR (business process redesign/re-engineering) versions assume process owners can steer and direct implementation, TQM and Six Sigma assign this role to statistical tools. In educational QMSs, this role can be protagonised by Vice Chancellors right to front-line workforce helped by mathematical and statistical tools such as those used in descriptions of costs, enrolments, etc. Descriptive and predictive analyses can be used to identify future opportunities and challenges. This also constitutes strategic risk management whose focus is ensuring that strategies and the strategic planning process are reassessed continually. This ensures that every objective attained becomes a means or tool for accomplishing future goals and objectives. This is referred to as 'resourcing for the medium term'.

The revisionist BPR, TQM and Six Sigma models are based on the BPP of 'resourcing for the medium term'. Resourcing for the long-term confer moderate risk to activities of QMS. This is mainly because the idea of 'resourcing for the medium-term' examines the present in terms of the future. It further ensures that an objective achieved now should be a resource and means for achieving future institutional objectives. In contrast, radical BPR confers high risk to quality strategies as its habit of starting from scratch forfeits it of the historical success of the institution. Radical approaches to institutional difficulties and problems often quickly run out of steam, budgets and support as people are bound to feel short-changed.

In interviews with school managers, it emerged that at the moments of strategic planning the main huddle was focusing on strategic issues because there always would be arguments between 'theorists' and 'pragmatists'. Others sited problems of individuals being unresponsive to suggestions on their learning needs or performance deficiencies. A principal explained how after agreeing on performance improvement plans with teachers 'two full terms down, no action, no response and things remained the same if not worse'. A district manageress had an intervention visit to a school labelled in a complaint letter from a union a 'witch-hunting expedition'. But to help another one needs to understand where the deficiency is first. The aforementioned instances show how even when people share a vision of quality improvement their mental models about how to do quality improvement may be quite different. Even when improvement strategies were crafted from the institution, some felt their operationalisation would be swamped by regulations and requirements. Implicitly, this would compromise the institution's home-grown strategies as they are left without monetary, psychological and time budgets. Thus, locally grown change needs and projects would always be scantly driven through. By implication it means that much of institutional budgets are spend on chasing issues that are valueless in terms of continuous institutional improvements. It also implies that the risks (positive or negative) perceived by the institution or part thereof are not exploited as they are left to compete with those dictated from above by top management. It was not always that dictates from top-management are irrelevant at the middle or lower institution echelons. Despite the alignments there are many chances that the requirements are felt by both but enjoy different priority levels with each group. Differences in priority result in either over-budgeting or under-budgeting on each activity. Either way, over-budgeting or under-budgeting exemplifies lack of strategic risk management.

The priority given to the improvement of a target value must correspond with the amount of value the target value or CSF (critical success factor) will leverage towards customer satisfaction performance. Kano diagrams (Kano model) should accomplish this. Focusing on an improvement vector and target value and the prioritisation of related budgets is an important part of system thinking-based strategic categorisation activity. Strategic categorisation should see the institution build its critical strategic capability on a continual basis. The magnitude of 'improvement ratio' on any improvement vector depends on the strategic capabilities deployed on that vector.

4.6. Knowledge management: meaning and implications

By knowledge management is meant a process of generating, sharing, managing and using the know-hows and information of an institution. Great amounts of knowledge can be generated where there is strong teamwork culture and managers and leaders acting as knowledge nodes and knowledge distributors. The tools for knowledge management include among others:

- a. on-the-job discussions,
- **b.** mentorship,
- c. discussion forums,
- **d.** corporate libraries and
- e. professional training,

Knowledge management continue to be hampered by individual idiosyncratic make-ups or personal mastery and the structural and cultural peculiarities of certain institutions. If an individual feels that they can use information and knowledge for personal progression or other individualist benefits, they are more likely to hoard it and stop its flow even to persons who actually would use it more and better. The use of knowledge management technologies continue to be low among roles in the education system and the content of the communications, where it exists, tends to sway towards social relations and commentaries than professional growth. This may be caused by that social media platforms are the main forums through which professionals continue to interact [22]. In western-world literature and practice, the following technologies of knowledge management seem to be commonplace such as groupware, workflow, content management, enterprise portals, e-learning, Microsoft Outlook and Project (scheduling planning) and video conferencing, these may not be the case for the majority of African educational institutions. Technology-driven communication is important in the delivery of data and in its application in improving quality of education. A wellconstructed knowledge management infrastructure should have robust knowledge management software that allows it to innovate, build and share knowledge that should help in improving customer experiences and satisfaction.

Large volumes of knowledge sources and information can be transacted via visual search models like: matrix search; tag cloud search; tree traversal; taxonomy navigation, etc. Lowdeveloped nations with marginal electric power infrastructures would be least able to use these technologies. In some of the institutions, the reasons for low usage range from the strategic (top) through management down to the technical level of the institution. The institution-wide impediments can only be overcome when people learn to be frank in discussing what potentials they see in these knowledge management technologies and how their contexts constrain the adoptions of the technologies. At the strategic/institutional level, knowledge management systems may be considered expensive or a luxury and therefore top management lacks commitment to related budgets. Function-based, closed institutions with their propensity for tuff-warring, fragmentation, competitiveness and dysfunction may not have a 'good' reason to share with their 'rivalries'.

At the management level [23] talk of the absence of Knowledge Management in the Strategy Plan and therefore absence of incentives, recognition, managerial direction and leadership as key impediments. Particularly at school and other operational levels, lack of skill and therefore the threat of exposure of those lacking skills to deal with vast amounts of knowledge may create avoidance or explicit resistance to adoption and diffusion of knowledge management technologies. The criticality of knowledge management in institutions cannot be overemphasised, with [24] lamenting that schools and local education authorities are notoriously poor knowledge sharers albeit being in the learning business.

4.7. Measurement, reporting and learning from business results: meaning and implications

Business results are characterised by the outputs and outcomes from the operation of sets of performance management and analytic processes across the institution. Such results can be at any point along the 'disappointing-to-delightful' continuum where the Q_D (quality of business output perceived) depends on the difference between Q_e (expected quality) and Q_o (offered quality).

$$Q_{perceived} = Q_{expected} - Q_{offered}$$
 (3)

Various assessment and measurements techniques can be used to measure business performance mid-course or at the end of an instructional period. Table 2 indicates expected results if the Six Sigma roadmap was applied on the EFQM model. The value in deriving expected targets from the institution's key stakeholder groups is that the results analysis will impact strategic planning, the strategy plan and the many processes (QMS) that result in the (re) configuration of a strategy implementation infrastructure that created the sets of results. The impact will be twofold: reflection and feedback on how the QMS was rolled out and reflexion and feed-forward, that is, informing what can be done to make the future experience with QMS more fruitful. Figure 5 illustrates this flow reasoning which however is far from being so structured and an exemplar of cause—effect relationship in real life.

4.8. Partnerships

The term partnership defines the 'relationship either, contractually supported or otherwise, between two or more parties, each of whom shares joint and several liabilities for the actions of the whole' say [25]. During examining, the potential benefits of partnering managers must look at and completely understand what is driving them into choosing partnering. They must run a similar assessment of the target partner and understand the positive and negative risks based on their own and others' vision. Understanding the others' drivers for partnership with your institution is a critical success factor not only for the project you are partnering in but also for the sustenance of your vision as well. In education, partnerships may be at the following levels:

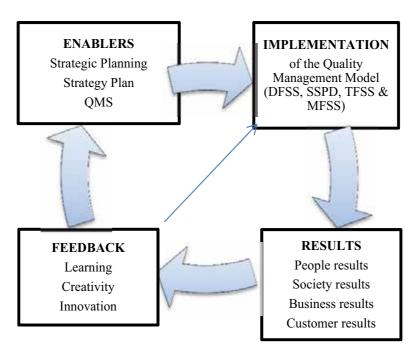


Figure 5. Relation among enablers, implementation, results and feedforward in QMSs.

- a. institution institution;
- **b.** institution department;
- **c.** department department;
- **d.** department individual(s);
- e. individual individual level, etc.

Important in any such partnership is the gaining of a benefit in terms of improving quality of expected results. It becomes good practice then that in the gestation of the partnership parties review, feedback and feed-forward with an eye to improve management of quality. It is worth noting at this point that most partnerships in education are based on exchange and sharing of competencies and expertise.

4.9. Resources

Resources are a critical element in quality management. Quality education depends on the presence of a supply of resources at the strategic, management and operational levels of the institution. Learning resources are a critical success factor for quality scholarship just as are teaching resources. A number of factors variably influenced the quality and relevance of resources in institutions. These ranged from procurement (purchased or donated) of irrelevant resources, incompatibility of resources with the mentality of proposed users and/or with the extant infrastructure of the institution. Management were blamed for investing in facets that increased institutional visibility and image at the neglect of less impressive resources however important they would be in improving quality of teaching and learning.

4.10. Information management

Information management is defined as the planning, organising, processing, structuring, evaluation, controlling and reporting on activities relating to acquisition, dissemination and disposal of information. One of the cornerstones of quality management is management by facts and this makes the flow of information of high importance in strategy formulation and implementation. In quality management, it is also important that data transforms into information that is worked into knowledge usable for effective decisions. Decisions in turn, are effective to the extend they guide appropriate actions that in turn impact delivery of customer, business and societal results. Excellence in information management in the education sector should see institutions better aligning the volume and quality of acquired technologies with the institution's quality strategy. This deliverable is covered in the Six Sigma roadmap-Technology for Six Sigma. Schools that refuse students to use smartphones as learning resources are depriving their own students of a chance to get more information and presented in more animated and interactive forms than it would be in textbooks and on chalkboards. Early familiarisation with knowledge and information management technologies should expedite students' metacognitive skills as well as the institution's ability to catalyse and enable it. There is nothing that exemplifies information management than the learning process and TFSS becomes of immense importance to institutions as to students. i-Pads, smartphones, notepads should move into the centre of the instructional relationship in and out of the classroom. Most critical learning conversations for the young 'digital natives' generation of learners are occurring online, anytime at any place with virtual mates thousands of kilometres away.

5. Conclusions

Understanding each component of a QMS in its individuality should help in building a coherent picture of how a QMS can be at the service of a student-focused and market-oriented education delivery system. However, efforts to build an infrastructure for quality management and quality assurance are often constrained by the apparent inability of the stakeholders to share at least a near-common vision of how to do 'quality' in education. One way forward would be starting at the level of personal mastery and change the deep-sited attitudes and developing skills in strategic thinking so that the cause for team learning and reconfiguring our mental models becomes more urgent. The chapter worked on seven quality management models showing how they converge on nine categories. For effectiveness, these categories must be implemented in the framework of the 14 BPPs discussed herein. Important would be for the institution to create strategic capabilities in each category and thereon has roadmaps for continual skills updating as the institution co-adapts with changing customer needs and wants. Profound co-adaptive change calls for consistent changes in strategic focus, set of key performance indicators, behaviour change indicators and the institution's bundle of critical success factors.

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Heidegger and Althusser on Quality Management Systems in Open and Distance Learning

Victor J. Pitsoe and Moeketsi Letseka

Additional information is available at the end of the chapter

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Abstract

The quality management system (QMS), as an intricate of interacting elements, is a fundamental property of higher education and is fluid and very complex in nature. With this in mind, this chapter explores the symbiotic relationship between the notions of QMS and open and distance learning (ODL). Our thesis is that the notion of QMS is not value-free. Yet, it is a fundamental pillar of higher education institutions and commercial organizations. Among other things, it shall be argued that (1) constructs of *Being* and *Becoming* are the hidden epistemological and ontological dimensions of QMS and (2) QMS is a carrier of ideology. And to borrow from Michel Foucault, it shall be postulated that QMS perpetuates docile bodies. As such, this work shall draw on the works of Martin Heidegger and Louis Althusser.

Keywords: quality management systems, open and distance learning, ideology, docile bodies, *Being* and *Becoming*, temporality, Heideggerian model of temporality

1. Introduction

Quality management system (QMS) is a fundamental property of higher education, more specifically the Open and Distance Learning (ODL) mode of delivery. This chapter is premised on the assumption that accomplishing quality in ODL is not just about fulfilling standards and criteria required by an external quality agency, but that it is about growing ODL practitioners and students' interest and obligation to teaching and learning. The chapter is philosophical in that it explores the symbiotic relationship between the notions of QMS and ODL. Notwithstanding its exploratory nature, the chapter contributes to the on-going debate on knowledge and *quality* in higher education. Hence, the authors attempt to defend the view that the notion of QMS is not *value-free* and that it is a fundamental pillar of higher education



institutions and commercial organizations. It is worth mentioning that both as a social and power relations construct, QMS plays a major role in ODL and has sparked ample discourses in and outside academia. Apart from the shifting definitions and contested understandings of QMS, the central thesis of this chapter is that QMS is a carrier of ideology and that it perpetuates docile bodies; the latter will be analyzed in greater detail below. Despite the fact that much has been written about QMS, one of the most noticeable gaps in many contemporary texts on the *dominant* QMS (in terms of ideas, values, norms, beliefs, and behaviors) is a failure to see it as an (a) ideology, (b) ontological and (c) ontological and epistemological problem.

Against this backdrop, one possibility is to unpack QMS, both as a discourse and *emancipatory* dialog. The works of Martin Heidegger (a German philosopher and a seminal thinker in the Continental tradition and philosophical hermeneutics), and Louis Pierre Althusser (a French Marxist philosopher) are significant to the understanding of QMS in the ODL sector. They offer diverse analytical frameworks to consider the meaning of quality in higher education. Among others, therefore, this chapter argues that constructs of *Being* and *Becoming* are the hidden epistemological and ontological dimensions of QMS. It is the authors' view that QMS is always in the state of *Being* and *Becoming*. It is in a temporal mode of *being* and fits through Heidegger's [1] lens of "thrownness" (*Geworfenheit*). Thus, the concept of QMS is central to ODL praxis. This chapter assumes that the QMS is a complex of interacting elements that are fluid in nature. It consists of "interrelationships of complex phenomena (as parts of the system) on the system as a whole" [2].

While exponents of the systems theory such as Ludwig von Bertalanffy, Talcott Parsons, and Norbert Wiener conjure that systems should be studied as a whole, this chapter starts with Aristotle's claim that knowledge is derived from the understanding of the whole and not that of the single parts. This chapter is divided into five sections. The first section begins by conceptualizing the notion of QMS in the context of higher education space. The second section presents Heidegger views on *Being* and *Becoming*. The third section reflects on QMS as a carrier of dominant class ideology. This reflection is against the backdrop of Althusser's *Ideology and Ideological State Apparatuses*. The fourth section presents QMS as a key pillar in the higher education industry. The fifth section proposes a (re)thinking of QMS through the Heideggerian lens of *temporality*. Finally, the conclusion gives a brief summary and the concluding remarks.

2. Conceptualizing the notion of QMS in the context of higher education space

To begin with, the notion of *quality*, as a virtue of professional practice, is not a new phenomenon in the higher education landscape. It is about content and intellectual innovation. It is noteworthy that in the higher education space, *quality* is conceived as an *exception*, *perfection*, *fitness for purpose*, *value for money* and *transformation* [3]. Notwithstanding the fact that *quality* remains an elusive and contested concept, in recent years, "there have been increased efforts to bring total quality management (TQM) to academia and make academics more accountable

for the quality of their product" [4]. Most importantly, TQM has become a critical component of higher education reforms; and plays a vital role in improving the performance of higher education. As Pratasavitskaya and Stensaker [5] point out, "historically, one could argue that quality management in higher education had already been introduced during the 1980s, and in the beginning of the 1990s the idea of applying the popular industrial quality models—such as TQM, aiming at customers' satisfaction—to the higher education area was also quite widespread".

The QMS has turned into a management thought for the government, funding bodies, and higher education institutions. The notion 'management' in this instance is compatible with Michel Foucault's framework of Governmentality. It denotes 'authoritative control over the affairs of others', or 'an act or instance of guiding'. From a Foucauldian perspective, governmentality implies the way in which the state exercises control over the body of its populace. It allows for the creation of *docile bodies* to be used in modern economic and political institutions. In Discipline and Punish: The Birth of the Prison, French philosopher Michel Foucault [6] comments as follows regarding the prison as a system that renders bodies 'docile': "...by locking up, retraining and rendering docile, it merely reproduces, with a little more emphasis, all the mechanisms that are to be found in the social body? The prison is like a rather disciplined barracks, a strict school, a dark workshop, but not qualitatively different" (p. 233). He further argues that "The labor by which the convict contributes to his own needs turns the thief into a 'docile' worker" (p. 243). In this chapter, QMS is regarded as a tool for (a) improving professional standards; and (b) helping organizations run effectively. It is appropriate for instruction in post-secondary educational institutions. In Faganel and Dolinšek's [7] words, "being quality minded in higher education means caring about the expectations of students and other customers as well as all involved parties, and ensuring they are met". They further argue that "quality systems in higher education have been important for decades to help higher education institutions improve professional standards by comparing them with international educational qualifications.

With this in mind, it could be argued that factors such as "competition, cost, and accountability have encouraged higher education's interest in quality" [8]. In her doctoral thesis titled Applying Deming's philosophy and principles to the instructional process in higher education, Jane Andrews [8] notes, "there are several major reasons why higher education institutions should adopt the quality philosophy, principles, and practices". First, survival is the first order of business for any organization. Second, colleges and universities are in a competitive environment. And third, students, like business customers, will simply take their business elsewhere if they are not satisfied (p. 3). Andrews furthermore argues that "besides competition, the cost is a prime consideration for students enrolling in higher education". For her, "when there are pressures for tuition increases, students are going to come down with a vengeance about [the quality of] what they are getting [for their money". Hence, QMS helps co-ordinate and direct an organization's activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis. While implementing a QMS affects every aspect of an organization's performance, it is worthwhile mentioning that the QMS is complex, diverse and serves many purposes (including improving processes; reducing waste, lowering costs; facilitating and identifying training opportunities; engaging staff).

With these considerations in mind, one may suppose that teaching and learning are the nuclei of an educational institution. In recent years, higher education institutions have begun to follow William Edwards Deming's management philosophy. Although Deming originally applied his philosophy and principles to Japanese businesses after World War II, it could be argued that the philosophy and principles are applicable for the twenty-first century changing educational paradigms of colleges and universities and can be applied to college and university classroom instruction. Deming's management philosophy is foundational to TQM and its successor, QMS. Most scholars see Deming as "the Father of the Third Wave of the Industrial Revolution". His theories are premised on the assumption that "most product defects resulted from management shortcomings rather than careless workers, and that inspection after the fact was inferior to designing processes that would produce better quality" [9]. Most importantly, his emphasis is on meeting and exceeding customer expectations.

It should be mentioned that Deming's theory of management philosophy is grounded in systems theory. Deming [10] believed that "each organization is composed of a system of interrelated processes and people which make up system's components". For him, "94% of quality issues are caused by management problems". He writes, "Management's failure to plan for the future, he claims, brings about the loss of market, which brings about loss of jobs". Thus, "management must be judged not only by the quarterly dividend, but by innovative plans to stay in business, protect investment, ensure future dividends, and provide more jobs through improved product and service". Most importantly, Deming recognized that "improving quality will reduce expenses while increasing productivity and market share".

In his work *Out of the Crisis,* Deming offers 14 key principles that serve as QMS guidelines. These are:

- 1. Create constancy of purpose for improving products and services
- 2. Adopt the new philosophy
- 3. Cease dependence on inspection to achieve quality
- **4.** End the practice of awarding business on price alone; instead, minimize total cost by working with a single supplier
- 5. Improve constantly and forever every process of planning, production, and service
- 6. Institute training on the job
- 7. Adopt and institute leadership
- 8. Drive out fear
- 9. Break down barriers between staff areas
- 10. Eliminate slogans, exhortations, and targets for the workforce
- 11. Eliminate numerical quotas for the workforce and numerical goals for management
- **12.** Remove barriers that rob people of pride of workmanship and eliminate the annual rating or merit system

- 13. Institute a vigorous program of education and self-improvement for everyone
- **14.** Put everybody in the company to work accomplishing the transformation

While his teachings on quality and productivity have elevated him a hero status in Japan, Deming believed that "quality narrows the wide gap between customer requirements and process performance". As he aptly puts it, "it is not enough to just do your best or work hard. You must know what to work on". It is the authors' view that Deming's 14 points are also applicable to higher education. They have the potential to improve quality, production, and service in ODL. Hence, implementing QMS can benefit ODL in "(1) meeting the customer's requirements, which helps to instill confidence in the organization, and in turn lead to more customers, more sales, and more repeat business. And meeting the organization's requirements, which ensures compliance with regulations and provision of products and services in the most cost- and resource-efficient manner, creating room for expansion, growth, and profit" http://asq.org/learn-about-quality/quality-management-system/

3. Heidegger views on Being and Becoming

German philosopher Martin Heidegger (1998–1976) was mainly interested in an ontology or the study of *being*. In his magnum opus, *Being and Time*, he outlines the notion of *being* (*Sein*) by means of phenomenological analysis of human existence (*Dasein*) with respect to its temporal and historical character. He postulates that "its temporal character is derived from the tripartite ontological structure: *existence*, *thrownness*, and *fallenness* by which *Dasein's being* is described". He re-iterates his thesis, "this characteristic of *Dasein's* Being – this 'that it is' – is veiled in its 'whence' and 'whither', yet disclosed in itself all the more unveiled; we call it the 'thrownness' of this entity into its 'there'; indeed, it is thrown in such a way that, as *Being-in-the-world*, it is the *there*". He emphasizes that the "expression 'thrownness' is meant to suggest the facticity of its being delivered over."

Perhaps, it is necessary to mention that *Being* and *Becoming* are both philosophical problems and policy imperatives in QMS. Heidegger [1] confirms that "*Being* and *becoming*" is neither simple nor static process—it is both an ontological and ontical inquiry and inquiry into *Being*". He suggests that *Being* is "made visible in its *temporal* character in the sense that time is part of the identity and character of things". For Heidegger, temporality dependents on existential spatiality, and not the other way round. Hence, Heidegger calls the being or 'essence' of *Dasein* 'existence'. Heidegger' works, *Introduction to Metaphysics* [11], *The Essence of Reasons* [12] and *Being and Time* [1] are relevant in discussing QMS in this chapter. For Heidegger "*Being* goes beyond particular things, it is rather the ground of all beings and the source from which all beings derive their being". In his book, *Introduction to Metaphysics*, Heidegger [11] asks the question *Why are there beings at all, instead of Nothing?* He maintains, "the human being is not the lord of *Beings*, but the shepherd of *Being*" [1]. Central to Heidegger's [1, 11, 12] thought is the assumption that the understanding of *Being* is itself a determination of the *Being* of *Dasein*.

For Heidegger [1], "...Dasein itself – and this means also Being-in-the-world – gets its ontological understanding of itself in the first instance from those entities which in itself is not

but which it encounters 'within' its world, and from the Being which they possess". He theorized, "being the rational animal, man must be capable of thinking if he really wants to". Still, he argues, "it may be that man wants to think, but cannot" [1]. Heidegger [1] declares that:

"What is meant by "Being-in"? Our proximal reaction is to round out this expression to "Being-in" 'in the world", and we are inclined to understand this Being-in as 'Being in something'as the water is 'in' the glass, or the garment is 'in' the cupboard. By this 'in' we mean the relationship of Being which two entities extended 'in' space have to each other with regard to their location in that space...Being present-at-hand-along-with in the sense of a definite location-relationship with something else which has the same kind of Being, are ontological characteristics which we call 'categorical.'

Informed by Heidegger's [1] work, the notions of QMS and temporality (Zeitlichkeit) have a symbiotic relationship. Closer to present time, QMS fits to be seen as the question of temporality – it carries the substance and attributes of existence, thrownness, and fallenness. While the notion of temporality is first hinted at in Aristotle's Physics, Heidegger [1] maintains the Dasein's being is founded on temporality and Temporality. As Heidegger writes, "the term Temporality does not wholly coincide with the term temporality [Zeitlichkeit], despite the fact that, Temporality is merely the translation of Zeitlichkeit". He identifies the three ecstasies of temporality as the past, present, and future (retaining, representing, and expecting). Among others, he stresses that "in expressing itself, temporality temporalizes the only time that the common understanding of time is aware of". Hence, the ecstatic nature of temporality can be understood if we delve slightly deeper into the future, past, and present. Heidegger accepts that "time needs to be explicated primordially as the horizon for the understanding of Being, and in terms of temporality as the Being of Dasein" [1]. He concludes that (a) "the world is neither present-at hand nor ready-to-hand, but rather temporalizes itself in temporality" and (b) "Temporality is temporality as fundamental ontology" [1].

In summary then, from a Heideggerian perspective, it could be argued that ODL practitioners are always in the state of Being and Becoming – they are in a temporal mode of being. It is also worth noting that within the field of QMS ODL practitioners are 'thrown' into the world and that their Being-in-the-world aligns with Heidegger's [1] lens of 'thrownness'. For this reason, Heidegger's notion of Being and Becoming is hidden ontical and ontological dimensions of QMS. In the next section, QMS is discussed within the context of dominant class ideology.

4. QMS as a carrier of dominant class ideology

The history of QMS can be traced back to the 1920s. It is rooted in Frederick Winslow Taylor's (1865–1915) classical management theory. The QMS also derives from Foucault's [13, 14] notion of governmentality. Chen et al. [15] note that "regulating academic quality assumes state sovereignty in defining and enforcing academic standards through policy steering". This section draws on the work of French Marxist philosopher, Louis Pierre Althusser (1918–1990). Althusser's work provides conceptual tools for unpacking QMS as a carrier of the dominant class ideology. It is important to state at the outset that the notion of QMS, as a site of class struggle and a product of ruling ideology, perfectly fits the lens of *Ideological State Apparatus*

(ISA). It is the authors' view that, like other social practices of everyday life, the notion of QMS is fueled and imbued by ideologies.

The authors postulate that QMS is not "abstractions that merely represent some form of spiritual or non-materialistic reality, but are rather a direct result of the structures of the materialistic reality itself" [16]. It is important to state that ideology is a vague and controversial notion. As a subjective dimension of social life, the concept of 'ideology' has a very rich history and carries diverse connotations. As Schmid [17] aptly puts it, "ideology is a human condition, a medium in which and by means of which we live our lives" (p. 57). Schmid [17] emphasizes, "the term ideology usually refers to ideology as a systematic, elaborated and delimited systems of thought, like political ideologies or religious" (p. 57). Schmid's contention concurs with that of van Dijk. According to Van Dijk [18], "ideologies have something to do with systems of ideas, and especially with the social, political or religious ideas shared by a social group or movement".

Eagleton [19] states that "all ideology is teleological, totalitarian, metaphysically grounded (p. xii); passionate and rhetorical (p. 4) and has to do with legitimating the power of a dominant social group or class (p. 5). He argues that "a dominant power may legitimate itself by promoting beliefs and values congenial to it; naturalizing and universalizing such beliefs so as to render them self-evident and apparently inevitable; denigrating ideas which might challenge it; excluding rival forms of thought, perhaps by some unspoken but systematic logic; and obscuring social reality in ways convenient to itself" (p. 5). With this in mind, the authors depart on Shils's [20] assumption that "ideologies are characterized by a high degree of explicitness of formulation over a very wide range of the objects with which they deal; for their adherents, there is an authoritative and explicit promulgation".

Looking closely at Althusser's [21] work *Ideology and Ideological State Apparatuses*, conceptually the QMS, both as a social representation and the *basis* of social practices, is a carrier of ideology. Althusser furthermore argues that "ideology has a material existence because an ideology always exists in an apparatus, and its practice, or practices; and always manifests itself through actions, which are *inserted into practices*". He remarks, "all ideology hails or interpellates concrete individuals as concrete subjects, and ideology represents the imaginary relationship of individuals to their real conditions of existence". Althusser concludes by saying that ideology, "as a material practice, depends on the notion of the subject." His propositions are that "there is no practice except by and in an ideology" and "there is no ideology except by the subject and for subjects".

From a Heideggerian view, an interpellation is a temporal form. As Althusser [21] aptly puts it, "becoming-subject happens even before we are born". He further declares, "an individual is always-already a subject, even before he is born, is [...] the plain reality, accessible to everyone and not a paradox at all". With this in mind, the main purpose of QMS as a carrier of ideology is in constituting concrete ODL practitioners as subjects — "individuals are always-already subjects". Althusser concludes that, "the individual is interpellated as a (free) subject in order that he shall submit freely to the commandments of the Subject, i.e. in order that he shall (freely) accept his subjection, i.e. in order that he shall make the gestures and actions of his subjection 'all by himself".

For van Dijk [18], "ideologies form the basic social representations of the beliefs shared by a group, and precisely function as the framework that defines the overall coherence of these beliefs". Thus, "ideologies allow new social opinions to be easily inferred, acquired and distributed in a group when the group and its members are confronted with new events and situations" (p. 15). Notwithstanding the fact that QMS ideologically is biased, it is critical to mention that QMS serves as a tool for social reproduction, ideological control, and regulation.

In summary, from an Althusserian perspective, QMS as a carrier of ideology has the function of constituting concrete individuals as subjects, that is, of enlisting them in any belief system. It also has a function of interpellating ODL practitioners as subjects. It could, therefore, be concluded that the individual is interpellated as a (free) subject in order that he shall submit freely to the commandments of the Subject. In the section that follows, it will be argued that higher education industry is driven by consumerist tendencies.

5. QMS as a key pillar of the higher education industry

Notwithstanding the fact that *The Universal Declaration of Human Rights* of 1948, declares (in Article 26) that "everyone has the right to education" and further declares that higher education "shall be equally accessible to all on the basis of merit", it can be reasonably argued that in the 21st century higher education has become definitely a *commodity* that is up for sale. It is critical to mention that higher education is *market-driven* and underpinned by what Slavoj Žižek, Ernesto Laclau, and Chantal Mouffe call a *consumerist* ideology. For instance, Žižek [22] argues that "the very act of egotist consumption already includes the price of its opposite". Nonetheless, calls for quality in the higher education industry today are loud and clear. It is correct that higher education industry as a "business", must embrace the notions of *quality*, TQM and best business practices in order to remain competitive and financially sustainable. While the cost of providing higher education continues to rise, higher education institutions face overwhelming challenges to long-established business models. Further worsening this challenging climate, the public is beginning to question the *quality* of higher education.

The notion of quality in higher education is as old as medieval ages and is traceable to the 13th century [23]. Hitherto, the definition of *quality* that "prevails in industrial/business environments, based on the idea of satisfying customers' needs and expectations, is problematic in higher education" [23]. It is worth mentioning that in recent years, higher education institutions have encountered growing pressure to operate like businesses. Nonetheless, higher education institutions must change to meet the needs of its 21st century students; and embrace the notions of *efficiency*, *productivity*, and *innovation*. It is the authors' view that the students are customers of higher education institutions. The authors equally assume that if the customer is satisfied, the product has good quality. Notwithstanding that the term 'customer' is central to Total Quality Management (TQM), our thesis is that in order to be effective higher education organizations must be customer-driven. The TQM is potentially the solution as to how to improve the quality of the services provided by higher education institutions – its central theme is the importance of meeting customer needs.

For Taiwo [24], "customer-oriented organizations are successful because they have a unified focus on what they do and who they serve. Taiwo continues by noting that "customers have wants, opinions, perceptions, and desires which are often referred to as the voice of the customer". He argues that "the voice of the customer can also be defined in technical terms as the "standardized, disciplined, and cyclic approach to obtaining and prioritizing customer preferences for use in designing products and services". Despite the fact that quality is defined as meeting or exceeding customer expectations, it is critical to ask the question, to what extent are higher education sectors are meeting or exceeding customers' needs and expectations? As Deming rightly puts it, "the customer is "one who gets your work."

Willis and Taylor [4] observe that "quality concerns have spread from manufacturing and service businesses to the public sector including public and private educational systems". They further argue that "an increasing number of higher education institutions are adopting a TQM approach to enhance the school's ability to attract and retain students by implementing processes to continually improve quality. In line with this, the authors argue that the fundamental purpose of QMS models is to serve the customer better. Even though QMS models were established mainly for manufacturing and industrial sectors, within higher education sectors they can contribute to the process of standardization of academic degrees. In spite of the fact that "TQM models developed for higher education are consistent with models frequently used in the manufacturing, business, and service sectors" [25], it is the authors' view that the QMS and ODL have a symbiotic relationship. Like contact universities, the ODL institutions are the "key drivers in the knowledge economy and thus, are encouraged to develop links with industry and business in a series of new venture partnerships" [25].

As Chen et al. [25] observe, "universities are generally facing fiscal constraints and increased competition, increased calls for accountability, growing demand through growing enrolment and student diversity, and challenges from developing technologies". They argue that "universities and higher education systems, in general, are expected to have a sophisticated approach to documenting performance excellence that is accountable, evidence-based, outcomes-focused and geared towards continuous improvement in spite of contextual challenges". While QM principles are more widely accepted within the university today, Chen et al. [25] postulate that "the difficulty in translating TQM into an educational setting stems from the difficulty in measuring learning because the core processes of learning are too subtle to be measured meaningfully". They emphasize that "some of the notions of quality management (QM) do not have simple equivalents in higher education such as managerial responsibility for quality, empowering staff for quality improvement purposes, setting standards to reflect customer requirements, and avoiding error/minimizing variation".

In summary, many would believe that QMS in higher education has been important for decades. Notwithstanding that there exist many models of QMS, different quality tools and standards, the rise of QMS in higher education remains "a product of market ideologies of the 1980s and the managerialism that accompanied it" [26]. As Faganel and Dolinšek [7] write, "quality management systems in higher education have been developed for a number of years to improve professional standards". They conclude, "several attempts have been made

to develop methods that would be modeled on ISO 9000 and TQM, but some of these models were developed to evaluate a business process in the quality field".

6. (Re) thinking QMS through the Heideggerian lens of temporality

Despite the fact that Heidegger was overwhelmingly captivated by the concept of *being*, his commentaries are fundamental to re-imagining QMS (as a temporal phenomenon) in higher education. In his seminal work, *The Science of Being and Art of Living*, Maharishi Mahesh Yogi [27] provides an account of the concept *Being*. He writes, "as the omnipresent, essential constituent of creation, *Being* lies at the basis of everything, beyond all relative existence, beyond all forms and phenomena". He further argues that "Being is the most glorified, most precious, and most laudable basis of all living. Being is the basis of cosmic law, the basis of all the laws of nature, which lies at the root of all creation and evolution". His thesis is that "the conscious basis of Being is like a ship without a rudder, ever at the mercy of the tossing sea".

Against this backdrop, the *being*-ness of QMS is a philosophical problem deeply embedded in existential temporality. Standera [28] contends that "temporality, as a fundamental condition of the possibility of our experience, unifies all the structures that comprise our particular way of *Being*, which includes *Being*-in-the-world". For him it is the crucial glue binding all the elements and processes that Heidegger ascribes to our existence into a coherent whole, providing "the unitary basis for its existential possibility"; it "regulates the possible unity of all *Dasein*'s existential structures". This corresponds with Orr's (2014) view. He conjures, "whatever exists in the mode of temporality does not possess its being but receives it ever anew as a gift". From the Heideggerian view, temporality should be conceived not as "clock-time", but "ecstatically". As Heidegger [1] notes, "ecstatic temporality is a process with three dimensions which form a unity; and confers unity on one's entire existence, and not simply episodes in one's conscious awareness". His temporality provides a spectrum or factor for classifying cognitive complexity that establishes a radical continuity through the shared participation. Hence, temporality provides "a kind of framework or medium in which *Dasein*, which literally means 'Being-there', pursues its existence" (Orr's 2014).

From a Heideggerian perspective, the notions of *being* and QMS have mutual connections and are tightly intermingled. The *being*-ness of QMS, as a phenomenon of life in higher education space, takes its meaning in *temporality* and *historicity*. Heidegger's thesis is that temporality is not an entity, not a sequence of self-contained moments that move from future to present to past, and not a property or feature of something, but is, rather, akin to a self-generating and self-transcending process. He observes, "temporalizing does not signify that ecstasies come in a 'succession'. The future is not later than having-been, and having-been is not earlier than the Present. Temporality temporalizes itself as a future which makes present in a process of having been".

It is prudent to believe that QMS, as a social construct, is neither a simple nor a *static* process. On the contrary, it is a fluid and changing the concept that is in a perpetual state of *Being* and *Becoming*. From a philosophical perspective, the QMS carries categorical ontological and

epistemological attributes/appeals of temporality, spatiality, being-in-the-world, worldliness, nearness, disclosedness, and thrownness). It is the authors' view that the notions of temporality, spatiality, and thrownness influence the *being*-ness of QMS. It is worth mentioning that the ontology of the *being*-ness of QMS is rooted in the phenomenon of time.

Given the fact that the 21st century ODL is trapped in *temporal flux*, among others, it calls for Heidegger's model of temporality, which unifies and enables practice and purposiveness. It is critical to mention that the Heideggerian model of temporality strongly resonates with the temporal dimension of meaning-enacting cognition [28]. Standera as such, emphasizes that the Heidegger model of temporality.

"invites us to understand purposiveness as inherently temporal and temporality as shaped by purposiveness; to view the futural dimension as having a special significance, one that can be cashed out in terms of a radical indeterminacy that transcends mere predictive or anticipatory models of futurity; and, finally, to take temporality as being structured by and structuring the self-concern that defines Dasein".

As Stendera [29] points out, the *Heideggerian model of temporality* "is thick enough to accommodate and account for the valance and can connect self-concern with future-directedness in a way that makes sense of precariousness". It is the authors' view that Heidegger's model of temporality requires a regiment of critically reflexive ODL practitioners and leadership with temporal and disclosedness attributes. Gordon & Howell [30] recount that "the need for competent, imaginative, and responsible leadership is greater than ever before; the need becomes more urgent as the business grows ever more complex and as the environment with which it has to cope continues to change at an accelerating tempo."

In summary, Heidegger's model of temporality presents an alternative view of how the temporality makes meaningful experience possible. It has a critical role to play in the reimagination of QMS in the 21st century; and captures the originary, and overarching sense of temporality. Its attributes are complex, inextricable entanglement with purposiveness; an emphasis upon radical futurity; and a fundamental connection to self-concern. Most importantly, the model of temporality has the prospects of guiding and informing the interpretation of ODL practitioners' experience of the world, changing from pragmatic temporality to what Heidegger calls *existential temporality*.

7. Conclusion

This chapter has argued that QMS is a set of intricate and interacting elements that are fundamental to higher education. It is the authors' view that while QMS plays a vital role in improving the performance of higher education it can also serve as a management tool by the government, funding bodies, and higher education institutions, to engender a controlled, and an unquestioning environment. This paper attempted to show, using Foucault's perspective, that as a form of control, QMS can be regarded as a tool geared towards the creation of *docile bodies*, that is, like the prison system, QMS requires unquestioning compliance, which can be attributed to docility. The building platform of this study drew on the work of Heidegger to

argue that ODL practitioners are always in the state of *Being* and *Becoming*. That is, they are in a temporal mode of being. This work showed that ODL practitioners are 'thrown' into the world and that their Being-in-the-world aligns with Heidegger's lens of 'thrownness'. In this regard, Heidegger's notion of *Being* and *Becoming* projects hidden ontical and ontological dimensions of QMS.

Drawing on Althusser's *Ideology and Ideological State Apparatuses* the authors suggested that QMS can be regarded as a carrier of ideology in that it functions to constitute the individuals as subjects, and of interpellating ODL practitioners. It was noted that the rise of QMS in higher education is the product of market ideologies of the 1980s and the managerialism that accompanied it. However, the authors suggested that Heidegger's model of temporality can be regarded as an alternative view of how the temporality makes meaningful experience possible. This paper called for a re-imagination of QMS using both Heidegger and Foucault, given that QMS' attributes are complex, inextricable entanglement. Finally, it was argued that the model of temporality has the potential to guide and inform the interpretation of ODL practitioners' experience of the world, drawing on what Heidegger calls *existential temporality*.

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TQM Is Alive but Not as We Know It: The Use of a Novel TQM Model in a Private Healthcare Company

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Additional information is available at the end of the chapter

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Abstract

UK healthcare has been facing an unprecedented quality crisis in recent times. In this context, the author setout to develop and evaluate the use of a novel total quality management (TQM) model in a private healthcare firm with the aim of improving patient care. By integrating contemporary organizational theories with TQM, an innovative model called EALIM—ethical, adaptive, learning and improvement model—was devised. Using an action research study, qualitative data were gathered in three research cycles, (1) preimplementation, (2) implementation, and (3) post-implementation. Initial results showed EALIM's adoption generated a moral organizational perception among employees, increased organizational commitment, emergence of a learning culture, and improvements in patient self-advocacy and independence. However, other findings indicated poor leadership produced variability in service quality. Although outcomes from this study clearly indicated that EALIM generated organizational improvement, commitment from all internal stakeholders is required to achieve sustainable quality patient care.

Keywords: TQM, quality improvement, healthcare, corporate social responsibility, organizational complexity, knowledge management

1. Introduction

Providing quality goods and services to satisfy customer needs has been a long-term strategic goal for both manufacturing and service organizations. Indeed, it may be argued that it is due to the basic fundamentals of quality policies and principles that organizations are successfully competing in an ever-growing antagonistic marketplace [1]. Whether it is an automobile recall, a failed medical operation or a poorly performing school, the consequences of poor quality underscore the significance of quality management. A particular quality management approach that emerged in the latter part of the twentieth century was total quality management (TQM). Though many descriptions of TQM exist, it can be defined as "Total—everyone associated with



the company is involved, Quality—customers' expressed and implied requirements are fully met, and Management—executives are fully committed [2]." However, unlike its many definitions, little disagreement exists among authors on TQM's key principles, which include top management leadership, customer focus, continuous process improvement, employee education and participation, statistical reporting, as well as recognition and reward.

Largely spawned by the success of TQM in reversing Japan's broken post war economy, during the 1980s and 1990s a global TQM revolution emerged. Consequently, many western companies adopted TQM principles into their corporate strategies to boost competitiveness and financial performance. However, by the early 1990s, empirical investigations began to emerge, asserting that most TQM efforts failed to produce desired results, including TQM initiatives in healthcare. By the late 1990s, critics had grown, claiming TQM had lost its dominance, emphasizing the need to focus on more contemporary management approaches [3–5]. Although various authors have attributed TQM failures to implementation issues, others have been more critical, pointing to theoretical limitations. Nonetheless, a number of scholars commonly agree that the underlying reason for TQM's decline was its incompatibility with a postmodern organizational context [6, 7]. This point suggests TQM requires reform to become a contemporary management approach, fit for the 21st century.

Over the last 10 years, UK healthcare has been encountering an unprecedented quality crisis, especially considering the overwhelming challenge of improving patient care in the face of growing demands and budget constraints. These bottlenecks gave rise to research the development of an innovative and sustainable TQM model that could yield quality patient care. The target organization used to conduct the research was a private healthcare provider, offering specialist services to adults with learning disabilities and mental health disorders in London and the Home Counties.

This chapter draws upon that five-year research in two main parts:

The first part deals with the conceptual development of the model, which began by reviewing the literature to identify the theoretical and implementation issues of TQM. These findings were then used to inform the selection of contemporary organizational theories for integration with TQM that could ameliorate the issues identified. Following this process, three contemporary organizational theories were selected:

- corporate social responsibility (CSR),
- complexity theory (CT) and
- knowledge management (KM).

The reasons for choosing these, along with their distinct advantages and conceptual links with TQM, are stated. For the purpose of this study and within this context, organizational theory is defined as a body of thinking that conceptualizes organizational phenomena based on specific principles and assumptions [8]. By integrating these three organizational theories with TQM, a novel model called EALIM—ethical, adaptive, learning and improvement model—was devised, an acronym that captures the nexus of each theory. The ethical part of the model relates to the integration of CSR, the adaptive part to CT, the learning part to KM and the

improvement part relates to TQM. This part of the chapter ends by presenting the main principles of EALIM, along with its methods that link to each of its theories, forming a coherent conceptual framework.

The second part of this chapter provides a research overview of EALIM's implementation within the target organization. An action research (AR) methodology was chosen, since it holds features congruent with the author's professional practice and the participatory context of implementing the model. A qualitative strategy of gathering data was used as this seemed best suited for understanding contextual factors and explaining the internal logic of human action in response to interventions. Data gathering methods included depth interviews, participant observation and focus groups, which fall within the scope of qualitative research. Data were gathered over an 18-month period in three AR cycles. In the first cycle, data were collected to form a baseline assessment of the firm.

In the second cycle, a collaborative action plan was developed and EALIM's implementation was examined. In the third cycle, further data were accumulated and findings were evaluated against the baseline assessment to identify EALIM's overall impact.

Although other authors [9, 10] have conceptually developed healthcare-specific TQM models, a dearth of research exists with regards to the implementation and evaluation of such models. It follows that the research presented in this chapter addresses this paucity. Moreover, since no other conceptual framework fully integrates corporate social responsibility, complexity theory and knowledge management within TQM, EALIM can be relied upon as an original contribution to TQM theory. In essence, EALIM presents a broadening conception of TQM that could yield better results, since it is more suited to a postmodern organizational context.

2. Theory building and model development

The research began with a qualitative review of the organizational literature to identify key issues with TQM theory and implementation in manufacturing and service industries. The initial search located about 400 studies. However, after a narrative review, only 41 were selected for analysis because the other studies did not adequately critically review TQM. Thematic analysis was then applied to the selected studies, using open, axial and selective coding. This coding involved comparing the textual accounts of each study to identify codes, forge connections between codes, and organize them into meaningful thematic categories [11]. Results from this analysis are depicted in two tables. The first is **Table 1**, which describes seven commonly reported TQM implementation barriers.

Although some studies found the use of TQM had yielded increased levels of product quality and organizational performance, most studies reported mixed results or high failure rates caused by implementation issues. For example, while Joss's study of TQM initiatives in UK healthcare reported some success in improving teamwork, these initiatives failed to make a direct improvement in service quality because of implementation obstacles like the lack of top management commitment and a disregard of cultural factors [12]. Barriers like these, not only give insights about why TQM efforts were disbanded,

Barrier 1 Description	Lack of top management commitment and ethics TQM message is incongruous with the behavior of management. Conflict between the espoused message of TQM and its practice. Lack of visible participation by top management.			
Barrier 2 Description	Limited stakeholder approach from top managers Emphasis on customers and suppliers at the expense of other stakeholders. Managers fail to recognize their organizational responsibilities to society. Insufficient employee participation.			
Barrier 3 Description	Lack of adaptability to change and unintended outcomes Lack of spontaneity to unpredictable events. Slow response to changing customer requirements creates market drift. A controlling culture inhibits staff from adapting to dynamic customer needs.			
Barrier 4 Description	Too much emphasis on hard TQM factors Too much focus on the technical and analytical aspects of TQM. Statistical process control (SPC) is inadequate for evaluating metaphysical attributes like attitudes and motivation, warmth, care, etc.			
Barrier 5 Description	Disregard for contextual factors Top managers hold taken for granted assumptions about controlling culture. TQM dogma and framework is applied as a universal approach without adapting it to fit the organizational context.			
Barrier 6 Description	Middle management resistance Middle managers lack involvement and place too much reliance on a quality manager or department. TQM is perceived as a political threat to their authority.			
Barrier 7 Description	Inadequate learning Lack of a learning culture. Failure to apply knowledge in practice. No reflexive learning. Managers fail to learn how their leadership methods and actions contribute to implementation problems.			

Table 1. Key TQM implementation barriers in manufacturing and service firms.

but also highlight differences between the rhetoric and reality of TQM adoption. Even in cases where TQM had succeeded, studies show this was after a 5-year implementation period, far too long for executives who require more immediate results [13]. Hence, for achieving sustainable TQM success, the newly developed model ought to address all the implementation barriers identified.

From the studies that problematized TQM theory, nine TQM theoretical limitations were identified, as depicted in Table 2. Most of these studies took a postmodern approach of making explicit TQM theory's unstated philosophical assumptions. For instance, Boje and Winsor argue that TQM methods are designed as social and psychologically engineered tools to efficiently extract maximum output from labor resource [6]. From this view, TQM is predicated on theoretical assumptions of scientific management, i.e., Taylorism—an approach that tends to disregard employees' emotional and psychological needs. Other limitations like TQM's managerial obsession with statistical process control reveal a technocratic ideology that treats workers akin to machine parts, at the expense of employee discretion and dignity [7]. These sorts of theoretical limitations lead to the conclusion that TQM is incongruous to a postmodern age of pluralism, uncertainty, organizational interdependence, employee knowledge and autonomy, because it emerged from an era of modernism where the emphasis was on labor resource efficiency and managerialism. This change in emphasis underscores the need to adapt TQM to fit within a postmodern organizational milieu. As previously discussed, the approach toward achieving this is to integrate more contemporary organizational theories with TQM that can address its theoretical and implementation issues.

Limitation 1	Investment	and	consumer	capitalism
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Description Limited to serving shareholder interests and customer needs. Fails to adequately address the quality of

experience of other stakeholders.

Limitation 2 Formal rationality

Description Simple means-ends calculation using rules and laws. Lacks regard for the personal qualities of individuals

and the impact decisions have on their wellbeing.

Limitation 3 Utilitarian rationality

Description The efficient use of resources to achieve maximum output. Disregards employees' emotional and

psychological needs, consequently harming quality efforts.

Limitation 4 Executive vision

Description A vision constructed and imposed by executives. Reinforces control and undermines collaboration.

Limitation 5 Technocratic ideology

Description Emphasizes following technical processes and systems. Removes employee discretion from work

processes, treating them akin to machine parts.

Limitation 6 Single loop learning

Description Restricts learning to means-end relationships. Occludes new ways of thinking and learning.

Limitation 7 Newtonian paradigm

Description A linear and reductionist worldview. Cannot work in disequilibrium where cause/effect is non-linear.

Limitation 8 Codified and explicit knowledge sharing

Description Reliant on the systematic sharing of express information. Occludes knowledge sharing that is informal and

context dependent.

Limitation 9 External customer focus

Description Emphasizes satisfying consumers. Lacks regard toward other key stakeholders.

Table 2. TQM's theoretical limitations.

The process of selecting contemporary organizational theories for integration with TQM, involved a broad review of the organizational literature. Qualitative methods of analysis were deployed as purported by Golden-Biddle and Locke [14], which included constructing intertextual coherence (i.e., focusing on key contributions and forging connections between concepts), and problematizing the literature (i.e., identifying key issues that have not been addressed and presenting arguments for alternative perspectives). From the 20 or so organizational theories examined, three were selected based on the following criteria: (1) their fit with a postmodern context, (2) their potential to overcome TQM's theoretical limitations and implementation barriers, and (3) their conceptual links with TQM. This criterion was chosen because it would enable the expansion of TQM with organizational theories better suited to current contexts, while redressing the barriers and limitations previously identified. A description of each theory, reasons for selecting them, and their fit with TQM, are given in the next three subheadings. The number assigned to each finding from Tables 1 and 2 have been included in parenthesis, to systematically account for how these theories redress TQM's shortcomings.

2.1. Corporate social responsibility (CSR)

By adopting concepts like stakeholder management, employee welfare, philanthropy and ecological sustainability, CSR can be defined as an organizational approach that demonstrates ethical regard for people, society and the planet [15]. Unlike CSR, TQM theory neglects the

importance of corporate philanthropy and ecological sustainability because its key premises are based on creating value for shareholders and meeting customer expectations. It follows that integrating CSR with TQM would enable a shared vision among a wider range of stakeholders. This approach could address TQM theory's prevalence on investment and consumer capitalism [Limitation 1], its restriction to an executive vision [Limitation 4], and its confined external customer focus [Limitation 9]. Since CSR involves a stakeholder approach, its integration could also overcome TQM's implementation issue of a limited stakeholder approach from top managers [Barrier 2]. Therefore, by conflating the instrumental activity of TQM and the ethics of CSR, a moral form of capitalism can be achieved, linking the success of the organization to the prosperity of its environment.

As noble as CSR sounds, it has been criticized for ignoring the wellness of employees. Lay-offs, long working hours, work–family conflict and inequality, are often overlooked in both the CSR and TQM literature [16]. To address these shortcomings, a CSR approach that includes socially responsible business practices on employee wellbeing should be adopted. This type of CSR approach denotes a Kantian duty ethic, where people are treated as both the means and the end [17]: a more humane rationality than TQM theory's utilitarian rationality [Limitation 3].

The adoption of a Kantian CSR approach can result in several outcomes: namely, it can enable managers and workers to understand their jobs are not merely a means for generating shareholder wealth, promote a sense of pride in the organization, and create awareness that their work is producing a far greater end for the human race, resulting in opportunities for commitment and action. These outcomes have the potential to redress two particular TQM implementation issues: lack of top management commitment and ethics [Barrier 1], and middle management resistance [Barrier 6].

2.1.1. CSR's fit with TQM

Although distinct differences exist between CSR and TQM, some mutual conceptual links have been identified, making their integration possible. For instance, while Ahmed and Machold argue that CSR's moral philosophy is incompatible with quality models that use rational economic principles [18], McAdam and Leonard contend TQM's focus on quality has affinity with CSR, since both are founded on respect for employees and customers [15]. Moreover, CSR principles like employee empowerment, responsibility and collaboration also have affinity with TQM, indicating that TQM can exist in a symbiotic relationship with CSR. It follows that TQM could provide a strong foundation in which to embed CSR values, since they share the common principle of "doing the right things right [19]." Finally, by coalescing the two theories, a more substantive rationality can be realized, a point that redresses TQM's formal rationality [Limitation 2], which tends to overlook the impact decisions have on people's wellbeing.

2.2. Complexity theory (CT)

Proponents of CT generally regard it as a body of concepts explaining the dynamic interaction of interdependent variables and how these generate bifurcation at the edge of chaos (i.e., disequilibrium), leading to unpredictability and emergence [20]. In organizations, its use has been focused on conceptualizing how local human interactions produce organizational,

societal and global patterns that are paradoxically linear and non-linear, predictable and unpredictable, for developing new ways of thinking about how organizations cope with conditions of uncertainty.

Various authors [21–23] have argued that because TQM was largely designed through a Newtonian paradigm of reductionism, objectivism and linear causality [Limitation 7], it fails in its contingency toward chaos, unpredictability and non-linear events of major change. It follows that a CT approach could overcome TQM's Newtonian limitations and foster new decision-making capabilities, an advantage particularly useful when organizations are subject to dynamic conditions. Since the lack of adaptability to change has been a common TQM implementation issue [Barrier 3], adopting a CT perspective could also enable organizational members to better adapt and self-organize in an environment of disequilibrium.

Although a number of complexity theories are presented in the literature, a complex responsive process theory was selected because it regards a corporate social ethic as a durable quality [24], which fits well with CSR. This may also be justified that unlike other complexity authors who adopt a mechanistic system view of organizations, Stacey predicates his view on communicative interaction among people: a humane ideology that addresses TQM's technocratic ideology [Limitation 5].

2.2.1. CT's fit with TQM

Although TQM's Newtonian and linear concepts have paradigmatic differences with CT's ideology of non-linear causality and unpredictability, some links can be made between the two. Dooley *et al.* have argued that TQM factors such as collaboration and empowerment have affinity with CT, in terms of encouraging emergence and self-organization [21]. For example, collaboration allows divergent and emergent thinking on the alternative routes individuals can take at bifurcation points, and empowerment enables individuals to spontaneously make decisions on their own when facing an unpredictable reality. Another link can be found in the way TQM cross-functional team members interact to develop new products in the face of changing customer needs, which has similarity with CT's focus on the interaction of organizational variables as a source of influence. Although some authors claim that TQM is contingent on equilibrium and CT on disequilibrium, Stacey contends the tension between the two is necessary. Stacey argues that managers should be effective in both paradigms because organizations exist in a paradox of predictability and unpredictability, certainty and uncertainty [20]. From this view, TQM and CT can co-exist, as they are not mutually exclusive.

2.3. Knowledge management (KM)

KM can be defined as a body of theory involving sharing, creating and applying explicit and tacit knowledge to advance organizational objectives [25]. For the purpose of clarity, explicit knowledge is knowledge made "explicable" and tacit knowledge "is that which has not or cannot be made explicit [26]." Since TQM relies heavily on a codified approach of collecting and disseminating explicit knowledge through formal processes [Limitation 8], it fails to properly consider tacit kinds of knowledge typically shared through experiences, practice, storytelling and informal networks. Hence, adopting a KT approach of tacit knowledge

sharing would allow individuals to acquire "know-how, expertise, experience and savoir faire [27]." Inferred aspects such as these are difficult to acquire through a codified approach because this treats knowledge as an external object that people transfer through purely cognitive means—an underpinning assumption of TQM theory [see limitation 8]. In contrast, a knowledge-as-practice perspective treats knowledge as something interpreted and inseparable from human activity. Thus, by integrating practice-based learning within TQM, employees could develop tacit understandings of work processes. Since inadequate learning has been identified as a common TQM implementation issue [Barrier 7], especially in terms of failing to apply knowledge in practice, adopting practice-based learning could redress this issue.

While tacit knowledge is fundamental to acquiring know-how, Collins asserts three different kinds of tacit knowledge that are seldom differentiated in the literature: "relational, somatic and collective [28]." According to Collins, relational tacit knowledge (RTK) is acquired through human relationships and guidance over an extended period of time—factors that can ameliorate TQM's implementation problem of placing too much emphasis on hard factors [Barrier 4]. On the other hand, somatic tacit knowledge (STK) involves the use of individuals' physical bodies and is more difficult to explicate, since it is derived through demonstration—analogous to practice-based learning. The third kind, collective tacit knowledge (CTK), is a domain of knowledge with a strong resistance to being made explicit, since it involves learning cultural nuances (i.e., savoir faire) that are only acquired by embedding one's self in society. As such, adopting an approach that elicits CTK could enable people to gain increased knowledge of cultural factors, ameliorating the TQM barrier of disregarding contextual factors [Barrier 5].

Another important reason for selecting KM is that its body of theory supports double and triple loop learning, addressing TQM's one-dimensional use of single negative loop learning [Limitation 6]. The problem with single loop learning is that it restricts individuals to correcting actions toward one's goals, whereas double and triple loop learning are reflexive, allowing individuals to critically question their goals and practices, leading to transformation [29].

2.3.1. KM's fit with TQM

According to Zhao and Bryar, some principles of KM have affinity with TQM in respect of the way information is taken as inputs and processed with applied knowledge to produce outputs [30]. Although TQM has been described as more mechanistic than the living system of KM, Zhao and Bryar contend that both theories share principles of empowerment, collaboration, teamwork and customer centricity. Additionally, the KM strategy of "getting the right knowledge to the right people at the right time [27]" could be used to support TQM's aim of continuous improvement and customer satisfaction. Hence, combining KM with TQM could help solve a missing piece of the quality puzzle.

2.4. EALIM's key principles

In conceptual model building, principles provide structure and serve as rules for its operation, creating a paradigmatic boundary in which other constructs can be added. To advance the model building process further, 10 key principles were inductively conceived from the

literature, which reflect the synthesis of EALIM's four organizational theories (CSR, CT, KM and TQM).

- **Moral anchor:** a Kantian duty ethic that treats people as both the means and the end. This ethic not only reflects CSR's regard for the wellbeing of people and the planet, but also grounds the model in a moral form of capitalism.
- Exemplary leadership: an approach to leading that models service and trust. This approach is epitomized in servant leadership, defined as a way of leading by serving others in the absence of extenuating personal benefits, which empowers followers to become healthier, autonomous individuals. This kind of leadership denotes a CSR approach that encourages wellbeing and links with CT's notion of self-organization.
- Boundaryless collaboration: removing boundaries across disciplines, hierarchies and cultures through effective stakeholder collaboration, which can promote mutual trust and wide organizational support. Collaboration also promotes knowledge sharing and interdependence among stakeholders, prerequisite elements of both CT and KM.
- Empowerment and democracy: devolving power to employees and finding democratic ways of working. The importance of empowerment and democracy cannot be overstated, since numerous studies have found these to be critical for TQM success, factors that also feature in CSR, CT and KM.
- Emergence and self-organization: encouraging new patterns of social order to emerge that allows people to adapt and innovate in the face of change. This CT principle is critical for surviving in a complex environment, and links to KM because it promotes the application of knowledge from learning communities.
- Learning communities and team working: sharing explicit and tacit (relational and collective) knowledge, as well as creating new knowledge to produce innovation. Learning communities are KM groups that are either homogenous (e.g., practitioner-based) or heterogeneous (e.g., intra-disciplinary), and team working is a key factor for successful problem solving in TQM applications.
- Practice-based learning: learning derived in and through practice, which provides both context and experience for learners. From a KM perspective, this kind of experiential learning enables individuals to develop somatic tacit knowledge, resulting in increased know-how and expertise.
- **Continuous improvement:** incremental improvements to work processes by everyone. Improvement is continuous because it is a never-ending journey of detecting and preventing errors. This TQM principle is critical for nurturing a quality culture, and can also include breakthrough improvements such as redesigning an entire system.
- Quality chain: deems every employee as an internal customer and supplier. This process involves employees obtaining what they need from their internal suppliers, to satisfy the needs of their immediate internal customers. Forming strong quality chains is vital to the success of TQM, as any weak link or error could find its way to the external customer at the end of the chain.

10. Customer satisfaction: the end goal of TQM and critical to any organization, for without it, no organization could prosper in a competitive market place. Attaining customer satisfaction requires commitment from all organizational members toward identifying, meeting and reviewing customer needs. This process must involve capturing the voice of the customer through feedback and suggestion schemes.

2.5. EALIM's methods

To implement EALIM, suitable methods need to be selected that can translate its principles into practice. Since numerous methods exist in the organizational literature, those chosen are by no means exhaustive, and neither are they written in stone. Methods can be changed or added to, as long as they fit EALIM's principles and link to any one of its organizational theories.

The methods listed here have been carefully selected to provide a synergetic blend of soft and hard factors. The soft factors reflect the people-oriented elements of organizational culture, i.e., leadership, people and communicative interaction, while hard factors relate to the analytical and technical processes people use. Selecting the right blend is important because various authors claim a balance of soft and hard factors produce a higher probability of success [31, 32]. Fotopoulos and Psomas go further on this point by asserting successful quality improvement efforts are more influenced by soft factors than hard [33]. Accordingly, most of the following methods are expressive of soft factors, capable of advancing EALIM's principles.

2.5.1. CSR methods

Shared vision: a CSR vision that is commonly shared by stakeholders, as opposed to one imposed by management. This could create social legitimacy and enable employees to realize the impact of their personal work beyond the organization's primary task.

Stakeholder approach: the crossing of boundaries between internal and external stakeholders through collaboration in order to create mutual trust and wide organizational support.

Corporate philanthropy: discretionary cash contributions direct to charities and social causes, which can build strong community relations, motivate the workforce and significantly enhance people's quality of life.

Community volunteering: empowering employees to volunteer their time and talents toward social causes, for the purpose of integrating with community organizations and effect positive change in the world.

Socially responsible business practices: support of human and ecological sustainability in order to protect the wellbeing of employees and the environment.

2.5.2. CT methods

Complexity mental model: the adoption of a mental model that welcomes disorder as a partner, uses instability positively, sees change as a necessity and understands that complexity is unavoidable.

Planned strategy: a long-term business strategy that enables stable and incremental change with clear goals designed to advance the organizations primary task.

Emergent strategy: spontaneous strategies of a novel kind that allow the organization to selforganize, adapt to uncertainty, and engage in revolutionary change.

Ordinary management: the deployment of rational, formal and analytical management methods within a constant shared paradigm, i.e., single loop learning.

Extraordinary management: the use of creative, informal and intuitive management methods that alter the shared paradigm, i.e., double loop learning.

2.5.3. KM methods

Triple loop learning: single, double and triple loop learning that allows individuals and groups to engage in (1) improvement, by learning new ways of doing, (2) reflection, by learning new ways of thinking, and (3) transformation, by learning new ways of learning.

Communities of practice: practitioner-based (homogenous) groups for mutual support, knowledge sharing, and learning of best practices.

Project teams: intra-disciplinary (heterogeneous) teams for specific projects, problem solving, knowledge creation and building innovation.

Storytelling and narratives: the use of storytelling and narratives among organizational members for the purpose of creating identity, deep meaning and tacit knowledge sharing.

Knowledge brokers/boundary spanning: organizational members who act as sources and facilitators of knowledge, due to their interaction with different communities of knowledge and discipline.

2.5.4. TQM methods

Voice of the customer: the continuous monitoring of dynamic customer requirements, so changes can be rapidly identified in order to avoid customer dissatisfaction and market drift.

Force field analysis: the identification of factors that block movement toward a goal, i.e., restraining forces, and factors that support movement toward a goal or solution, i.e., driving forces.

Nominal group technique: a democratic technique for acquiring group ideas for the detection and correction of errors.

Affinity diagram: the collaborative arrangement of a large number of ideas into groups for review and analysis, to stimulate creative improvement.

Pareto principle: data analysis of the vital few and the useful many, which helps identify the biggest problems to solve.

2.6. EALIM's conceptual framework

The conflation of EALIM's four organizational theories, 10 principles and methods, form a coherent conceptual framework as illustrated in Figure 1. The framework's permeable boundary has two meanings: first, it symbolizes the removal of barriers to teamwork through collaboration and second, it represents the boundaryless connection and reciprocal flow of influence between an organization and its external environment. The dynamics between these two domains emerge from two types of feedback loops: negative (self-correcting) loops that balance change and positive (self-reinforcing) loops that amplify change. The bi-directional

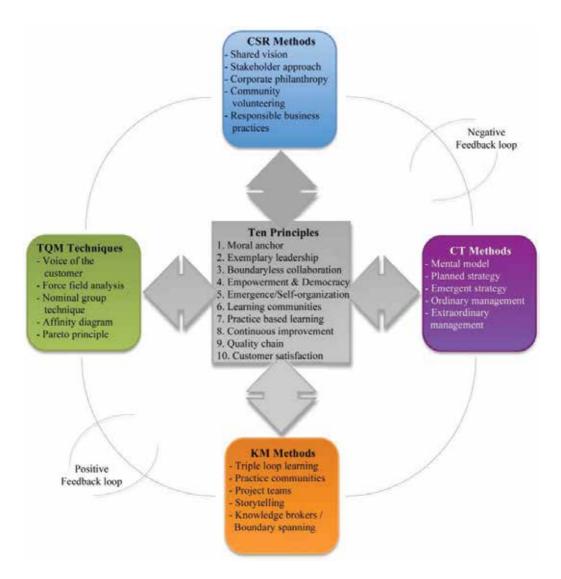


Figure 1. Conceptual framework of EALIM.

arrows between the 10 tenets and 4 theories connote how they shape and are shaped by each other, allowing the model to adapt reflexively.

2.7. Advantages of EALIM's conceptual framework for theory

Although authors have examined conceptual links between TQM and CSR, TQM and CT, and between TQM and KM, no other authors have fully integrated all four of these organizational theories into one coherent conceptual TQM framework. On this basis, EALIM can be regarded as a novel contribution to TQM theory. As previously discussed, integrating CSR, CT and KM with TQM present advantages that address TQM's theoretical limitations. **Table 3** presents a summary of these limitations and the elements of EALIM that hold advantage over them.

Conventional TQM	EALIM		
Investment and consumer capitalism	Moral capitalism		
Formal rationality	Substantive rationality		
Utilitarian rationality	Kantian rationality		
Executive vision	Shared vision		
Technocratic ideology	Humane ideology		
Single loop learning	Triple loop learning		
Newtonian paradigm	Complexity paradigm		
Codified and explicit knowledge sharing	Explicit and tacit knowledge sharing		
External customer focus	Stakeholder focus		

Table 3. Limitations of conventional TQM addressed by EALIM.

3. Implementation of EALIM

The target organization used to implement EALIM employed 270 people and provided care services to 74 patients. The fieldwork involved 91 participants spread across 10 hospitals and care homes. The structure within the organization consisted of top managers (executives), middle managers (hospital and care home managers), staff nurses, care workers and a multidisciplinary clinical team. Participants were selected from different disciplines and hierarchical positions using non-probability sampling techniques (i.e., opportunistic, convenience and snowballing): techniques congruent with participatory research [34]. The broad selection of participants allowed insights into the divergent perceptions and experiences of organizational members, and to generate a broad in-depth analysis of organizational culture. In terms of participant's ethnicity, 46% were white British, 32% were black African, and the others were composed equally between Asian and black Caribbean. The largest age group was 22–29 (37%), while the 30–39 and 40–49 age groups made up 29 and 24%, respectively. The remaining participants fell into the 50 and above category.

Data were generated between July 2011 and January 2013 in three AR cycles. The first cycle involved gathering data for 4 months prior to the adoption of EALIM and was critical for developing a baseline assessment of the organization, as well as constructing a collaborative action plan with top management. In the second cycle, EALIM was implemented over a 12-month period and data were gathered with a focus on examining participants' acceptance and resistance to its interventions, along with its impact on organizational improvement, if any. In the third cycle, data were gathered over a final 3-month period and findings were evaluated against the baseline assessment from the first cycle. This allowed me to identify the overall impact EALIM had on organizational culture and improvement.

As previously stated, the methods used to gather data included depth interviews, participant observation and focus groups. Depth interviews were generally informal and involved open questions with a low degree of structure to allow participants the liberty to talk about what is important to them. A total of 45 participants were interviewed of differing rank, discipline, location, gender, age, ethnicity and length of service. Although my selection of interview participants was not a proportional reflection of the population, it nevertheless produced an illustrative profile that included a diversity of participants from management and non-management positions.

Participant observations involved prolonged periods of social interaction with the researched, and included board meetings, informal and formal discussions, luncheons, and EALIM seminars. The idea is to study participants' everyday experiences, thinking and actions, which may include talking to them about their feelings and interpretations. The total number of observational cases selected from fieldwork notes and transcripts amounted to 37 entries. The author's level of participation ranged from a total researcher—full observation without participation in the flow of events, to a total participant—completely involved in activities.

On the other hand, focus groups were used to collectively generate future action and gain insights into the divergent views of participants. A total of eight groups were held during EALIM's implementation, with an average of five participants in attendance in each group. While an interested volunteer group of snowball participants attended, top and middle managers were invited with the intention of forming a strong political alliance toward EALIM's adoption. In fact, many of the ideas for EALIM's adoption came from focus group participants, a feature that became a success factor for EALIM's implementation. Another success factor was the commitment of senior executives, of whom several consistently attended focus groups and actively implemented agreed action plans. This finding supports many other studies showing top management commitment is a key factor for TQM success. The following subheadings setout the key research findings as a result of EALIM's implementation.

3.1. Increased moral perception of the organization

During EALIM's implementation, executives agreed to fund the construction of an orphanage in India and publicize the project to its employees. During interviews, when participants were asked about their views on the company's philanthropy in India, most middle managers and frontline staff implied the India project had increased employees' moral perception of their employer. Their responses include "People need to know the company is not just about shareholder wealth," "They are doing a good job helping the ones in need ... it changed my

perspective of [the organization]," "Giving back to society is such an important aspect of the company," and "The company is not profit orientated and willing to give back." These responses suggest that because employees identified their employer's philanthropy as a moral ideal, they perceived their employer to be moral. This organizational perception is a significant improvement from that identified in the first cycle, when employees held the view that the company valued profit more than staff.

3.2. Increased organizational commitment

Corporate philanthropy under EALIM had generated greater organizational commitment among employees. For example, during an interview one middle manager claimed, "One staff was moaning about her wages, but after realising what the company was doing in India, she wanted to volunteer her pay rise to help projects like this." This middle manager's claim was consistent with comments from most frontline staff, particularly care workers. For instance, when care workers were asked what they thought of the India project, their responses include "It changed me. Nothing will make me leave ... I appreciate the work this company does," "It made me feel good and inspired me to work more so they can support the countries outside" and "It drew me to the company." Compared with the low care worker commitment found in cycle one, these responses indicated an increase in organizational commitment and that corporate philanthropy inspired motivations to act toward the good of the organization.

3.3. Emergence of a learning culture

Under EALIM, an initiative called microteaching was introduced to promote the principle of practice-based learning. Spawned from a focus group participant, this initiative involved clinicians' role modeling, observing, and providing feedback to employees during their shifts. Instead of relying on classroom training courses, this initiative focused on increasing the knowledge of staff in practice through a question and answer approach during the shift.

Participant responses indicated that a learning culture had emerged as a result of microteaching. Interview responses from top and middle managers that support this finding include "There is a lot more emphasis on learning," "The culture allows for people to learn from their own desire and effort," and "There's now a theme of learning in the organization." The perception of a learning culture was shared by focus group participants, who gave insights as to why they thought a learning culture had emerged. These include "Learning in the organisation has increased because we are microteaching on the unit and staff make a proactive effort to develop their knowledge ... it's certainly changed the culture," "Staff are asking more detailed questions," and "What I've observed is staff get to see the people that deliver the training around the units and ask them questions about this or that during the shift." These responses suggest an increased commitment to learn was stimulated by meaningful interaction between educators and employees, who found practice-based learning more relevant to their learning needs than classroom training courses.

Interview responses from care workers appeared to support the views of focus group participants. These include "Microteaching is helpful...they [trainers] show us how to do the MDT notes and complete incident reports," "Trainers show us how to look after clients" and "Local

training is more specific to clients." These responses indicated the use of practice-based training had created greater tacit knowledge among employees.

3.4. Improved patient self-advocacy

During a focus group at the start of EALIM's implementation, participants were asked to share ideas on how EALIM's principles could be adopted in the organization. An idea shared by the chief operating officer (COO), was to launch the use of community groups. He described them as 20-min daily morning meetings that could take place in the main communal area of hospitals and care homes, so local patients and staff could collectively discuss ideas and agree "what's going to happen for the day." He stated that community groups could "...bring the important decision-making of the unit to staff and patients, rather than the typical hierarchy of management." His idea resonated with EALIM principles of empowerment and democracy, emergence and self-organization, as well as learning communities and team working. The following month, the COO reported that community groups were implemented.

Three months later, the use of community groups was reviewed during a focus group. In that discussion, a director described being "really surprised" after he attended a community group the previous day, where he observed a patient who instead of "normally sitting in the background without saying much," was "quite assertive about what she wanted to do." A care worker who attended the focus group also added, "This morning one of the patients chaired the community meeting...you can really see it's boosting her esteem really. It was just nice that she could sort of have the conversation with her fellow service users and speak to them, because usually she's quite intimidating to the others and for her to be able to talk to them reasonably rather than shouting was really encouraging." According to these empirical accounts, patients' participation in community groups enabled greater confidence in their self-advocacy and more meaningful interaction with others.

3.5. Improved patient independence

Interview responses also indicated an increase in patient independence. One middle manager claimed, "Before EALIM was introduced, we were making the decisions and the focus was on nursing, instead of creating independence. What we now do is let people [patients] do things for themselves." Her claim was consistent with responses from several care workers, such as "...before, we had a different approach. It was like our job was to babysit clients as opposed to now, where it's more therapeutic," "Staff are working more to help patients as opposed to keeping them" and "The care approach has changed from care-taking patients, to helping them become independent." These kinds of responses support the finding that EALIM's adoption contributed to an improvement in patient independence.

Several participants also implied community groups played a role in improving patient independence. Two care workers remarked, "In community meetings, we'll ask clients what they need" and "Community meetings involve patients in making decisions," while one middle manager claimed, "We do community meetings daily. The difference it's making is patients are more involved in making choices and planning their activities."

3.6. Poor leadership was a barrier to consistent service quality

Although there had been organizational improvements during EALIM's adoption, several top managers stated that there were inconsistencies in service quality because of poor leadership. For example, one top manager stated, "There are inconsistencies across the units because of the way managers lead, especially at [hospital X]. When I'm on call, the majority of calls are from there." This view was supported by another top manager who stated, "EALIM has been welcomed by everyone but it hasn't been successfully implemented at [hospital X]."

Interview responses from care workers at hospital X supported the view from top managers. When care workers were asked to describe their experience of the way their manager leads, their responses include, there are problems here, clients are ignored and people don't feel safe. If a person pulls the alarm it could take five minutes for somebody to come...when I first joined [two months ago] I was told I would meet with the manager every month, but that hasn't happened, and "I feel there is no leadership here, someone needs to say 'this is what's going to happen'." These accounts suggest the manager's lack of clear leadership and visible commitment was detrimental to the wellbeing of patients and staff.

4. Conclusion

The development of EALIM presents an evolutionary step in TQM theory. While it possesses theoretical features congruent with TQM, it goes beyond its paradigmatic boundaries by adopting divergent organizational perspectives. Rather than build a new model by comparatively analyzing extant TQM frameworks, the eclectic model building approach used here proved useful in two ways. First, it provides different organizational perspectives without annulling each other, achieved by identifying distinct viewpoints from each theory while highlighting their interrelatedness with TQM. Second, the interplay between these organizational theories offers different perspectives that enable a broader understanding of organizational processes, since any one theory only offers a restricted view of a complex phenomenon.

The synthesis of EALIM's four organizational theories makes explicit links between theoretical constructs that are excluded from other TQM models. As such, EALIM's development is a move toward a more complete gestalt of quality improvement theory. In addition to making a theoretical contribution to TQM, this model holds the prospect of increased success toward organizational improvement, since it is better suited to a postmodern organizational milieu. Although other QI models include CSR principles (e.g., EFQM, Baldrige) within their frameworks, EALIM's integration of a Kantian ethic presents a step further, in that it forms a novel moral anchor that binds organizational members to altruistic decision-making and behavior. Not only does this moral anchor connect stakeholders to a social ideal judged as intrinsically good, but also forms the basis for promoting a moral kind of capitalism, epitomizing the next stage in the evolution of quality.

Research findings from EALIM's implementation reveal its capability to achieve organizational transformation, evidenced by the development of a moral organizational perception, increased organizational commitment, and the emergence of a learning culture. Various authors agree that learning organizations hold advantages, which include increased innovation, sustainability and competitiveness [35, 36]. A prerequisite for promoting a learning culture was the adoption of practice-based learning, which holds greater potential for human development than codified and explicit knowledge sharing. Practice-based learning also had a positive impact on employee commitment to learn, a finding noticeably absent from the TQM literature, perhaps because TQM theorists do not commonly advocate practice-based learning.

The finding that EALIM's adoption improved patient self-advocacy is also novel since a search of the literature yielded no evidence of this from any quality improvement initiative. This finding is particularly important for patients with a learning disability or mental illness because they typically lack opportunities to contribute to their own lives and shape the service they receive. From this perspective, this finding demonstrates an essential element of research quality: namely, "quality as engaging in significant work [37]."

Improved self-advocacy and independence among patients show a direct improvement in patient care. Since most TQM healthcare studies do not indicate a direct improvement to patient care, this study demonstrates an original contribution to TQM practice. Despite these improvements, inconsistencies existed in local services due to poor local leadership. However, some inconsistencies among local services are to be expected, especially since services are prone to variability because of their heterogeneous nature [38]. On this basis, the commitment of all internal stakeholders would be required to achieve sustainable service quality.

4.1. Limitations and implications for future research

A limitation of this study is that its findings should not be generalized across all healthcare sectors, as each environment is bound by its own contextual factors. Nonetheless, in contexts where there is wide commitment to EALIM's principles, the results of this study could be replicated. Researchers may wish to take this study further by examining EALIM's applicability in contexts outside of healthcare, especially where ethics are at the fore (e.g., financial services). Alternatively, others may wish to use this research to explore various themes, such as the adoption of complexity perspectives in management, or the use of practice-based learning. Furthermore, EALIM could be of particular interest to managers working in environments with a high degree of disequilibrium (e.g., capital markets) or innovation (e.g., technology industries), because its CT and KM methods promote emergence in the face of instability, and knowledge creation in highly competitive markets.

As a final point, decision makers wishing to adopt EALIM should be aware of what it is they are committing to and what barriers they may encounter. To avoid inconsistency between the message and practice of EALIM, top managers are recommended to not only espouse EALIM's principles, but also particularize them in their everyday work with others: thus providing a personal exemplar of action. As William Shakespeare wrote in Coriolanus, "Action is eloquence, and the eyes of the ignorant more learned than the ears [39]."

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Use of IT in ISO 9001 Systems for Better Process Management

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Additional information is available at the end of the chapter

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Abstract

This book chapter focuses on process management as one of the key requirements of ISO 9001. This research highlights an issue of raising the effectiveness and efficiency of process management in implemented ISO 9001 Quality Management Systems (QMS) by its integration with information technology (IT) support. Performed research reveals this to be an area of further scientific work. This is just a preliminary study to prepare the background for practical implications and further empirical research. The latter research includes literature review, ISO 9001 requirement analysis and a case study on practiced process management in South-East Europe countries as identified from external audit reports. The new standard ISO 9001:2015 is less formal regarding the documentation than the previous ones, while being more focused on effective running and improvement of the company processes. Actually, ISO 9001 requires basic elements and activities of Business Process Management (BPM). However, there are no obstacles to provide the required evidence of the defined, running and improved processes through the business IT support. Indeed, IT support to the ISO 9001 process management is not generally practiced nor encouraged enough.

Keywords: Quality Management System (QMS), ISO 9001, Business Process Management (BPM), information system/IT system, process effectiveness, process efficiency

1. Introduction

The subject of the chapter is focused on Quality Management Systems (QMS) combining three scientific disciplines:

Quality Management (QM) by addressing ISO 9001 requirements;



- Business Process Management (BPM) focusing on process description, characteristics, management, methodology and tools;
- Business informatics and information technology (IT) systems for running everyday business in the companies, their prevalence, availability, characteristics and features.

Process approach including BPM is one of the ISO 9001 key requirements. This chapter is pointing out an important but not commonly addressed way to make BPM in ISO 9001 QMS more effective and more efficient by its integration with internal IT system of the company. It highlights a number of topic-related elements described herein.

ISO 9001 is still the most prevalent international QM standard with the highest number of certificates worldwide; however, the number of granted certificates is continuously decreasing in the last 7 years (from 1,118,510 in 2010 to 1,033,936 in 2015) [1]. Considering the ISO 9001 requirements, especially customer and process orientation, the certified companies should stand out and develop competitive advantage based on the developed internal quality culture, process effectiveness and efficiency all resulting in better products and better customer service. On the other hand, presence or absence of ISO 9001 certification is a poor predictor of organizational performance and product or service quality [2]. The new revision of the standard in 2015 (ISO 9001:2015) tries to make the QMS more business oriented and thus, more appealing for companies again.

Performed research indicates that implemented ISO 9001 QMS should positively affect the company performance and its image [3]. The core process management practices in the certified companies should have a strong, positive and direct effect on quality improvement [4]. Although the process orientation is an important focus of ISO 9001, the impact of the standard on rising performance in the business sector is limited (also because of the fact that ISO 9001 certified companies represent just over 0.5% of the estimated 190 million companies worldwide [5]). Sometimes also positive results of other undergoing activities in the companies are (wrongly) attributed to the implemented ISO 9001 [6]. The research on ISO 9001 effectiveness in the last decades was not balanced (mostly exploring positive practices and successful cases of implementation) and might reveal a wrong picture of generally improved performance of certified companies.

The "customer pressure" is still one of the main motives to achieve ISO 9001 certification mentioned by companies. As such, there is a lack of real internal motivation and management support to develop an effective QMS and process approach as its vital part. In many cases, ISO 9001 is implemented and operated with minimum effort and in such a way that many opportunities for improvement are lost [7]. Although having strong internal IT systems for running their everyday operation, many companies still develop and run their QMS as a separate (stand-alone) and frequently bureaucratic system including process documentation and reporting. Hence, QMS with its process approach is not considerably linked with the operation management and business IT system supporting it.

"Digital business is a reality now and it is expected to be a very significant aspect of achieving competitive advantage and differentiation using information and technology" [8]. Applications for planning, running and controlling everyday business activities (as required

by the ISO 9001) are available, affordable and implemented not only in bigger but also in small companies [9]. The most widely used software packages are Enterprise Resource Planning (ERP) systems and Business Process Management Systems (BPMS) [10]. Along with it, ISO 9001 is one among the business drivers causing organizations to focus on business process change [11]. These claims and findings of IT analysts and researchers might be an incentive to think about possible digitalization of the ISO 9001 QMS. Thus, management and running the processes according to ISO 9001 requirements would be much easier, more effective, less costly and better accepted by management and employees.

1.1. The research purpose and questions/objectives

The purpose of the research is to get an insight into the situation of BPM in the ISO 9001 certified companies and use of IT support to facilitate it. The main research focus is on whether the requirements of the standard are well accepted and effectively implemented. The intent of the research is to encourage some more research in this field and improvement initiatives for the practitioners.

In view of the above, the aims and objectives of this work are outlined below:

- 1. the elements of BPM required by ISO 9001;
- 2. the elements of BPM practiced in the companies;
- 3. the benefits, disadvantages and barriers of QMS and IT integration;
- 4. the practiced IT support to the QMS process approach in the companies;
- **5.** encouragement for integration of the QMS and IT.

1.2. Research methodology

In order to address observed bottlenecks in companies, this paper will introduce an ISO 9001 text analysis and a preliminary empirical BPM maturity evaluation model fostered by statistics.

The research approach takes an analytical comparison approach regarding ISO 9001:2015 and BPM requirements. In doing so, it will analyze corresponding features and functionalities of the most frequently used IT business solutions, followed by analytical and empirical investigation of the current global situation in ISO 9001 and BPM implementation in the companies upon the literature review and the presented case study.

The latter tries to give an insight into the praxis of process approach in ISO 9001 certified organizations on the information collected from ISO 9001 audit reports of a certification body operating internationally. The "SIQ Ljubljana - Slovenian Institute of Quality and Metrology, Ljubljana" kindly agreed to co-operate in this research, as it is a certification body covering several international standards and countries in South-East Europe. The case study includes analysis of BPM-related records in 48 randomly chosen ISO 9001 audit reports from the year 2016 from 6 countries in South-East Europe.

The described frame of research in "Introduction" is followed by a hypothetical research model addressing major bottlenecks exposed in the "Introduction" and evidenced praxes from literature review (in Section 2) making the theoretical background for the case study (in Section 3). The results are discussed (in Section 4) including implications and limitations of the research. A conclusion follows in Section 5.

2. Literature review

2.1. Processes and BPM

A process is a collection of events, activities and decisions that collectively lead to an outcome that brings value to the customers of an organization. Zairi [12] defined a process as an approach for converting inputs into outputs in a way in which all the resources of an organization are used in a reliable, repeatable and consistent manner to achieve the company goals.

Every organization has processes. Understanding and managing these processes in order to ensure that they consistently produce value is the key driver of effectiveness and competitiveness of organizations. Through their focus on processes, organizations are managing those assets that are most important to serve their customers well [13].

In any company there are different types of processes [14]: core processes oriented on the customers and covering the main business (e.g. purchase, production, sale); supporting processes (e.g. IT support, maintenance, administration) and management processes (company management – planning and control). Generally, a process flows through different business functions in the organizational structure of the company enabling their harmonized work for achieving the same common goal – making value for the customer. The majority of the business processes are complex. Therefore, they are hierarchically split into sub-processes until reaching down to activities and basic tasks. Hence, these may facilitate better management. In doing so, the elements of the processes, their various inter-connections should be identified and properly determined. That means that at least basic elements and characteristics of a process should be set and applied for each business process. Summarizing different definitions of a process, the following list of characteristics for a business process may be compiled [15] and may provide the following:

- **1.** the process *owner* or process manager (the manager responsible for the process, its performance and improvement);
- 2. target groups of internal or external *customers* and *suppliers* for the process;
- 3. customer-oriented process *objectives*, performance *criteria* and performance *indicators*;
- **4.** process *borders* (beginning and end points), *inputs* and *outputs* and *connecting points* with other processes;
- **5.** *sequences of the process activities and tasks,* their internal connecting points, inputs, outputs, timing, conditions and task description;
- 6. responsibilities for each task;

- 7. skills needed to perform each task;
- **8.** *the required resources (skilled workers, infrastructure,etc.);*
- 9. control points and required measurements; established measurement, control and information feedback loops close to the operation activities;
- **10.** recognized possible risks and defined preventive actions;
- **11.** *effective non-compliances-handling and process improvement formal procedures.*

A scheme of a process with the listed process elements is presented in Figure 1. The process elements are marked with their bullet numbers from the list.

The importance of adopting a process view and their continuous improvement has led to the creation of the process management philosophy. After defining the processes they should be systematically applied, managed and improved. The systematic approach covering it is called Business Process Management (BPM). BPM is defined as "supporting business processes using methods, techniques and software to design, enact, control and analyze operational processes involving humans, organizations, applications, documents and other sources of information" [16]). Companies can decide to use BPM to manage only one or more chosen core processes or to manage all its business processes. In a company, BPM is frequently introduced through its IT support development (implementation of ERP or BPM systems) or through QMS initiatives [17].

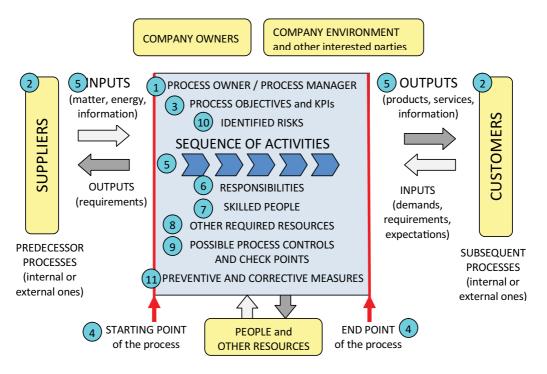


Figure 1. Schematic representation of the elements of a single business process.

As a methodology BPM comprises of the following [18]:

- · process selection;
- · process description;
- organizing for quality;
- process quantifications;
- process improvement.

The BPM methodology can be facilitated by the following tools: (1) process mapping and process measurement (as foundational pillars for managing processes); (2) process re-engineering or redesign; (3) models for continuous improvement such as the "plan-do-check-act" cycle and (4) instruments for benchmarking.

Performed literature review indicates that a shift from product orientation to process orientation and from functional to process organization emerged in the 1990s by emerging holistic (ERP) software solutions. It continued in the 2000s by development of the QM and Business Process Orientation (BPO), suggesting that the whole organization should be viewed as a system of processes that should be mapped, improved and controlled [19]. "BPO of an organization is the level at which an organization pays attention to its relevant (core) processes" (end-to-end view across the borders of departments, organizations, countries, etc.) [20].

Interestingly, the majority of authors of 15 reviewed papers on BPO regard this as a means to achieve operational excellence and tend to ignore its strategic potential for establishing a long-term competitive advantage [21].

2.2. ISO 9001 principles and requirements on process approach that call for IT support

The release of 2000: ISO 9001 for the first time sets process orientation and requirements for indicating, defining, describing, controlling and improving performance [22]. The process approach is even more emphasized in the latest release of ISO 9001:2015 [23] where not only process effectiveness but also process efficiency is searched for. Additionally, the latest standard release is more flexible regarding the form and quantity of documentation depending on the company context (size, industry, culture, strategic frame and business environment).

Principles and requirements of the ISO 9001:2015 are set in the 10 chapters (Ch.) of this standard. Process approach is the core principle for implementation of "Plan-Do-Check-Act" (PDCA) loop. In the introduction chapter of the standard (Ch. 0.3), this QM principle is described and other six are listed (customer focus; leadership; engagement of people; improvement; evidence-based decision-making; relationship management).

The aims of the process approach are (Ch. 0.3.1): (1) development, implementation and improvement of the *effectiveness of a QMS*; (2) enhancing *customer satisfaction* by meeting customer requirements and (3) *organization's effectiveness and efficiency* in achieving its intended results in accordance with the quality policy and strategic direction of the organization.

The means of the process approach are (Ch. 0.3.1): (1) systematic definition of processes, and their interactions; (2) understanding and managing interrelated processes as a system and (3)

controlling the interrelationships and inter-dependencies among the processes of the system, so that the overall performance of the organization can be enhanced.

The expected benefits of the process approach are (Ch. 0.3.1): "(1) understanding and consistency in meeting requirements; (2) the consideration of processes in terms of added value; (3) the achievement of effective process performance; (4) improvement of processes based on evaluation of data and information."

Figure 1 in Ch. 0.3.1 gives a schematic representation of any process and its basic elements ("input; sources of input; activities with their starting and end points; possible controls and check points for measuring performance; output; receivers of output") and shows the interaction of its elements.

"Management of the processes and the system as a whole can be achieved using the PDCA cycle (see Ch. 0.3.2) with an overall focus on risk-based thinking (see Ch. 0.3.3) aimed at taking advantage of opportunities and preventing undesirable results" (Ch. 0.3.1).

The PDCA steps and risk-based thinking philosophy are shortly described in these chapters with no guidance of a proper methodology or tools to be applied.

The BPM requirements in the standard: specific requirements considered essential to the adoption of a process approach are included in Ch. 4.4. It states that the organization shall establish, implement, maintain and continually improve a QMS, including the processes needed for the QMS, their application throughout the organization and their interactions, in line with the requirements of this international standard. According to Ch. 4.4.1 organizations shall perform the following process management activities:

- a. "determine of the inputs required and the outputs expected from these processes;
- **b.** determine the *sequence* and *interaction* of these processes;
- c. 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;
- **d.** determine the *resources* needed for these processes and ensuring their availability;
- e. assign the responsibilities and authorities for these processes;
- **f.** address the *risks* and opportunities as determined in Ch. 6.1;
- g. evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;
- **h.** *improve* the processes and the QMS".

To the extent necessary, the organizations shall also (Ch. 4.4.2):

- a. "maintain documented information to support the operation of its processes;
- b. retain documented information to have confidence that the processes are being carried out as planned."

The above-listed requirements of the standard (Ch. 4.4.) match with the content (activities and defined data set) of BPM which is IT applicable and mostly implemented together with IT support (see Sections 2.1 and 2.3 for details).

It is supposed that the activities that need extensive data management support; identification and tracking; time, status and access control; workflow and automation; group work, data exchange, data analytics can be nowadays performed more effectively using IT support [24].

The standard leaves open space for use of different technologies and infrastructure, including IT support and process automation although there is no guidance in the standard about it. It is rather strange that the *standard expects "improvement of processes based on evaluation of data and information"* (Ch. 0.3.1), however, it gives no technical support to it. In ISO 9001:2015 and its past revisions no requirement nor any suggestion is given for the QMS as a whole nor for the process approach as its core requirement on how to facilitate the implementation and operation of both with modern technologies. Such approaches are not clearly suggested, encouraged and commonly practiced [25]. Moreover, the research on IT supported QMS is rare.

Facilitating the QMS requirements with IT support would make QMS and BPM as its part more integrated in everyday business, thus, making it more effective, more comprehend and easy-to-use [26]. Only little general suggestions are given in additional guidelines (ISO 9004:2009, ISO/TS 9002:2016) on how to effectively implement the requirements with the aid of technological support [27–29]. However, more emphasis regarding the use of technology (a special chapter) is planned in the next revision of ISO 9004 which is at present in a draft phase (DIS ISO 9004) [30].

2.3. Implementation of BPO and BPM in companies: different approaches

2.3.1. Development of practiced BPM in companies

Advances in IT over the years, have changed business processes within and between enterprises. In the 1960s, operating systems had limited functionality and any workflow management systems (WFMS) that were in use, were tailor-made for the specific organization. In the 1970s–1980s, the development of data-driven approaches was brought, as data storage and retrieval technologies improved. Data modeling rather than process modeling was the starting point for building an information system. Business processes had to adapt to IT because process modeling was neglected. In the 1990s, the interest in business processes increased and the shift toward process-oriented management occurred, initiated by emerging of Six Sigma, Business Process Reengineering, ERP software with workflow management components, such as SAP, Baan, PeopleSoft, Oracle and JD Edwards. BPM has been high on most lists of important business topics since 2003. The most recent trends in BPM are influenced by the emergence of cloud technology, the prevalence of social media, mobile technology and development of analytical techniques [31].

In 2016, a global ERP report involving 215 respondents showed that 82% of respondents improved either key business processes or all of their business processes by implementing ERP system [32].

2.3.2. Prevalence and maturity of practiced BPM in companies: a global research

A worldwide BPM research on the state-of-the art pertaining to the years 2005–2015 [33] included companies of different size and different industries. It shows that there has been no real trend of rise in use of BPM in the last 10 years. Individual companies may have become more process-oriented and may have invested in BPMs or may have created business process architecture, but most companies have not. The state of BPM, as defined in 2005, is roughly the same today (in 2016).

Among business drivers causing organizations to focus on business process change, the ISO 9001 and business risk management (by 17%) and management of IT resources by ERP (by 15%) were recognized in stated international research.

According to this research, the share of companies practicing BPM is still low. Only 2% of the respondents perform the planned BPM activities regularly covering all the processes. Among all the respondents, less than 50% of them have their processes documented, less than 40% of them have their processes automated, less than 30% of them have standardized key process indicators (KPIs) for measuring process performance (see the shares of organizations with maturity levels 3-5 in Figure 2). Just 10% of all the managers are trained to think as process managers. Most respondents think that BPM is about managing process change throughout the business and not an implication of introducing a new software technology.

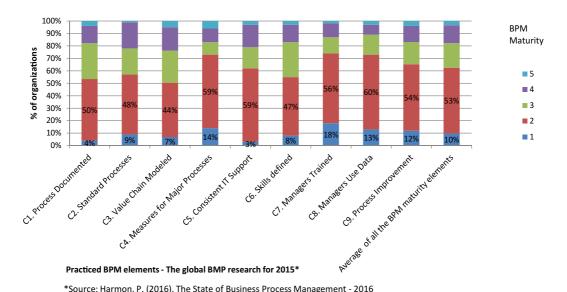


Figure 2. Global BPM maturity survey results for 2015.

This BPM study investigates also the maturity of BPO and BPM. For the assessment, the maturity model called Capability Maturity Model Integration (CMMI) was used. It defines five levels of process maturity, namely:

- 1. "no organized processes" (immature);
- 2. "some organized processes";
- 3. "most processes organized";
- 4. "processes are managed";
- 5. "processes are continuously improved".

Most organizations in 2015 are at Level 2 on the CMMI maturity scale. They have invested in defining their processes, but have not invested in aligning processes throughout the enterprise. Significant differences in specific elements of BPO maturity can be found among countries, however, this is not presented in this global study on BPM.

2.3.3. Introducing BPM through ERP and BPM software implementation

The role of IT was always important in BPM – as an initiative to develop BPM when developing or changing the core business software in a company and as a set of tools facilitating BPM. According to performed empirical research, introducing BPM through business software implementation is still a way of starting BPM in a company. Many companies have their own tailored IT business solutions or combination of more standard partial solutions that cover the business needs. Implementation of an ERP or BPM system is a more holistic approach to facilitate the operation. However, implementation of such a system takes more time and money and is not a general approach in smaller companies [34]. Regardless of having more partial business solutions or a holistic one, managing processes with such a support is possible if the data model matches with the required process data (see requirements of the standard in Section 2.2) and enables management features.

ERP systems are integrated systems of applications for planning, operation and control of the company business. They typically operate in (or near) real time, use a common database that supports all the applications and provide a consistent look and user interface across the modules that cover specific business topics and functional areas [35]. ERP services and operations management include integrated application suites designed to automate a range of business processes from back-office operations to financial management and from sales order capture to customer information management. Currently, ERP also covers functions not being addressed by other functional markets, such as environment, health and safety, governance, risk and compliance, as well as vertical industry-specific solutions [36]. Functional areas of an ERP system are financial accounting, management accounting, manufacturing, order processing, supply chain management, project management, customer relationship management (CRM) and data services [37].

CRM systems are not always considered as a part of ERP systems, but rather as Business Support Systems (BSS). The implementation of an ERP is quite a complex project and cannot be realized in small steps. ERP systems can be also implemented through implementation of BPM, while ERP matches with the first four phases (steps) of BPM. Important part or upgrade to an ERP system can be Business Intelligence and Business Analytics (BI, BA) applications that enable better decision-making information.

The Business Process Management System (BPMS) software provides "automation of a business process, in a whole or just in a part, during which documents, information or tasks are passed from one participant to another and put into action according to a set of procedural rules" [38]. BPMS will increasingly offer an alternative to the companies to manage their business – or at least a way to "adjust" their ERP with more flexible process models that can be more easily changed. According to a global study (see Section 2.3.2), it is estimated that well over a third of the BPMS applications developed to date have been developed as an alternative to ERP, or to make ERP more agile.

BPMS software typically includes following tools and features [39]:

- BPM engine (server);
- organization modeling tool;
- business process modeling tool;
- process simulation tools;
- · business rules;
- · developer;
- administration tool;
- integration capability;
- business process monitoring;
- measurement and management tools;
- process adaptability.

Such modeling, workflow, administration and control tools are supported with a database, keeping all the process-related data (as defined in Section 2.1), process rules and operation constraints, performance criteria and results (Key Performance Indicators – KPIs).

A detailed description of each activity (as a guidance for workers) and a description of a process as a whole may be embedded in the software, as well, or kept separately in the form of an electronic or printed document. The planning and reporting about process performance, including historical data, trends and hierarchical consolidation of data and KPIs is possible directly from the included IT tools. Data entry from different sources is feasible and each data needs to be entered only once.

2.3.4. Introducing BPO and BPM through ISO 9001 implementation

ISO 9001 tries to make a shift in mind of managers and employees by introducing process orientation as a business principle. This way the standard raises awareness about it. The requirements on process identification, definition, documenting and measuring often result in one or more documents (quality manual, optional process map and optional additional process description documents) and some summarized reports (at least for the required management review). Companies that have complex business and high structured organization often decide to merge the ISO 9001 documenting requirements with the documenting and reporting capabilities of their current IT system or even implement special software to facilitate both better. Generally, in real life, the QMS and its process approach are still paper-driven or managed with support of office tools only [40], although the new ISO 9001:2015 eliminated the need for extra documenting for the sake of the system or audit requirements. In companies, where the QMS does not produce process-related documents and records that are used as a guidance to work and decision-making support, the ISO 9001 requirements might still be formally met and the company is still granted a certificate. However, the effect on the business is more than less negative and perceived as "useless extra work".

It might be quite demanding and hard to follow to map, document and regularly update the processes manually. A simple, actual, detailed and user-friendly process mapping is needed (but it is not required in the standard). To make it easier Carmignani [41] proposed a structured methodology to successfully apply BPM as required by ISO 9001. The process definition approach is in a top-down principle (from the general to the particular), while the drafting of descriptive documents, if necessary, is bottom-up (from the particular to the general, that is, from instructions and procedures to the manual) and prepared after the actual implementation of the OMS.

The steps of the proposed methodology are the following:

- **1.** identify macro-processes, their mutual relations, inputs, outputs, constraints and necessary resources;
- **2.** specify, progressively, the single macro-processes to the activity level;
- 3. build complete flow charts for priority activities and successively for all activities;
- **4.** define the gaps between the activities, the fixed targets and the norm and, if necessary, rethink (re-engineer) the activity;
- 5. check the effectiveness of the activities and of the process that subsumes them;
- 6. draft a document that describes the activity (instruction) or the process (procedure); and
- 7. document the QMS globally, from process map to policies, to choices and activities (manual, procedures, instructions, indicators, plans, etc.).

It is important to achieve management commitment in order to implement BPM successfully. However, there are only a few articles mentioning how to do it practically [42]. Beer [43] argues that there is often a gap between the management rhetoric about their intentions for QM and the reality of the implementation of the concept within the company.

2.4. Integration of QMS and IT for better process management in ISO 9001 QMS

2.4.1. Integration need

The use of IT systems is not part of the requirements in the standards; nevertheless IT is often used in larger organizations to efficiently meet the standard enforcement and documentation

required for compliance to QMS procedures (see Section 2.2). As recognized from the practice and Carmignani's research (see Section 2.3.4), a broad mapping of the processes appears to be insufficient. Actually, it does not enable setting the modalities of activity management and control. The need for appropriate instruments to represent and manage "sequences and interactions" and "objective deployment" in a simple way is pointed out in that research. Furthermore, retrieving past data on monitoring and control and activity trend information is recognized as an issue, especially at the operational level. The QMS often needs information from the basic operational IT systems of the company or contributes to it.

Manual data handling raises issues, such as:

- 1. a lack of visibility and availability of data (scattered information, personal hold of data and documents, technical barriers and no proper channels for sharing the data, inability to extract the data, too many personalized and incompatible reports);
- 2. human errors because of multiple input of the same data, manual control and reporting resulting in biased or even incorrect reporting and wrong actions;
- 3. time spent for data clarification;
- **4.** repetitive tasks and repetitive tiresome reporting that could be automated;
- 5. a lack of data transparency making errors, frauds and corruption hardly discoverable and thus possible.

These issues are implied by data management needs (see Section 2.2) upon the requirements of the standard.

Finally, it is the author's view that running ISO 9001 BPM separately beside the IT system running the business causes additional costs and requires extra efforts. Moreover, it is not motivating to maintain such a paper-driven BPM system that is not applied in business operation. As such, more often than not, QMS BPM documentation is not promptly updated following the applied changes in operation and is more or less a burden to the business. However, such a BPM may barely formally meet the minimal requirements of the standard and suffices for gaining or keeping the ISO 9001 certificate.

Authors already tried to make the implementation of BPM as a part of QMS easier and more effective. Carmignani developed a structured approach to implement BPM as a support to QMS. It offers a systematic approach to map and describe company business processes. The steps in this approach are close to the ones applicable in BPM software tools, however, no IT support is explicitly demanded in the presented approach. Despite a clear approach updating process parameters and controlling processes in more complex environments would be hardly feasible and costly without IT support (manually).

Literature review shows that only a carefully considered combination of process redesign efforts coupled with appropriate IT support offer the most beneficial potential to organizations embarking on transformation path to BPO. Use of process-oriented IT systems and the principles of BPO in combination yields most noticeable increase in quality and success of individual processes [44].

Measurement and metrics are the basis for any improvement program and software makes it feasible and more effective. The emphasized shortcomings of paper-based solutions for process approach in ISO 9001 QMS (mentioned above and in Section 2.2) could be eliminated or at least reduced by a proper IT support. Therefore facilitating QMS process approach (BPO and BPM) with IT is called for.

2.4.2. Integration applicability and feasibility

Three aspects of an IT support are recognized as important for implementing an effective QMS:

- well defined and essential processes;
- related QM processes;
- related process improvement practices.

The listed elements of such IT support to the core and supporting business processes and to the QMS background system processes (planning, control and improvement processes) match with the defined BPM elements by theory (see Section 2.1). They also match with ISO 9001 BPM requirements in Ch. 4.4 (see Section 2.2) and with the features and data models of general BPM and ERP applications (see Section 2.3). Upon these findings from the presented analysis and former research it may be concluded that:

- all the ISO 9001 requirements on BPM are IT applicable;
- the set of data and features, required by ISO 9001, is even narrower that generally provided in company business IT support;
- ERP systems generally cover the requirements of the ISO 9001 [45] or offer QMS as a part (module) of an ERP. Furthermore, the majority of companies already use IT support, it is affordable also to SMEs and it is vital for effectively and competitively running the business.

2.4.3. Recognized positive praxis

A number of research papers show that there are cases of IT facilitated BPM in ISO 9001 certified companies – for example, through implementation of an ERP, BPMS or CRM system, with support of Document Management System (DMS) and workflows [46].

2.4.4. Integration advantages and disadvantages

Integration of the classical QMS process approach with a company's IT support may result to advantages. One integrated, IT supported and more effective BPMS is established instead of having not really valuable extra QMS process documentation and separately operating business processes through the company business IT system. The benefits of digitalization may be expected (one entry for each data; real time, accurate, valid and reliable information always available; easier information availability and sharing; automatic or at least facilitated data retrieval, consolidation, analytics and reporting; built-in process rules; process automation, etc.) [47].

The compliance evidence (in case of audits and controls) can be taken directly from the business IT system. This way meeting ISO 9001 process approach requirements becomes a part of everyday activities. The process rules, instructions, controls and reporting are embedded in the IT system people are using every day. A single data entry and automatic data retrieval for reporting is provided. In view of the above, the process and QMS requirements are better known to the workers, less manual documenting, reporting and training is needed, process control is improved. Consequently improved availability and reliability of data may contribute to less errors, disruptions and possible frauds [48]. Less manual work due to (1) easier data collection and clarification; (2) better process control and less re-work and (3) implemented process automation can result in reduced operating and labor costs and improved process effectiveness and efficiency is improved [49].

As such, it may be argued that BPO becomes a part of organizational culture. Furthermore, BPM as a part of the QMS turns from a bureaucratic burden into an important management tool for decision-making and continuous improvement. Such BPM is actually applied on all the company levels and supported by the company management.

There may be also some barriers to the suggested integration. An IT part of the QMS process approach should be developed, implemented and applied, so the QMS implementation might be more complex, taking more time and money, and requiring cooperation of IT specialists [50].

However, such implementation should later result in better performance and satisfaction. It is also hard to develop a common integrated solution if there is a lack of a single interface for decision-making on data management and budgeting of IT support development.

Therefore, instead of one strong management system, several separate partial systems are developed and the gaps among them raise issues and reduce performance (see Section 2.3.4). Additionally, there is no guidance from ISO for a proper QMS and IT integration. Furthermore, ISO 9001 consultants and certification bodies may not have proper knowledge and experience to motivate and support IT integrated implementation of a QMS.

In case of such an integration, it is the author's view that one should be aware of its possible risks and disadvantages. For instance, BPM effectiveness is to a great extent dependent of the effectiveness of the basic IT solutions, in which it is integrated. It means that if there are any troubles in IT support (e.g. access lost, data or programs temporary unavailable, not friendly user interface, low software and hardware performance), this might affect the BPM performance. The extent of this influence depends on the way and the depth of integration of both systems (IT and BPM).

2.4.5. Practiced non-integrative approach

Performed research indicates that the positive role of quality thinking and QM is not often applied in IT application development. The findings of a survey involving 160 organizations in Serbia and the wider region do not support the theoretical assumptions related to the direct effect of IT application on organizational performance. The mediating role of QM is crucial for overcoming the shortcomings of IT application development.

The research results can be used as guidelines for the implementation of an integrated approach in the application of QM in the IT context. In particular, managers should consider the application of QM techniques for the improvement of IT quality [51].

The companies often do not point out the link between IT and QMS when presenting the IT support development in the company, even if they are certified to the ISO 9001 [52] or some other management system standards [53]. It looks like the ERP and BPM development in the ISO certified companies is often dedicated only to IT departments. The literature review on synergies between IT systems and QMS [54] similarly shows that 80% of the papers address the limited perspective of one type of system being dominant.

Additionally, the global research on use of BPM tools reports no major impact of ISO 9001 on implementing BPM (see Section 2.3.2). In only 17% of ISO 9001 cases and business risk, management were drivers for implementing the BPM and in 15% of cases management of IT resources by ERP was mentioned as a driver for BPM. Therefore, one can hypothesize that integration of both (QMS and IT) is not a general praxis, moreover it is still rare and downsizing. Namely, according to this research, the use of ISO 9001 in companies practicing BPM was reduced from 2005 (49%) to 2015 (23%) to half of their share. These findings contradict the claim raised in handbooks [55] that point out that efficient BPM is based on "process thinking," "quality thinking" and "automation".

2.4.6. Room for improvement

The findings herein indicate that there is indeed room for further improvement. At first, research methodology was aimed at getting an insight into the situation through the eyes of certification bodies, which are regarded as the most influencing actors in this case [56]. In addition to the above, information about BPM maturity and the use of IT in certified organizations was gathered, so as to gain an insight regarding ease-of-use concerning BPM.

3. Practiced process approach in the ISO 9001 certified organizations: a case study in South-East Europe

3.1. Research methodology

This paper discusses process management-related information in audit reports (ARs) of the Slovenian certification body SIQ Ljubljana (SIQ). The latter was covering over a third of Slovenian certification market that included 1481 certified organizations in the field of ISO 9001 in Slovenia at the end of 2015 [57]. SIQ was equally operating in neighboring countries, such as Italy and countries in the Balkans. Among the issued certificates in 2016, 61% of them belonged to QMS (ISO 9001), 75% of them were issued in Slovenia and other countries took a share of 1–8% [58].

A random sample of 48 ARs was taken from the SIQ database of 1073 ARs pertaining to the year 2016 [59]. This database included ARs addressing ISO 9001 and other systems, different

types of audits and different countries. In the present study, a sample of ARs from different countries (Slovenia, Italy, Croatia, Bosnia and Herzegovina, Serbia, the former Yugoslav Republic of Macedonia) were randomly selected. The structure of the selected audited organizations was quite diverse also regarding business sector or industry and size of organization (see **Table 1**).

With regard to the ARs, records were searched about BPM and for identifying documented non-conformances and recommendations addressing it. Then the findings were grouped and analyzed following nine BPM maturity criteria from a global BPM research from 2015 (criteria C1-C9 – see **Table 2**) and using the same grading scale (from 1 = immature to 5 = mature) (see Section 2.3.2).

Thus, the results were comparable with this global research. For each organization the information related to each of nine BPM maturity criteria was searched for. All criteria were assessed and the number of non-conformances and recommendations addressing these criteria was recorded.

If the demanded data was not found in the AR, it was marked with "-".

Results of the study are presented in **Tables 2** and **3**, respectively.

For each BPM maturity criterion, there is a number or a share of organizations attaining that grade under each grade (from 1 to 5). In the same grade column, there is a total number of non-conformances and recommendations on this criterion, given at the audit to the group of organizations assessed with this grade. This way maturity level of the selected sample of organizations is presented (**Table 2**) and a comparison to the global BPM research is made (**Table 3**).

There was no intention to prepare this preliminary study in greater detail by including analyses by country, industry or size of organizations. This would form part of further research.

3.2. Research results

Less than 20% of all the research conducted on ISO 9001 effectiveness is dealing with disadvantages, negative effects, issues and non-realized expectations of ISO 9001 implementations, such as bureaucracy, a lot of people engagement, costs and superficial integration [60]. Thus, instead of operating effective process planning and control following the "Plan-Do-Check-Act" loop, some additional general process-related documentation is prepared just for the sake of the audit and not for being used at work. In such cases QMS is not perceived as a tool for managing processes, but as a tool for handling documentation. This way it may boost bureaucracy and become a burden for the company. The important role of better managed processes is recognized (see Section 2.1). The results of the empirical part of this research show the level of practiced BPM in certified organizations.

The structure of the analyzed ARs and the related audited organizations in **Table 1** shows that the structure of the selected organizations is quite balanced and in some relation with the structure of the certification business of SIQ. They came from different industries and also from the public sector. The data about the size of organizations was not found in the ARs, so this data could not be presented. A total of 17 organizations (= 35% of them all) were certified

to some other standards as well. Most frequently these standards were ISO 14001, ISO 13485, BS OHSAS 18001, ISO TS 16949 and ISO/IEC 27001.

Two-thirds of ARs were from control audits, 15% of them represented certification audits and 18% of them included re-certification/surveillance audits. Two organizations came from IT services, what may be important for the analyses of practiced IT facilitated BPM in the audited organizations.

Structure of the analyzed organizations	Country (number of organizations)							
Organizations by country	BA	HR	IT	MK	SI	SR	Total	
Number	2	4	4	4	26	8	48	
Share (%)	4	8	8	8	54	17	100	
Organizations by the audited standards								
Only ISO 9001:2008	2	1	2	4	10	5	24	
Only ISO 9001:2015 or in transfer to it			1		6		7	
ISO 9001 + 1 another standard		2	1		9		12	
ISO 9001 + 2 or more other standards		1			1	3	5	
Type of the audit								
Certification audit		1	3	1	2		7	
Control audit	2	2		2	22	4	32	
Re-certification/surveillance audit		1	1	1	2	4	9	
Business sector of the organizations								
Food production					1	1	2	
Technical production					11	1	12	
Construction	1	2			1		4	
Transport		1	1				2	
Гrade	1			1	2	4	8	
Education			1		2		3	
Other business services		1	2	1	7		11	
Public services – public sector				2	2	2	6	
T-related business:		1			2		3	

Note: Countries: BA = Bosna and Hercegovina, HR = Croatia, IT = Italy, MK = The former Yugoslav Republic of Macedonia, SR = Serba, SI = Slovenia.

Table 1. Structure of the analyzed audited organizations.

The number of organizations from the analyzed sample earning each level of BPM maturity and the number of their recorded shortcomings (non-conformances and recommendations) in the ARs is presented in **Table 2**.

Practiced BPM elements	Maturity level (number of organizations)							
	_	1	2	3	4	5	Total	
C1. Process documented	0	0	1	21	16	10	48	
Number of NCRs	0	0	0	0	0	0	0	
Number of recommendations:	0	0	0	15	11	4	30	
C2. Standard processes	23	0	2	3	12	8	48	
Number of NCRs	0	0	0	0	1	3	4	
Number of recommendations:	10	0	1	0	9	3	23	
C3. Value chain modeled	4	0	6	10	20	8	48	
Number of NCRs	0	0	0	1	0	0	1	
Number of recommendations:	0	0	0	1	0	2	3	
C4. Measures for major processes	4	0	4	8	25	7	48	
Number of NCRs	0	0	0	0	0	0	0	
Number of recommendations:	0	0	1	3	5	1	10	
C5. Consistent IT support	20	6	6	9	5	2	48	
Number of NCRs	0	0	0	0	0	0	0	
Number of recommendations:	0	0	0	0	1	0	1	
C6. Skills defined	-	-	-	-	-	-	-	
C7. Managers trained	-	-	-	-	-	-	-	
C8. Managers use data	-	-	-	-	-	-	-	
C9. Process improvement	2	1	1	23	16	5	48	
Number of NCRs	0	0	0	0	0	0	0	
Number of recommendations:	0	0	0	6	2	0	8	
Total number of organizations	53	7	20	74	94	40	288	
Total number of NCRs	0	0	0	1	1	3	5	
Total number of recommendations:	10	0	2	25	28	10	75	

Note: "-" means "data unavailable".

Table 2. BPM maturity levels and evidenced BPM shortcomings in the ISO 9001 audited organizations.

As expected from the ISO 9001 focuses in the last years (after the year 2000) the majority of organizations earned at least grade 3 in almost all the documented criteria. That means that the majority of the audited organizations (more than 79%):

- 1. had their processes documented (criterion C1);
- 2. had their process objectives set and regularly reviewed in accordance with the organizations strategic goals and values (criterion C3);

- **3.** had the performance measures for the core processes set and the processes measured (criterion C4);
- **4.** established systematical and effective process improvement mechanism (criterion C9). It should be commented that C9 was broadly established (in 92% of the organizations); however, it was mostly used to only set and follow corrective actions from the audits (in 48% of organizations the organizations with grade 3).

There was a lack of information in ARs on the extent of standardized procedures and on following their rules in praxis. If only the assessed share of organizations (organizations providing information on this criterion) is taken into account, this criterion (C2) is also covered very well (almost 90% of them earned grade 3 or more).

In ARs, there was also a lack of information on the IT support to the QMS and its BPM. There is no requirement about it in ISO 9001 and probably also from the certification body itself. Only some general information on it was provided in a good half of the reports. Besides, this information was short and not much informative. This criterion (C5) attained the worst grades. 42% of ARs included no information on it, 57% of the rest had at least some support identified from the ARs at grade level 3 or more. Grade 3 means a step more than just using office tools like Word and Excel. At this level, data and document sharing and group work through the common IT network of the organization are enabled and facilitated.

For each criterion (C1–C5, C9) the number of findings (non-conformances and recommendations) is presented, as well. It varies between 1 and 30 findings per criterion (see **Table 2**) for all the 48 audited organizations. The highest number of findings was related to the process documentation (C1) and the lowest one to IT support (C5).

There was no information in ARs related to the knowledge management, training and use of data for decision-making (criteria C6, C7, C8). Occasionally, some corresponding information was given in some reports, but it was not a general report content that could be analyzed.

The comparison of results (see **Table 3**) from this case study and the global BPM research (see Section 2.3.2) comparing the chosen criteria (C1–C5, C9) shows much better grades and thus, a higher level of BPM maturity of the organizations contained in this study regarding all the criteria but one (C5).

Practiced BPM elements	Maturity level (% of organizations)							
	_	1	2	3	4	5	Total	
The case study results:								
C1. Process documented	0%	0%	2%	44%	33%	21%	100%	
C2. Standard processes	48%	0%	4%	6%	25%	17%	100%	
C3. Value chain modeled	8%	0%	13%	21%	42%	17%	100%	
C4. Measures for major processes	8%	0%	8%	17%	52%	15%	100%	
C5. Consistent IT support	42%	13%	13%	19%	10%	4%	100%	

Practiced BPM elements	Maturity level (% of organizations)							
	_	1	2	3	4	5	Total	
C9. Process improvement	4%	2%	2%	48%	33%	10%	100%	
The global BMP research for 2015*:								
C1. Process documented	0%	4%	50%	29%	14%	4%	100%	
C2. Standard processes	0%	9%	48%	21%	21%	1%	100%	
C3. Value chain modeled	0%	7%	44%	26%	19%	5%	100%	
C4. Measures for major processes	0%	14%	59%	10%	11%	6%	100%	
C5. Consistent IT support	0%	3%	59%	17%	18%	3%	100%	
C9. Process improvement	0%	12%	54%	18%	13%	4%	100%	
Average assessed % of BPM maturity leve	1							
In the case study	18%	2%	7%	26%	33%	14%	100%	
In the global BPM research for 2015	0%	8%	52%	20%	16%	4%	100%	

Note: "-" means "data unavailable".

*Source: Harmon [33].

 $\textbf{Table 3.} \ BPM \ maturity \ level \ of \ ISO \ 9001 \ audited \ organizations \ compared \ with \ results \ of \ global \ BMP \ research.$

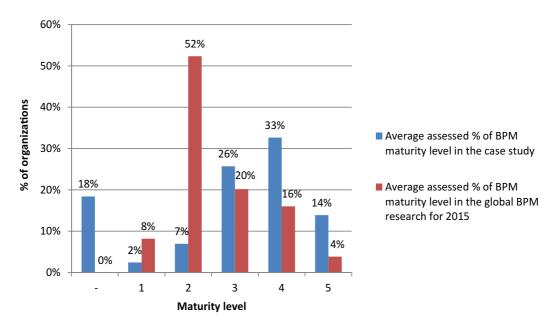


Figure 3. Practiced BPM elements of ISO 9001 audited organizations compared with results of global BMP research.

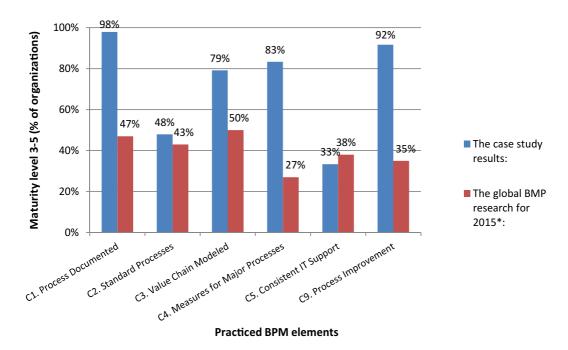


Figure 4. ISO 9001 audited organizations at BPM maturity level 3-5 compared with results of global BMP research.

With regards to the global research the majority of the organizations (52%) earned grade 2 (= some organized processes indicating very low maturity) (see **Figure 3**); in this case study organizations performed at least one grade better.

It is worth noting at this point that the highest shares were gained at grades 3 and 4. Besides, all the shares for the grades 3–5 were much higher in certified organizations (72% in average) than in the global research (40% in average) (see **Figure 4**). Consistent IT support (C5) was the only criterion that could be performed at lower maturity level in our analyzed organizations than generally (upon the data from the global report). However, this can not be claimed yet due to a lack of the data on the ARs.

4. Discussion, research implications and limitations

4.1 Discussion

In view of the above, it may be stated that ARs are very condensed giving only short information and basic facts on meeting the requirements of the standard. As a matter of fact, that was their basic aim. In the ARs also the identified shortcomings were recorded in the form of nonconformances (if the requirements were not met) and recommendations (if there was identified room for improvement). Therefore, the records in the report were generally not descriptive

enough to show the maturity level of a specific criterion. Sometimes, it was possible to identify it from the AR, sometimes not. Some topics (on knowledge management) were not covered in the ARs at all (the corresponding fields are empty and shadowed in the **Table 2**). Additionally, ARs could not give the complete picture of the QMS operation and the managed processes in its frame, because they were based on a sampling method.

Evident differences in BPM maturity levels among countries and industries were not noticed in this case study; however, this was not statistically tested.

A comparison of results of the case study with some global research on BPM (presented in Section 2.3.2) shows (see Table 3) that BPM is more mature in the audited (= ISO 9001 certified) organizations than generally according to the analyzed criteria (C1, C2, C3, C4, C6). That global research involved organizations from all over the world regardless of their ISO 9001 certification or implementation, however, the sample in this case study included only ISO 9001 certified organizations.

Non-existent or incomplete information on criteria C2 and C5 in 42-48% ARs disabled making a complete maturity assessment for these criteria for all the organizations. At this stage the grades for these two criteria are not final, yet. The real maturity level in the analyzed sample might be higher.

4.2. Implications for practitioners

Some room for improvement is recognized in IT support to ISO 9001 certified organizations from this case study. General global BPM research (see Table 3) shows 97% of organizations having at least some kind of IT support to BPM (grades 2–5), while in this case study only 45% of organizations were IT supported. Slovenia is an IT developed country similar on one hand to other EU-countries, as well as to non EU-countries [61].

As IT support and IT systems are an important element of BPO (see Sections 2.1 and 2.4) that contributes to operating BPM and QMS more effectively and efficiently such approach could and should be more encouraged by certification bodies who have an important role in QMS development in the organizations.

As such – and based on the findings presented herein – it may be stated that certification bodies do not systematically follow the elements of QMS and BPM that are not explicitly required by the standard but make the QMS more effective. Similar findings were identified in some other empirical research, too [62].

In view of the above, a number of questions may appear:

- "Do auditors pay any attention to such elements (like IT support)?
- Do they give any initiative to the audited organizations for improvement in that field and in which form?
- Are the auditors properly skilled to see the IT integration gaps?
- Where can organizations get proper guidance on the IT and QMS integration issues?"

It is worth mentioning at this point that this case study did not reveal any information or even hint pertaining to IT support to the QMS (criterion C5) in 20 of all the 48 analyzed ARs. In other ones some solutions were explicitly or implicitly mentioned when describing some parts of the QMS. Many times only use of office tools (6 cases) and document sharing through the company network (6 cases) were reported (see **Table 2**). In other 16 cases, different levels of use of company IT business solutions were reported as a support to the company process and project management.

The attractiveness of ISO 9001 QMS for organizations may be related with their added value. The research shows that the certification has probably reached the saturation level and became less attractive as a sign of quality [63]. Certification bodies could help raising the value of ISO 9001 QMS and certificates among their users and in general, by motivating organizations for making their QMS and BPM systems more effective and more efficient. The audits could broaden their focus also to BPM maturity and give messages (recommendation) for BPM improvement. This is probably not a general praxis, yet. The reported findings in ARs, their focus and the number of them might indicate what the main focuses of the audits are. In the case of this study the highest number of findings (30 recommendations) was reported on documentation and the lowest number of findings (1 recommendation) was focused on IT support to the QMS. It is worth noting that this only one recommendation addressing IT support did not come from ISO 9001 audit. It was related to the audit of ISO/IEC 27001 information safety system that was audited at the same time and documented in the same AR.

When implementing the QMS and its required BPM the mindset and professional knowledge of consultants, auditors and certification bodies is very important [64]. They are the first contacting point for the implementation of QMS, so a positive attitude to the use of IT support and some knowledge and experience in this field would be expected from them. It is the author's view that knowledge may be further empowered as this might act as a barrier to foster QMS BPM and IT integration. As such, it could be argued that the provision of proper courses, trainings, properly skilled consultants and auditors could help to improve it.

Some considerable advantages may be gained already by filling gaps where necessary and integrating IT systems with risk management, process control and QM in mind. The improved procedures and processes will not only provide compliance, but will also reduce cost, improve product quality and ultimately improve customer satisfaction and the bottom line [65].

Additionally, the suggested QMS BPM and IT system integration is in line with the current trend of digitalisation in the 4th Industrial Revolution. It will also contribute to better common attitude to the ISO 9001 which is still often considered as bureaucratic.

4.3. Implications for researchers

This research calls for further investigation of the addressed issue. There is a lack of research on integration of IT and BPM as a part of QMS. Only some reports from praxis on IT facilitated QMS cases and only a few research papers dedicated on linking of QMS and IT were found. The one of them that best discusses the issue was already 20 years old [66]. Only a few papers were found addressing the issue in some part. For instance, among 86 papers found in the period 2001–2012 regarding the use of ERP, no papers were found on supporting QMS by ERP [67].

There is still much room for improvement in the field of use and integration of BPM and ERP with the QMS. The new standard ISO 9001:2015 is more open to it, requiring just the evidence of realized requirements and no extra documentation therefore.

Some more empirical research is called for to identify the praxes in organizations, the reasons for the recent downsizing of the use of BPM tools and low integration of IT support and BMP as a part of QMS in the companies, expected improvements following the new standard and possible obstacles on this way.

4.4. Limitation of the research

This empirical research is just a preliminary study. It has a limited sample and period of observation. Additionally, the ARs are not informative enough to make more deep and complete analysis on the addressed issue. Some other sources of information should be used for deeper analysis, such as dedicated questionnaire survey and interviews with different groups of stakeholders involved (certified organization, consultants, auditors, certification bodies). On more detailed and advanced level of such a research also special site visits at organizations (like focus-related audits) would be called for.

5. Conclusion and further work

Effective management of the identified business processes in the company should be a core ingredient of an effective ISO 9001 QMS as required by the standard since the year 2000. The latest revision of the standard ISO 9001:2015 enables better effectiveness and easier running of the QMS and it required process management by becoming more business oriented and more flexible and less demanding regarding documentation.

Following the objectives from the "Introduction" the research lead to the following conclusions:

- 1. The review of requirements of ISO 9001:2015 shows that the requirements on process approach call for IT support; in particular, the process management requirements of the standard match with the BPM characteristics. The latter is prone to IT implementation and development. Proper software solutions exist and they are applicable and affordable also to SMEs;
- 2. In many cases, QMS is not properly implemented. In such instances, it is incorporated as an inefficient and bureaucratic paper-driven parallel system, running separately from the real business management system that is mostly IT facilitated (by ERP, BPMS, DMS, WFMS, BI, solutions). This study shows that the elements of BPM are practiced more frequently and at higher level in organizations certified according to ISO 9001 than generally in organizations. The level of maturity 3-5 on a 5 level scale for the assessed criteria in the analyzed group of certified organizations was attained at 72% of organizations (in average). In general, this level was reached at 40% of organizations (in average) only;
- **3.** Integration of the QMS BPM and IT system would make running the ISO 9001 BPM much easier, more effective and less costly to maintain. As such, the QMS requirements are more visible to

everyone in the company, easier to understand and to follow by the employees and easier to control by the management. It is the way to make QMS more embedded into everyday operation in a very natural and effective way. It also prevents splitting QMS from operation management system and boosting bureaucracy. Nevertheless, there may be some barriers and disadvantages related with the integration, such as making QMS implementation more complex. Moreover, BPM performance and ease of use is to some extent dependent on the proper functionality and performance of the IT support;

- **4.** As evidenced from this research, *ISO* 9001:2015 gives no requirements or guidelines on use of *IT support to the QMS*, nor to the BPM as its vital part. Moreover, the literature review showed little research on integration of the company QMS and *IT system*. Only some specific aspects of such integration can be identified in the literature. However, no holistic analysis of the possible integration of the ISO 9001 BPM with the company's IT system was found. Some praxis may be evident only through some professional IT presentations and reports. This case study shows that there is not much attention given to the IT support in ARs of a certification body, neither in the body of the reports nor in the involved recommendations to the organizations. Despite a lack of such information, some sort of IT support was identified at 45% of analyzed certified organizations. This is much less than 97% of organizations reported generally in global BPM research;
- 5. The objective of such integration should be only one integrated and more effective IT the same information at the same time at the same place to all the eligible participants and requiring as little as possible additional paper work. The data for running the QMS shall be provided and shared through this very system in the same way and in combination with other business and operation data. Such approach should be encouraged through all possible channels.

It may be concluded that integration of ISO 9001 process approach including BPM with business IT support is possible, feasible and rational. To do it, the role of consultants, auditors and certification bodies as the first contacting point in QMS implementation and certification process research. They should give stronger initiatives, guidance and support to the organizations on facilitating QMS with IT and integrating them. A lack of knowledge, experiences and cooperation of all involved parties (internal and external ones) in BPM implementation is identified and should be overcome with a proper guidance, trainings and information exchange.

Some more detailed study of the praxes in the certified companies, especially under the conditions of the new standard ISO 9001:2015, is called for and could be a subject of further research.

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Quality Management in Spice Paprika Production: From Cultivation to End Product

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Additional information is available at the end of the chapter

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Abstract

There is ample historical and scientifically proven information regarding the health benefits of spice paprika, including favourable physiological effects, anti-oxidant and antiinflammatory properties. Nonetheless, even though it is consumed in small portions, spice paprika has occasionally been reported for chemical/microbiological contamination, as well as fraud or food adulteration. Quality management can guarantee effective reduction of such contamination cases. Different production stages within cultivation and production are subject to different contamination types. Cultivation is a common source of pesticide residues, and unfavourable harvest conditions may give rise to mycotoxins by pathogenic fungi. Storage and post-ripening prior to processing is attributed with microbial contamination and possible increase in mycotoxin content may significantly affect quality features. Technology steps, for example, washing, separation, drying may worsen microbial contamination or quality, but normally do not lead to increase in mycotoxins; nonetheless, decontamination technology is a prerequisite for microbial safety of the product. Upon effective decontamination, finishing steps in the processing technology, for example, grinding, packaging and end product handling do not affect the microbial status, but other, occasionally deliberate contamination due to mixing and adulteration may occur at this stage.

Keywords: *Capsicum,* agro-environmental and food safety, contaminants, technology, critical control points

1. Introduction

Spice paprika, including bell pepper and chilli, is the second largest spice commodity worldwide (after black pepper) both in terms of its production volume and trade value [1]: the overall paprika/chilli production of the EU ranged between 48.8 and 108.0 thousand metric tons per year



between 2002 and 2011, while 77.8–116.7 thousand metric tons per year was imported from non-EU countries during the same period. Spice paprika is a market leading commodity in certain countries such as Hungary. The latter is regarded as a spice paprika leader and the second largest per capita consumer in Europe, beside Spain [2].

Due to its agricultural origin, spice paprika is often naturally contaminated with various pathogenic or non-pathogenic bacteria (due to either poor growth, harvest/process sanitation or improper conditions during storage). Owing to its cultivation technologies and its volume in spice consumption, environmental and food safety of spice paprika cultivation and production expressed concern and can be assured by proper quality management along the entire technology chain from field to packaged end product. It is important to note, that deliberate contamination (e.g., food adulteration, intended malignant acts or even sabotage) may also cause safety risks.

1.1. Spice paprika as a Hungaricum

Spice paprika is a condiment that consists of dried and ground paprika or chilli, a family of the species Capsicum annuum, that originate in Central Mexico. The name "paprika" is Hungarian and stems from the Greek "peperi" and in the Latin "piper", both referring to pepper. The paprika varieties used to make spice paprika made their way to Hungary after Christopher Columbus brought them to Europe. From Spain, paprika cultivation spread to the South of France and to England. The industrialised production of the spice paprika started towards the end of the seventeenth century and grew to become highly developed by the mid-eighteenth century. It was during this period, when cultivation of the peppers in the Murcia region began. Paprika from Murcia would take on its own distinct character. In the years since the eighteenth century, the La Vera and Murcia regions have become the leading producers of Spanish paprika. The latter also arrived to Hungary as early as the sixteenth century. However, it remains unclear which route was opted. One hypothesis is that it was imported from Iberia as a substitute to spice pepper, when the Eastern trade paths were closed to the country being under Ottoman rule. Another theory is that it reached the country by the Southern Slavonic-Turkish mediation from the Balkan. Hungarians used paprika also as a medicine to prevent cholera and to treat typhus. Paprika varieties were afterwards cultivated there, and the climate of the regions of Kalocsa and Szeged proved ideal for growing. Central European paprika had a typically hot taste until the 1920s, when a Szeged breeder found a variety that produced a sweet tasting fruit, and then grafted it onto other plants. Both "hot" and "sweet" varieties of spice paprika have been cultivated in the Kalocsa and Szeged regions ever since, with practically closely similar cultivation and processing technologies, and similarly strict food safety requirements.

1.2. Food safety aspects

The EU food safety regulations, established in the time period 2002–2004, whilst being updated several times since, are based on strict and harmonised food safety standards. The EU agency responsible to ensure food safety is the European Food Safety Authority (EFSA) established by Regulation 178/2002. Subsequent regulations cover the entire food chain

from farm to fork, and enhance both prevention and follow-up. They include Regulations [European Commission (EC)] No 852/2004 and (EC) No 853/2004 (control food hygiene), and official controls to ensure compliance with feed and food, as well as animal health and welfare laws as outlined by Regulation (EC) 882/2004.

Effective enforcement of the legal regulations concerning food safety within the EU is assured, among others, by the Rapid Alert System for Food and Feed (RASFF) established in 1979. This is a public, reactive, hazard-based reporting system at EU community level, allowing rapid information exchange among EU member states on hazards related to distributed consumer products, including not only food contamination, but also food fraud [3]. Acting in concert with governmental or EU-specific level regulations and RASFF, expert advisory systems operating on market-based mechanisms and supported by the governments in member states also serve food product quality assurance in the overall food chain from crop cultivation, feed and food raw material production, to processing, storage, transport and trade.

Spices and herbs, in spite of their consumption in small quantities, are of special concern for environmental and food safety due to their use in dried form for seasoning, their long production and trade chains, and possibilities of their deliberate contamination. Spice paprika has been worldwide reported for chemical and microbiological contamination, as well as for fraud or food adulteration [4]. Different production stages within cultivation and production are subject to different contamination types. Cultivation is a common source of pesticide residues, and unfavourable harvest conditions may give rise to mycotoxins by pathogenic fungi. Spice paprika, as other spices, often becomes naturally contaminated with various bacteria (e.g., Salmonella spp., Bacillus cereus, Escherichia coli [5]) generating microbial hazard [6]. Storage and post-ripening prior to processing is attributed with microbial contamination and possible increases in mycotoxin content, and may significantly affect quality features. Technology steps (e.g., washing, separation and drying) may worsen microbial contamination or quality features, but normally do not lead to rises in mycotoxin levels. Nonetheless, decontamination technologies are a prerequisite for microbial safety. Upon effective decontamination, finishing steps in the processing technology (e.g., grinding, packaging and end product handling) do not affect the microbial status, but other, occasionally deliberate contamination due to mixing and food adulteration may occur at this stage. The implementation of proper quality control measures at each of the above steps, in conjunction with effective interaction between producers' quality management practices and government activities are regarded as key factors in the provision of environmental and food safety of spice paprika production.

1.3. Aims and objectives

To illustrate the need and the difficulties in provision of environmental and food safety of spice paprika production, quality assurance measures established along technologies are surveyed with main critical control points (CCPs) identified [7]. Thus, points of vulnerability and each step in the technology chain (cultivation and plant protection, storage and post-ripening, grinding, slicing and mixing and decontamination) are surveyed. If concerted performance of internal (manufacturer) and external (state) quality control measures act in synergy then these may guarantee good production practice and support product quality in spice paprika cultivation and processing.

2. Points of vulnerability

The leading risk factors and contamination cases, notified in the RASFF in the last 10 years (2007–2016), draw attention to the most important points of vulnerability in the supply chain and/or product flow, where entering contamination (hazard), according to the risk assessment concept, may cause medium or high risk and thus, requires the development of preventive and/or elimination processes. It is worth noting at this point that during the 10-year period mentioned above, 373 notifications in total were issued. These included the trade of spice paprika and chilli products, either between EU countries or between an EU country and a "third country" (exporting into the EU).

Aforementioned notifications regarding spice paprika and chilli showed an almost steady distribution within those years, with an average of 37 notifications per annum in total, with the highest number of incidence occurrence in 2010 (70) and the lowest in 2014 (17). The priority list of the reasons of the notifications for spice paprika and chilli according to RASFF indicate the most important points of vulnerability during the entire production line, and draw attention to the accentuated necessity of quality control and management. Mycotoxins are the main risk sources (78%), but in some cases illegal dyes or other foreign compounds were detected (11%), and in further notifications pesticide residues (7%) and microbial infections (3%) were also reported (Figure 1).

As seen, the most important hazard of spice paprika and chilli products is mycotoxin contamination, where 225 and 62 events have been reported for aflatoxin and ochratoxin presence, respectively. Considering the number of incidents in temporal distribution, the highest number of aflatoxin contamination was reported in 2010 (52) and 2016 (37), while the lowest in 2009 (9) and 2014 (11). As for territorial distribution, the majority of cases occurred in products that originated from India (45%). Another 13 countries contributed more than 1% (more than 4 cases of incidents in the period studied) to the priority list. Another 28 EU and non-EU countries are responsible for the further 48 mycotoxin contamination events.

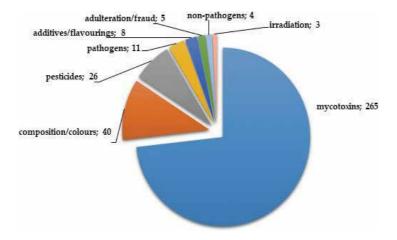


Figure 1. The number of notifications in RASSF between 2007 and 2016 regarding contamination of spice paprika.

To minimise the effects influencing quality, producers are obliged to operate quality management/assurance and food safety systems, for example, Hazard Analysis and Critical Control Points (HACCP), the documentation of which containing all steps of the technology, critical points, where human health risk could occur, self-control points, as well as solutions for possible problems. The authority is entitled to inspect and survey the documentation of self-control. For the latter to occur, own quality management systems are required to operate. These are similar among EU member states, yet may utilise different strategies in their approach. The implied reporting mechanisms (including data record systems) pertaining to biological and chemical contaminants are regulated by law.

In the analysis of the production line of spice paprika or chilli products, typical contaminants and technological errors have to be considered, and accordingly, the optimal positions of the CCPs in the production line have to be identified. A model was implemented for a HACCP system for prevention and control of mycotoxins during the production of dried chilli [8], in which the most important critical control points (e.g., drying and sorting) were identified. Good Agricultural Practice, Good Manufacturing Practice, Good Safety Practice and HACCP were shown to be necessary for processing plants in order to assure proper quality management.

3. Quality aspects of cultivation technologies, cultivated paprika varieties

For the grower side, there are several aspects that need to be taken into consideration. To control the quality of Hungarian ground spice paprika, the Government founded the Chemical Test and Spice Paprika Research Experimental Stations in Kalocsa (1917) and in Szeged (1921). The official selection of the commonly cultivated varieties began almost 80 years ago with the primal milestone: a non-pungent spice paprika cultivar was selected from the landrace populations by Ferenc Horváth. From the 1960s onwards, the selection and breeding continued in Kalocsa and Szeged at the reformed Research Stations, which were—and still are—supported by the Hungarian State.

Due to factors relating to the Hungarian soil and climate, the growers use only interior bred Capsicum annuum (L.) var. 'Longum' cultivars for spice paprika production. The breeding objectives are specified by the growers and the processing industry, according to the requirements of the consumers. Nowadays, a wide assortment of spice paprika varieties is available including the traditional varieties for the extensive growing technology and new hybrids for the most up-to-date paprika production under plastic tunnel.

The successful open field spice paprika production is based on the selection of the growing area considering the soil type and the crucial facts of the microclimate. The sandy loam soil around Szeged region is applicable for direct sowing, as well as for transplanting spice paprika seedlings. Around the Kalocsa region, the soil contains more clay, which—depending on the humidity of the surface—could cause crust and therefore some difficulties at the germination stage. In order to prevent this from happening, the vegetation period is been extended by a few weeks, giving the chance to growers to grow transplants under plastic tunnels.

Based on performed research, it is worth mentioning at this point that in any given 10-year period, 2 or 3 years may limit the vegetation period by the probable latest frost at the end of April and the unpredictable chill point between the end of September and the first week of October. For the most profitable crop production, the growers prefer early (semi-determinate) and midearly (indeterminate) cultivars for optimal yield (12–15 t/ha) at the harvest. Traditional open field direct sowing and transplanting cultivation technologies apply open pollinated semi-determinate (e.g., Kaldóm) or indeterminate sweet (e.g., Szegedi-80) and hot (e.g., Szegedi-178) varieties.

Considering the disadvantageous impacts of the climate change in the Carpathian Basin and the increasing demand for both quantity and quality of the crop, the cultivation technology requires continuous development and breeding high genetic potential, virus-resistant varieties or hybrids. Applying the black plastic covered ridge cultivation with drip irrigation and soluble fertilisers, the open pollinated indeterminate (e.g., Kárminvörös) and hybrid (e.g., Jubileum F1, Szikra F1) varieties could reach 20–25 t/ha yield with high quality. It is worth noting at this point though, that this intensive technology bears a number of risk factors such as extreme weather conditions and the insect (e.g., Aphids) transmission of viruses (e.g., CMV, Potato Y). Both open field production has the risk of yield loss caused by the bacterial leaf spot (*Xanthomonas campestris* pv. *vesicatoria*), which could be simply solved with the plantation of bacteria resistant sweet (e.g., Kaldóm) or hot (e.g., Kalóz) varieties.

Professional spice paprika production under non-heated plastic tunnel utilises the latest development of intensive growing technology with sweet (e.g., Bolero F1) and hot (e.g., Jubileum F1, Szikra F1) hybrids. The vegetation period is elongated from the middle of April to the end of November. The harvest period begins from the middle of July and ripened fruits could be harvested until the first serious frost. In case of continuous selective harvest, the average yield is up to 40 t/ha, approaching the genetic potential of the hybrid varieties. The fresh picked raw spice paprika material contains 150–180 American Spice Trade Association (ASTA) colour content with 16–18% dry matter content.

4. Pest control (biological, integrated)

In plant protection techniques, various agrochemicals, including numerous pesticide active ingredients and preparations have been registered for treatments in spice paprika cultivation. The choice of protection method is highly technology-dependent.

4.1. Intensive cultivation

Numerous pesticide active ingredients have been authorised on spice paprika over the decades, having been banned or withdrawn ever since. Currently, 51 active ingredients are authorised for paprika cultivation. RASFF notifications were issued in relation to the residues of 30 active ingredients, the vast majority (23) were insecticides, and the others were fungicides (5) and soil disinfectants (2) [8–10].

The effects of intensive cultivation conditions on the pesticide residue levels and the composition of bioactive substances were assessed [11]. In a cultivation modelling experiment, paprika plants were treated at three dosage levels of three recommended insecticides (pirimicarb, chlorpyrifos and cypermethrin) and a fungicide (penconazole). A small parcel experiment of intensively cultivated paprika was carried out, where the plants were treated 1-3 times with pesticide premixes at different dosages (three levels). The harvested and processed paprika was sampled and analysed for pesticide residues content and bioactive component amount. Residue levels of chlorpyrifos (0–1.747 µg/g dried paprika) detected in the differently treated paprika fruits negatively correlated the levels of capsanthin monoesters and β-carotene, as R² was obtained 0.65 and 0.74, respectively. The content of carotenoids and tocopherols compared to the negative control samples decreased by 3.3–6.2 and 10.6–21.5%, respectively.

4.2. Co-formulants and adjuvants used in pesticide formulations

Research conducted by the authors indicates that not only the pesticide active ingredients are subject to environmental concerns, but also the various additives used in their formulation to improve their physicochemical characteristics (stability, penetration and absorption). A recent outstanding example is the formulant polyethoxylated tallowamine used for the formulation of the herbicide active ingredient glyphosate, that has been found 2-3 orders of magnitude more toxic on given biochemical processes (e.g., cytotoxicity) or to nontarget organisms [12, 13], and has recently been banned from the use in glyphosate-based herbicide preparations. Research carried out by the authors shows that glyphosate, as a total herbicide, is not used on paprika, except for pre-sowing or pre-emergence treatments. For neo-nicotinoid insecticides registered for use on paprika cultivation, however, it has been shown that the formulating agent modifies the toxicity of the formulated pesticide, many of them used in spice paprika, as compared to the corresponding active ingredients (glyphosate, isoproturon, fluroxypyr, pirimicarb, imidacloprid, acetamiprid, tebuconazole, epoxiconazole and prochloraz) [14], (clothianidin) [15]. As a result, authorisation of the formulating surfactants is expected to stricten [16].

4.3. Integrated pest management

The profitable open field spice paprika growing technology is associated with plant protection by Integrated Pest Management (IPM), based on pest population dynamics forecast and the use of preventive and alternative solutions to decrease the environmental impact with chemical treatments. Among preventive solutions, plant rotation is essential, and the best fore crops for spice paprika are cereals. Avoiding the accumulation of pests (e.g., nematodes) and diseases (e.g., viruses, bacteria and fungi) after cultivation of paprika (or other Solanacea species) for 3 or 4 years, other crop cultivation is recommended. Utilisation of original, sealed and pelleted seed prevents the propagation of tobamo (TMV, PMMV) viruses both in direct sowing and transplanting technology. To avoid possible transmission of TMV by direct contact (e.g., planting), resistant hybrids are recommended by the breeders and seed trade companies. Plant nurseries are usually maintained in greenhouses or plastic tunnels, and it is crucial to keep them, free from any pests (e.g., aphids, thrips and nematodes).

Aphids (e.g., *Myzus persicae*) are non-persistent vectors of the cucumber mosaic virus (CMV). Paprika infected by CMV produce at 20–30% lower yield. Preventing the infection of CMV by spraying mineral paraffin oil is recommended. It is the author's view that this may raise environmental concerns. In case of serious aphid invasion, reasonable utilisation of pyrethroid insecticide (e.g., deltamethrin) is allowed until the withdrawal period prior to harvest.

Thrips (e.g., Western flower thrips—*Frankliniella occidentalis*) cause their major damage by the nymph laying eggs in the plant tissue or the bud. The plant, the flowers and the small fruits are subsequently injured by feeding. Thrips are the major vectors of a serious plant disease, tomato spotted wilt virus (TSWV). The damage by thrips and TSWV in nurseries and under plastic tunnels threatens the economy of the entire production. Even though survival of the thrips is highly temperature-dependent, protection against them is difficult due to their special, hidden life-cycle. Indication of the presence of thrips in the plantation is simple with blue sticky traps, but efficient application of biological plant protection methods, for example, the thrips' natural predators, like *Orius genus* and *Amblyseius cucumeris* requires special climatic conditions. Should other control techniques fail, a reasonable utilisation of certain mild insecticides (e.g., abamectin) is allowed within IPM.

To avoid problems with nematodes (e.g., *Meloidogyne incognita*), plant nursery must always use nematode-free medium and plant trays for sowing. Utilisation of fresh medium also benefits to avoid the plant pathogenic fungi *Rhizoctonia solani*.

Preventing the damages of broad mite (*Polyphagotarsonemus latus*) in cultivation, plant nurseries must be treated with ventilated sulphur powder or spraying with an acaricide. After planting, at the end of May and the first decade of June, larvae of the turnip moth (*Agrotic segetum*) harm by cutting the seedlings. The hatch of the larvae is predictable with sex pheromone traps, and as such, a well-timed parathyroid treatment may optimise protection against young larvae. The cotton bollworm moth (*Helicoverpa armigera*) is the most harmful pest of spice paprika in open field plantation before harvest. The larvae feed on leaves, flowers and fruits, and finally hide into the fruit, consuming most of the seeds and leaving excrements. The damaged fruits are not only worthless, but potential sources of contamination. The swarming period of the imagoes is July to September. Protection is also based on light and sex pheromone traps, but the number of the possible treatments is limited by the harvest schedule.

According to the food market demands, the importance of biologically protected, high quality and healthy spice paprika is increasing, as in 10 years (2004–2014) the cultivation area increased from about 30 to 50 ha in Hungary. The up-to-date non-heated plastic tunnel is the optimal solution for intensive spice paprika growing with biological protection. Due to the control of the climate conditions via insect-proof ventilation and shading, plant protection can be solved with preventive insect traps, predators or parasitoids. The main pests in growing equipment are virus vector thrips and aphids. To keep aphids and cotton bollworm out, a simple solution is the utilisation of vector nets, and the use of protective clothing for the workers. If the moth imagoes are already in the equipment, a mix of *Trichogramma* species (*T. pintoi*, *T. evanescens*) appears to be efficient. The glasshouse whitefly (*Trialeurodes vaporariorum*) is current in greenhouses and plastic tunnels, and causes crop damage through both direct feeding and propagation of viruses. As a side effect of feeding, honeydew is excreted and in turn, a sooty mould covers the leaves and the fruits.

Yellow sticky traps are suitable to indicate and to thicken the whitefly population in the growing equipment. Biological protection is applicable with the parasitoid wasp Encarsia formosa is supported with climate control. Powdery mildew (Leveillula taurica) fungi may cause heavy yield losses in growing equipment. To prevent the disease, climate control is crucial. Protecting the crop by spraying with sulphur and potassium bicarbonate is acceptable for biologically grown paprika.

5. Effect of storage and post-ripening on product quality

As mentioned before, the freshly picked raw spice paprika contains 16–18% dry matter. High quality ground paprika as raw material needs at least 4 weeks of after-ripening to decrease the rate of water content and increase the rate of dry matter and stable carotenoids. From the middle of July to mid-September, solar energy can be used for pre-drying in a hygienic equipment, like grids under a shaded and ventilated plastic tunnel.

6. Technology steps

Preparing the dried material for grinding, additional (max. 50°C) drying is needed until the dry matter content decrease to 6–8% or less. After gentle grinding, the final result is high quality paprika with excellent ASTA colour content, outstanding aroma compounds and bioactive components. There are three CCPs in the production line of spice paprika one occurs at the drying step, the second at the microbial decontamination stage and the third applies at mixing, if imported half-products are being used.

The first of these CCPs, the drying step requires the highest foresight, because improper drying impairs the sensory and compositional properties of the product. Its temperature conditions have an apparent optimum: extensively high temperatures should not be applied to avoid formation of unpleasant aroma, pigment and flavour compounds, while drying at low temperature can lead to poor grinding characteristics.

Quality control laboratories at the processing plants carry-out the basic measurements (e.g., moisture, ash, sand, pigment content, microbiological status and colour determination by the protocol of the American Spice Trade Association (ASTA) at each marked points). To summarise the effects of processing, different steps were in-depth investigated regarding microbial contamination and concentration changes of the bioactive compounds.

During slicing, the microbial contamination of paprika increases, as the microbes present inside the berries emerge to the surface (Figure 2A). Drying greatly reduces microbial contamination, as most of the vegetative cells are killed. The numbers of mesophilic aerobic total bacteria and coliform counts dropped by 2–3 orders of magnitude, while Escherichia coli, Enterobacteriaceae and yeasts have almost entirely disappeared (**Figure 2B**).

Comparison of the dried half-product before and after grinding indicated complete eradication of coliforms, Escherichia coli and Enterobacteriaceae, while the mesophilic aerobic bacterial count

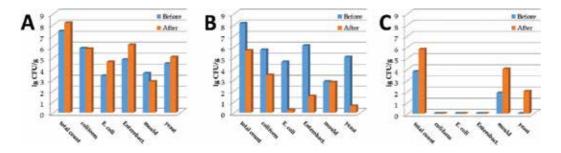


Figure 2. The effect of technology steps on the microbial status of the paprika half-product. **A**: slicing, **B**: drying, **C**: grinding.

and mould contamination increased by two orders of magnitude. This is due to the fact that the microbial load of paprika berries is not homogenous; a few heavily spoiled ones mixed with the healthy berries can contaminate the entire product (**Figure 2C**). The chemical composition, however, did not appear to undergo any significant change.

7. Effects of the decontamination steps on the quality of spice paprika

Another CCP in the technology chain is at the microbial decontamination. To enhance food safety of spice paprika, a decontamination step needs to be carried out to secure the microbial purity of the product and to avoid contamination of food seasoned with it [17]. Various methods are in use and are incorporated into the processing technology (generally after the grinding step) or available for decontamination [18]. Their efficiency in reducing the microbial load in dried spices has been evaluated in literature [19]. Nonetheless, even though red sweet paprika is appreciated being an excellent source of essential nutrients and bioactive compounds, these assessments generally do not evaluate the effects the decontamination step may exert on the composition of the bioactive, aroma and colour components.

7.1. Irradiation treatment

Microbial decontamination is most often carried out by steam treatment or by irradiation by ionising radiation (e.g., gamma irradiation—the maximum allowed average radiation dose being 10 kGy) [20]. In spite of the high efficacy of microbial decontamination by irradiation, and even though legal regulations allow (and even advise) this technology in the EU for decontamination of dried herbs and spices, producers tend to choose steam treatment due to consumer aversion from the food radiation technology [21]. Consumer acceptance of irradiation remains poor despite numerous efforts of food industry experts and the EU legislation to dispel misconceptions regarding the use of isotope techniques and ionising radiation [22]. It has to be also mentioned, that sensory and anti-oxidative properties of the finished product may be slightly affected by the technology used [23]. Irradiation (at 1, 5 and 10 kGy doses) was proven highly effective in the treatment of ground dry spice paprika: the aerobic mesophilic total count (log) decreased from 6.84 to 5.08, 4.71 and 2.91 log cfu/g, respectively, while the

mould count (log) from 3.78 to 3.54, 3.18 and 2.30, respectively. The numbers of coliforms (log) 3.71 and Enterobacteriaceae (log) 3.28 decreased under the detection limit after the treatments, even at the lowest dose, 1 kGy. Interestingly by irradiation, the dominant microflora of Bacilli (B. methylotrophicus, B. pumilus) gradually disappeared and species less sensitive to irradiation (Methylobacterium spp., Micrococcus spp. and Microbacterium spp.) came into consideration, meanwhile more bacteria of possible human relevance (Staphylococcus spp., Corynebacterium hansenii) were also isolated. While the microbial status improved by irradiation, the concentration of the bioactive components, such as carotenoids, tocopherols, vitamin C and the ASTA value decreased (p < 0.05).

Studies [24] conducted on different decontamination methods by comparing the effects on the microbial status and chemical composition, especially the bioactive compounds, colour and volatile components concluded that earlier methods, for example, irradiation and steaming effectively lowered the microbial decontamination rate, while only slightly affected the bioactive component content, however, decreased the levels of volatile aroma compounds. In contrast, alternative methods, for example, enhanced microwave treatment and radio-frequency heat treatment were less effective in the reduction of the microbial counts, and harmed the colour of the samples, but the bioactive chemical compositional parameters were not affected significantly. Even though the levels of carotenoids, tocopherols, vitamin C or other bioactive compounds and the ASTA values decreased, changing the composition rates of the volatile aroma substances, irradiation was considered to be of outstanding efficacy [25–26].

A technology-dependent issue is, whether irradiation is carried out in bulk or in sealed packages of the finished product. Bioactive compounds are anticipated to decompose less in the latter case, although radiolysis products, involatile or volatile, may diffuse into the product from the packaging material [27]. Reduced amounts of carotenoids were reported at high irradiation dosages and long storage (e.g., 11.1 and 42.1% decrease in capsanthin levels upon irradiation at 10 kGy and a subsequent 10-month storage period, respectively) [28]. Approximately 40% reduction in anti-oxidant activity was seen upon a 20-week storage period, compared to 13% decrease in the control non-irradiated ground black pepper [29].

7.2. Steam treatment

Steaming is a decontamination technique of spices of proven and high utility. Due to steam treatment (saturated dry steam, 108-125°C for 20-120 s) the mesophilic aerobic total bacterial count from 1.8×10^5 cfu/g to 6.0×10^2 cfu/g and moulds from 1.3×10^2 cfu/g to under the detection limit were reduced, while yeasts, coliforms, E. coli and Enterobacteriaceae could not be detected. According to the molecular identification, the dominant bacteria were spore forming rods, family Bacillaceae, namely B. methylotrophicus, B. pumilus, B. vallismortis and B. sonorensis before, while B. methylotrophicus, B. pumilus and B. amyloliquefaciens after treatment. The concentration of the main bioactive compounds, as capsanthin esters, total carotenoids, tocopherols, vitamin C and the ASTA value did not change significantly, however, the total tocopherol content decreased by 6%. The area percentage (%) of the volatile aroma compounds (e.g., acetic acid and pentanal) decreased, while in some cases (e.g., geranyl acetone, β-ionone and dihydroactinidiolide) a slight increase was detected.

Steam treatment was shown to cause a reduction of volatile oil content along with discoloration [30], and although high-temperature steaming is effective against contaminating microorganisms, it can decrease the volatile oil content, cause colour degradation and may increase the moisture content of dried paprika product, which then reduces shelf-life [31]. Furthermore, steaming is not suitable for spore inactivation. These results confirm that steaming provides a good possibility to reduce the microbial load, without drastically changing the content of bioactive compounds.

7.3. Microwave and enhanced microwave heating

Even though well-described and evaluated industrial decontamination processes are available, alternative methods are also being developed and investigated for efficacy and effects. Microwave heating is advocated for effective reduction of the level of mesophilic bacteria. The method (98°C for 20 min) was indicated to reduce the total number of mesophilic bacteria 6.3*10⁴-fold [32]. Microwave heating (30 s in dry and wet treatment) was found to allow the highest reduction of the bacterial level in chilli among different spices studied [33]. It is worth noting at this point that the method (100 s at various temperatures) did not result in a relevant reduction of the total counts of mesophilic aerobic bacteria even at 95°C, but affected the colour of the treated paprika lot unfavourably, giving it a darker, brownish character.

To avoid the detrimental effect of the treatment method on the colour of spice paprika, a modified microwave treatment (including re-wetting of the sample, intensive mixing during the entire treatment and post-drying to the initial moisture level) was also evaluated by the authors. Mesophilic aerobic total bacterial counts were not significantly affected by the enhanced microwave treatment, however, mould populations and coliforms were reduced, if samples were kept at the given temperatures for at least 10 min. Significant changes were detected in carotenoids, and total tocopherol content decreased by 6.2% only at higher initial moisture content (30% and higher, 10 min, 95°C). Thus, enhanced microwave treatment allows a reduction of microbial contamination (principally for moulds and coliforms) without a decrease in the levels of bioactive compounds. The temperature did not significantly affect chemical composition, but had a significant effect on sample colour.

Nonetheless, in spite the corrected moisture content, all samples became browner and darker after the treatment, and as colour changes did not correlate with the observed levels in carotenoids and the ASTA value, it has been concluded that colour changes due to the treatment are likely to be related to plant carbohydrates and proteins.

7.4. Other treatments

Oregano essential oil was attempted as a natural anti-microbial agent to reduce microbial count in paprika [34]. Although it was not found to be of adequate activity by itself to allow sufficient inactivation of microbial spores in paprika, when used in combination with high-pressure carbon dioxide, microbial inactivation largely increased (by 99.5%).

In a number of food products, high hydrostatic pressures increase shelf-life and maintain nutritional and organoleptic properties better, the effect of high hydrostatic pressures and pasteurisation (in a water bath at 70°C for 10 min) was examined on the levels of given

bioactive components and on the texture of spice paprika [35]. Pasteurisation treatment at high hydrostatic pressure (500 MPa) had less influence on the bioactive component content and on the texture, than at low pressure.

Chemical treatment with ethylene oxide is also a worldwide available decontamination technology, but the potential use is limited by its toxicity. Due to its carcinogenic potential to humans, the use of ethylene oxide is forbidden to be used in food processing in the EU [36].

8. The effect of the geographical origin

As mentioned above, the last one among the three CCPs within the spice paprika processing technology is at the mixing step, where the imported half-products get into the manufacturing process. Determination of the origin or ensuring the authenticity of red paprika products is of high importance from both food safety and commercial aspects. To assess the composition of bioactive ingredients in spice paprika and to support the safety of the spice product chains, a wide range of compositional examinations were performed on spice paprika samples of several geographical origins.

A method of combining strontium isotope ratios with a multi-element pattern by means of inductively coupled plasma mass spectrometry (ICP-MS) was used to create a unique fingerprint of authentic Szegedi Fűszerpaprika and to categorise authentic and purchased paprika from different known, declared and unknown geographical origins, using principal component and canonical discriminant analysis [37]. Changes in element and strontium isotopic composition (87Sr/86Sr ratio) were examined throughout the production process. As such, the geographical origin of the spice paprika can be determined even after processing. Strontium isotope ratios are combined with multi-element pattern analysis in the "fingerprint" method, using ICP-MS, and another proper indicator of cultivation types (agrochemicals) and geographical origin (e.g., a distinction between Asia and Europe) is the δ15N value. A clear distinction between Japanese and foreign paprika products was achieved on the basis of their Cu and Rb content by ICP-MS [38]. Similarly, sweet, hot and hot/sweet paprika samples from Spain were assessed by their micro-elemental composition by ICP-MS followed by chemometric classmodelling techniques on variables selected by stepwise linear discriminant analysis [39, 40].

Origin-protected Spanish spice paprika samples (Murcia and Extremadura) were analysed by colour characteristics to differentiate between geographical origins [41]. Co-ordinates in the CIELAB colour space and ASTA scale were measured from acetone extracts of paprika samples in UV-Vis spectral range. For origin discrimination multi-layer perceptrons, artificial neural networks models presented the best results for all types of paprika. According to another strategy [42], the entire absorbance range from 380 to 780 nm was used, and data was combined and reduced by means of principal component analysis. The anti-oxidant activity and the composition of polyphenolics and carbohydrates of spice paprika (Lakošnička and Lemeška) were investigated to attempt to verify the regional and botanical origin of Serbian autochthonous clones of red spice paprika using multi-variate statistical methods [43]. In addition, distinction was achieved to be made between Dutch bell peppers and those from other countries, using analytical strategies based on bulk δ 18O elemental analysis of source and paprika fruit water, and on compound-specific, n-alkane, δ 2H gas chromatography coupled to isotope ratio mass spectrometry analysis [44].

Gas chromatography-olfactometry was also applied for the evaluation and identification of the odour-active compounds combined with the flavour dilution (FD) factors [45]. For the control of aflatoxin B1 and total aflatoxins in spice paprika powder, NIRS technique as an alternative method was applied using the Modified Partial Least Squares (MPLS) algorithm as a regression method [46]. Moreover, the contamination of mycotoxins (e.g., fumonisin B1, ochratoxin A and sterigmatocystin) and pesticide residues (e.g. metalaxyl fungicide) in spices were investigated by ultra-high performance liquid chromatography (UHPLC) coupled to a high resolution Orbitrap mass spectrometry (Orbitrap-HRMS) [47].

To identify major differences in characteristics and chemical component composition of spice paprika by their origin, a set of samples (53 pieces) was investigated [48]. Samples from Spain and Peru showed outstandingly high total carotenoids content (in average 3709 and 3810 μ g/g, respectively), and the ratio of capsanthin diesters to free capsanthins was found to be a good indicator of origin, supposedly due to differing climate conditions in the two countries. The calculated capsanthin diesters/free capsanthins ratio was found to be in average 4.0, 5.3, 8.1, 8.2, 17.1 and 22.0 in samples from Serbia, Hungary, Spain, Bulgaria, China and Peru, respectively. According to the results of NIR evaluation of spice paprika samples, there occurred some clustering among the samples according the country of origin.

The geographical origin of spice paprika has also been successfully attempted to be characterised by their dominant microflora [49]. Although no substantial differences were found among the microbial loads of spice paprika samples from different countries (Brazil, Bulgaria, China, Hungary, India, Kenya, Peru, Serbia, Spain, Thailand and unknown origin) on the EU market, bacterial species in the dominant microflora, characteristic to climate, were identified. The presence of *B. mycoides* and *B. licheniformis* were found to be characteristic to Central Europe, *B. mojavensis* to Spain, *B. safensis* to tropical monsoon climate, *B. amyloliquefaciens* subsp. *plantarum* and *B. amyloliquefaciens* subsp. *amyloliquefaciens* to tropical climate, and no common species was identified for China.

9. Internal and external quality control measures

In addition to obligatory quality control and assurance measures by the producers and systematic analysis for compliance with food safety requirements at EU community level by RASFF, national authorities in EU member states also perform external control analyses to assure food safety (EC Regulation No 882/2004). At present, there are no microbiological criteria for dried spices in the European Community legislation, although, the Codex Code of Hygienic Practice specifies that dried spices should be free of pathogenic microorganisms at levels that may represent a health hazard. The European Spice Association (ESA) and the European Commission (EC) Recommendation 2004/24/EC specify that *Salmonella* spp. should be absent in 25 g of spice, *E. coli* must be under 10² cfu/g, and other bacteria requirements should be agreed between the buyer and the seller [50].

10. Conclusion

Proper quality control measures at each of the above steps along with effective interaction between producers' quality management practices and government activities are key factors in the provision of environmental and food safety of spice paprika production. To illustrate this, quality assurance measures established along spice paprika production technologies are surveyed with main CCPs identified. Concerted performance of internal (manufacturer) and external (state) quality control measures act in synergy to guarantee good production practice and to support product quality in spice paprika cultivation and processing.

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Adaptive CUSUM for Steady State Normal Data

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Additional information is available at the end of the chapter

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Abstract

This chapter deals with monitoring plans that exploit temporal predictable trends by adjusting the cumulative sum (CUSUM) plan to be efficient for their early detection. The adjustment involves changing the amount of memory the chart retains to detect persistent changes in location early. The focus is on steady-state situations when either the shift size is known in advance or when it is unknown. Several options are explored using simulation studies, and an example of application is considered.

Keywords: average run length, early detection, monitoring, persistent trends, statistical process control

1. Introduction

The adaptive CUSUM of Sparks [12] exploits temporal predictable trends by adjusting its design to be efficient for the early detection of such trends. The adjustment involves changing the amount of memory the chart retains to detect persistent changes in location earlier.

In the zero-state case, Moustakides [6] proved that a step change of δ is best detected by using Page's [7] conventional CUSUM with the reference value $k = \delta/2$. Gan [3] demonstrated that the conventional CUSUM with k = 0.5 is optimal in the zero-state in their **Table 1** for a shift of one and standard normal distributed data. The adaptive CUSUM has been shown to be better at times at detecting small shifts in location than the conventional CUSUM with the optimal k value for that shift. For example, in the standard normal distribution case, the shift of 1 for the adaptive CUSUM is detected with an average run length (ARL); in **Table 3** of Sparks [12] is 9.29 or 9.34, while the zero state optimal conventional CUSUM with k = 0.5 has an ARL of 9.34 (see also [5] **Table 2**). Hence, the adaptive CUSUM can have smaller out-of-control ARLs than the best CUSUM in the zero-state situation. The reason for this is that, for smaller shifts, the adaptive CUSUM can exploit the steady-state situation by making use of the local knowledge about the size of its shift. For unknown large shifts this is more difficult because one often flags the change before it can be accurately predicted. In other words the adaptive CUSUM



Table 1. Optimal offset values (k) for detecting certain size shifts when the in-control ARL = 200.

					(a)				
k	0.2	0.2125	0.225	0.2375	0.25	0.2675	0.275	0.2875	0.3
δ									
0.5	16.724	16.699	16.739	16.827	16.847				
0.525	15.720	15.716	15.733	15.734	15.754				
0.55	14.786	14.801	14.793	14.750	14.774	14.888	14.904		
0.575			13.936	13.935	13.917	13.907	13.996	14.050	
0.6					13.224	13.261	13.211	13.226	13.21
					(b)				
k	0.2675	0.275	0.2875	0.3	0.3125	0.325	0.3375	0.35	0.3675
δ									
0.625	12.589	12.509	12.556	12.574	12.697				
0.65	11.880	11.833	11.874	11.919	12.017	12.051			
0.675	11.320	11.253	11.310	11.357	11.355	11.373	11.395		
0.7	10.755	10.750	10.694	10.768	10.814	10.818	10.822	10.827	
0.725	10.301	10.269	10.236	10.266	10.276	10.299	10.308	10.332	10.38
					(c)				
k	0.3	0.3125	0.325	0.3375	0.35	0.375	0.3875	0.4	0.412
δ									
0.75	9.777	9.787	9.779	9.792	9.889	9.928			
0.775	9.351	9.341	9.372	9.352	9.379	9.441	9.482		
0.8	8.969	8.976	8.967	8.934	9.006	9.026	9.028	9.075	
0.825	8.617	8.617	8.605	8.583	8.586	8.650	8.651	8.692	8.736
					(d)				
k	0.35	0.3675	0.375	0.4	0.4125	0.425	0.4375	0.45	0.475
δ									
0.85	8.249	8.287	8.291	8.308	8.337	8.366			
0.875	7.964	7.969	7.973	7.962	7.970	8.046	8.077		
0.9	7.649	7.648	7.651	7.677	7.691	7.711	7.740	9.075	
0.95	7.101	7.091	7.110	7.114	7.110	7.144	7.146	8.692	8.736
					(e)				
k	0.375	0.4	0.425	0.45	0.475	0.5	0.525	0.55	0.575

s									
δ	((050	C (10	((20	C C 41		(F10			
1.00	6.6253	6.619	6.620	6.641	6.655	6.713	ć 2 00		
1.05	6.233	6.195	6.187	6.188	6.203	6.229	6.280	= 000	
1.10	5.860	5.796	5.812	5.795	5.797	5.818	5.823	5.899	
1.15	5.520	5.464	5.476	5.462	5.458	5.470	5.460	5.516	5.499
					(f)				
k	0.45	0.475	0.5	0.525	0.55	0.6	0.625	0.65	0.675
δ									
1.20	5.138	5.153	5.137	5.142	5.161	5.191			
1.25	4.864	4.854	4.863	4.853	4.870	4.883	4.909		
1.30	4.625	5.686	4.600	4.596	4.592	4.603	4.629	4.631	
1.35	4.403	4.401	4.362	4.367	4.372	4.357	4.365	4.385	4.396
					(g)				
k	0.5	0.5375	0.6	0.625	0.65	0.70	0.725	0.75	0.775
δ									
1.40	4.166	4.140	4.130	4.147	4.145	4.196			
1.45	3.968	3.964	3.938	3.962	3.945	3.969	3.989		
1.50	3.787	3.792	3.759	3.764	3.760	3.779	3.779	3.783	
1.55	3.647	3.626	3.587	3.598	3.591	3.607	3.609	3.609	3.609
					(h)				
k	0.65	0.70	0.725	0.75	0.775	0.80	0.825	0.85	0.875
δ									
1.60	3.434	3.443	3.441	3.445	3.440	3.441			
1.65	3.288	3.290	3.279	3.286	3.290	3.290	3.317		
1.70	3.161	3.160	3.148	3.154	3.152	3.155	3.164	3.164	
1.75	3.047	3.040	3.034	3.024	3.021	3.024	3.035	3.038	3.040
					(i)				
k	0.775	0.80	0.825	0.85	0.875	0.90	0.925	0.95	0.975
δ									
1.80	2.891	2.906	2.905	2.901	2.915	2.928			
1.85				2.795			2.804		
	2.796	2.795	2.794		2.799	2.806		2.607	
1.90	2.695	2.690	2.694	2.686	2.688	2.694	2.692	2.697	
1.95	2.606	2.600	2.598	2.595	2.597	2.593	2.598	2.598	2.600

Table 2. Optimal offset values (k) for detecting certain size shifts when the in-control ARL = 800.

					(a)				
k	0.2	0.2125	0.225	0.2375	0.25	0.2675	0.275	0.2875	0.3
δ									
0.5	26.563	26.568	26.496	26.449	26.543				
0.525	24.847	24.746	24.613	24.586	24.626				
0.55	23.307	23.038	23.010	22.951	22.900	22.953	23.010		
0.575	21.930	21.757	21.642	21.473	21.447	21.511	21.506	21.505	
0.6					20.141	21.144	20.119	20.061	20.236
					(b)				
k	0.2675	0.275	0.2875	0.3	0.3125	0.325	0.3375	0.35	0.3675
δ									
0.625	18.929	18.905	18.940	18.982	19.091				
0.65	17.877	17.833	17.798	17.881	17.854	18.034			
0.675	16.912	16.883	16.872	16.829	16.921	16.899	16.964		
0.7	16.076	16.026	16.054	15.979	16.022	15.928	16.033	16.021	
0.725	15.296	15.206	15.203	15.142	15.178	15.098	15.172	15.188	15.200
					(c)				
k	0.3	0.3125	0.325	0.3375	0.35	0.375	0.3875	0.4	0.4125
δ									
0.75	14.435	14.365	14.415	14.326	14.329	14.405			
0.775	13.707	13.703	13.749	13.679	13.679	13.697	13.740		
0.8	13.170	13.113	13.074	13.041	13.039	13.085	13.046	13.097	
0.825	12.586	12.540	12.521	12.450	12.414	12.428	12.467	12.468	12.477
					(d)				
k	0.35	0.3675	0.375	0.4	0.4125	0.425	0.4375	0.45	0.475
δ									
0.85	11.892	11.873	11.855	11.893	11.895	11.925			
0.875	11.390	11.377	11.364	11.364	11.373	11.374	11.434		
0.9	10.923	10.900	10.900	10.891	10.889	10.886	10.875	10.935	
0.95	10.128	10.079	10.014	10.013	9.999	10.017	10.004	10.069	10.09
					(e)				
k	0.375	0.4	0.425	0.45	0.475	0.5	0.525	0.55	0.575

δ									
1.00	9.379	9.309	9.272	9.263	9.289	9.329			
1.05	8.757	8.670	8.622	8.628	8.595	8.635	8.632		
1.10	8.206	8.112	8.050	8.028	8.025	8.019	8.029	8.053	
1.15	7.742	7.631	7.551	7.514	7.499	7.478	7.477	7.503	7.513
					(f)				
k	0.45	0.475	0.5	0.525	0.55	0.6	0.625	0.65	0.675
δ									
1.20	7.093	7.045	7.017	7.020	7.000	7.039			
1.25	6.676	6.642	6.609	6.567	6.578	6.575	6.602		
1.30	6.334	6.295	6.260	6.196	6.194	6.195	6.203	6.220	
1.35	6.013	5.971	5.942	5.869	5.857	5.848	5.854	5.849	5.865
					(g)				
k	0.5	0.5375	0.6	0.625	0.65	0.70	0.725	0.75	0.775
δ									
1.40	5.640	5.577	5.533	5.509	5.519	5.538			
1.45	5.375								
	3.373	5.308	5.254	5.233	5.223	5.228	5.252		
1.50	5.143	5.308 5.076	5.254 4.983	5.233 4.979	5.223 4.980	5.228 4.969	5.252 4.981	4.992	
1.50 1.55								4.992 4.725	4.738
	5.143	5.076	4.983	4.979	4.980	4.969	4.981		4.738
	5.143	5.076	4.983	4.979	4.980 4.726	4.969	4.981		0.875
1.55	5.143 4.913	5.076 4.831	4.983 4.756	4.979 4.747	4.980 4.726 (h)	4.969 4.725	4.981 4.717	4.725	
1.55 k	5.143 4.913	5.076 4.831	4.983 4.756	4.979 4.747	4.980 4.726 (h)	4.969 4.725	4.981 4.717	4.725	
1.55 	5.143 4.913 0.65	5.076 4.831 0.70	4.983 4.756 0.725	4.979 4.747 0.75	4.980 4.726 (h) 0.775	4.969 4.725 0.80	4.981 4.717	4.725	
1.55 k δ 1.60	5.143 4.913 0.65 4.512	5.076 4.831 0.70 4.499	4.983 4.756 0.725 4.504	4.979 4.747 0.75 4.498	4.980 4.726 (h) 0.775 4.499	4.969 4.725 0.80 4.509	4.981 4.717 0.825	4.725	

(when it can) exploits the steady-state situation to improve the zero-state performance. This, however, becomes more difficult for larger shifts. It only works for the smaller shifts where the steady state is reached while we are trying to accumulate enough memory to detect the change. For large shifts there is generally insufficient information on these shifts after its occurrence to exploit it before it is detected.

Automation and sensor devices that measure very frequently means that data stream in these days in real-time, and therefore steady-state situations have now become more common than when the CUSUM was first advocated by Page [7]. Most applications in environmental sciences are steady state since the process cannot be stopped. The majority of service processes, although can be stopped, are hardly ever stopped and restarted. Thus, they may be referred to as steady-state processes.

For this reason zero-state processes are less common, thus, revealing a scientific area that needs to be further researched.

2. Literature review

Sparks's [12] adaptive CUSUM improved the CUSUM early detection performance by appropriately adjusting the reference value k to improve its early detection performance. This paper will introduce and elaborate on a different approach to optimise equilibrium conditions and draw on observed outcomes. Jiang et al. [5] followed Sparks [12] in using the zero-state optimal reference value of the shift value divided by 2, but introduced a weighting function for the departures of the control variable from the zero-state optimal reference value. In particular, open-ended work should focus in optimising the CUSUM in steady-state situations (even for known shifts).

This paper starts by introducing the conventional CUSUM and the adaptive CUSUM statistics. It derives the thresholds for the CUSUM plans in steady-state situations for high-sided signals only. Low-sided charts can be established by symmetry and two-sided charts can be applied by simultaneously applying two one-sided charts and halving the in-control ARL of the high-sided chart. The high-sided charts for steady-state situations are designed to deliver a specific in-control ARL of either 100, 200, 300, ..., 1000 (see Appendix A). Monitoring plans are defined in Sparks [14]. If the location is known in advance then this paper establishes the reference value closest to the best plan for the steady-state situation. A simulation study is carried out to find the CUSUM p best for the early detection of a known location shift.

Methods that compete with the adaptive CUSUM in terms of performance involve the simultaneous application of multiple CUSUMs with differing levels of memory [4, 12], combining Shewhart and CUSUM charts [8, 11], the adaptive EWMA [1] and multiple moving averages [13]. Ryu et al. [9] assumes the shift is known and optimises the CUSUM plan without mentioning whether it is based on zero or steady state, and therefore it must be viewed as competing methodology. However, this paper's contribution is on improving the out-of-control performance of the adaptive CUSUM plan in the steady-state situation and provides formulae to estimate the thresholds for the high-sided conventional CUSUM in steady-state situations.

3. CUSUM and adaptive CUSUM plans

Let y_t the process variable measured at time t which has mean μ and variance σ^2 . Define the standardised score as $z_t = (y_t - \mu)/\sigma$. Then Page's CUSUM plan for high-sided location changes is given by

$$C_t^U(k) = \max(0, C_{t-1}^U + z_t - k) \tag{1}$$

where k is referred to as the reference value that determines the level of past memory held by the CUSUM statistic. The resetting to zero of the CUSUM statistic is the process that controls the memory in the plan. Large values of k will make the CUSUM statistic operate like the memoryless Shewhart chart by frequently resetting to zero. Smaller values of k retain more historical information in the plan by resetting to zero less often. Therefore, practitioners would like to have large values of k when the shift is large and small values of k when shifts are small. Small values of k allow the CUSUM to accumulate more information thus having sufficient power to detect small shifts. The conventional CUSUM statistic signals an unusual location shift on the high side whenever

$$C_t^U(k) > h(k) \tag{2}$$

where h(k) is the positive valued threshold that delivers a specified in-control ARL in the steady-state situation. Appendix A provides models for accurately predicting the thresholds for the conventional CUSUM in the steady-state situation.

The adaptive CUSUM allows the reference value to change over time *t* and is given by using the adaptive CUSUM statistic:

$$AC_t^U(k) = \max(0, AC_{t-1}^U + (z_t - k_t)/h(k_t))$$
(3)

and flags an out-breaks whenever this exceeds a threshold of approximately 1. The challenge in practice is how to change k_t over time t to improve the early detection performance of the plan. An alternative approach that is explored in this paper is how to select $(z_t - k_t)/h(k_t)$ to improve the early detection performance of the plan.

Sparks's [12] plan was based on the hypothesis that the zero-state optimal setting was going to be optimal in the steady-state situation. This is however, not the case. The examples that illustrate this are reported in **Figure 1(a)–(c)**.

Figure 1 plots the conventional CUSUM divided by its threshold (i.e., $C_t^U/h(k)$ for k=0.25 and 0.2125 both designed to have an in-control ARL of 200) for 100 observations from a normal distribution. The first 80 observations are in-control standard normal data and the last 20 normally observations that are shifted on the high side by 0.5. Note that k = 0.25 is the value which is the zero-state optimal value established by Moustakides [6] for this shift, while k = 0.2125 is a better alternative in the steady-state situation. Note that prior to the change point at time = 81 the $C_t^U(k)/h(k)$ with k=0.25 is almost identical to $C_t^U(k)/h(k)$ with k=0.2125 but after a near missed signal at time 71 the $C_t^U(k)/h(k)$ with k=0.2125 is higher than the $C_t^U(k)/h(k)$ values with k=0.25. This increase is enough to flag this change in the last 20 observations while the conventional CUSUM fails to signal.

Figure 1(b) illustrates that fact that the CUSUM plan with k=0.2125 is less likely to reset to zero than the CUSUM plan with k=0.25 and therefore is likely to flag the change in the last 20 observations sooner than the CUSUM with k=0.25.

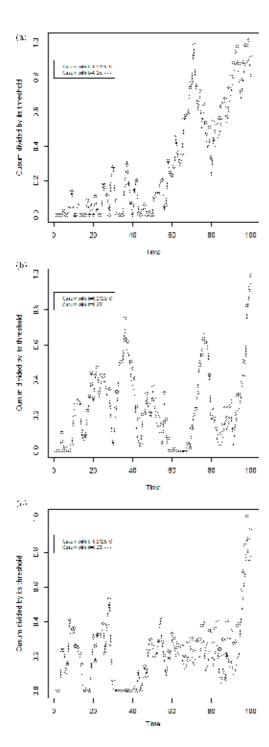


Figure 1. (a) Example 1 of when zero state optimal k = 0.25 does not do better than k = 0.2125. (b) Example 2 of when k = 0.2125 resets the CUSUM to zero than k = 0.25 and there has a better chance of detecting small shifts early. (c) Example 2 of when zero state optimal k = 0.25 does not do better than k = 0.2125.

Figure 1(c) exemplifies that the CUSUM plans with k = 0.2125 and k = 0.25 are almost identical for the first 60 in-control observations, but once the change occurs CUSUM with k = 0.2125 accelerates to the threshold quicker than the CUSUM plan with k = 0.25, and thus flagging this shift earlier. Extensive simulated examples not reported in this paper revealed that these plans, on most occasions, are almost identical. However, in a few examples as illustrated in **Figure 1(a)**–(c) the plan with k = 0.2125 exploits the situation better by being less likely to rest to zero and thus, more likely to flag an out-break in a steady-state situation earlier.

This begs the question of what reference values k in the steady-state situations are better at detecting location changes from the in-control mean than k equal to shift divided by 2 that is optimal for the zero-state.

4. Near optimal steady-state plans when the shift is known

A simulation study was carried out that started with running through 25 in-control observations before generating the out-of-control situations. This was designed to simulate a steady-state situation prior to the change point. The thresholds for this process are given in Appendix A for the standard normal distribution. There is no loss of generality by assuming mean of zero and variance of one, however the results only apply to normally distributed data. The smallest out-of-control ARLs for various scenarios are presented in **Table 1** for in-control ARL = 200, and for in-control ARL = 800 in **Table 2**.

The reference value with the smallest out-of-control ARL is highlighted in bold text, e.g., for incontrol ARL = 200 and a location shift of δ = 0.5 the near optimal steady state k is 0.2125 with an out-of-control ARL = 16.699 while the zero state optimal in the steady-state situation k = 0.25 delivers an out-of-control ARL = 16.847 (see **Table 1(a)**). In most cases the last entry in the rows of **Tables 1** and **2** is the zero-state optimal value of k equal to the location change divided by 2. Notice that k = δ /2 is never the plan with the smallest out-of-control ARL—the k with the smallest out-of-control ARL is always smaller than δ /2; in other words the better plan which resets the CUSUM statistic to zero a little less often.

The optimal reference value is reported in bold text in **Table 2**, for example, for in-control ARL = 800 and a location shift of δ = 0.5 the near optimal steady state k is 0.2375 with an out-of-control ARL = 26.449 while the zero state optimal in the steady-state situation k = 0.25 delivers an out-of-control ARL = 26.543 (see **Table 1(a)**). Notice that relative to **Table 1**, k = δ /2 is closer to the plan with the smallest out-of-control ARL than in **Table 1**, that is, the k with the smallest out-of-control ARL is always smaller than δ /2 but now the difference between the k with the smallest out-of-control ARL and δ /2 is less than was found in **Table 1**. For this reason we expect less relative gain by optimising the adaptive CUSUM for the steady-state situation with larger in-control ARL.

5. Improving adaptive CUSUM performance for the steady-state situation

The EWMA statistic in Sparks [12] and Jiang et al. [5] is used to forecast the change δ . However, this forecast always under-estimates the change in location. This bias in prediction is more

severe for large shifts where only a few observations can be used to optimise the CUSUM before the change is signalled. For this reason the EWMA statistic is thresholded to not fall below a certain minimum values, e.g.,

$$SP_t = \max(\delta_{min}, \alpha y_t + (1 - \alpha)SP_{t-1})$$
(4)

where $0 < \alpha < 1$, δ_{min} is the smallest positive location change one wishes to detect early and $SP_0 = \delta_{min}$. This paper takes $\delta_{min} = 0.5$ and $\alpha = 0.2$. Since this forecast is biased and the change in location is unknown in advance it is difficult to know what value to use for the reference value k_t given the knowledge of SP_t . Sparks [12] used $k_t = SP_{t-1}/2$ based on the assumption that this was the optimal zero-state situation. For additional information of adaptive plans see [10, 16, 18].

Given SP_t under predicts the change and the optimal k_t for in steady-state situation is generally lower than $SP_{t-1}/2$ (the EWMA one time ahead forecast divided by 2) or $SP_t/2$ (the local smoothed value) this may be a good compromise strategy. When a change occurs then generally $k = SP_t/2$ is less biased for this change than $k = SP_{t-1}/2$.

In other words the local smoothed value SP_t is used to establish k rather than the step-ahead forecast SP_{t-1} . This section explores whether this is a better alternative than the forecast. The comparisons of columns 2 and 3 in **Tables 3–8** indicate that using the reference value equal to $SP_t/2$ becomes less attractive as in-control ARL increases, for example, for in-control ARL equal to 100 it has the smaller out-of-control ARL in most cases, but when the in-control ARL = 800 it

Table 3. Comparison of adaptive CUSUM plans for in-control ARL = 100.

Delta	$\alpha = 0.2$	$\alpha = 0.2$	α=0.6	$\alpha = 0.7$
	$h_{adj} = 1.2271$	$h_{adj}=0.9215$	h_{opt} = 1.005	h_{opt} = 1.172
	$k = SP_t/2$	$k = SP_{t-1}/2$		
0.00	100.03	100.09	100.00	100.00
0.50	12.70	13.59	12.56	12.59
0.75	7.72	7.82	7.71	7.72
1.00	5.42	5.41	5.50	5.50
1.25	4.14	4.08	4.30	4.24
1.50	3.35	3.31	3.52	3.45
1.75	2.82	2.79	2.99	2.90
2.00	2.43	2.44	2.62	2.51
2.25	2.15	2.19	2.32	2.19
2.50	1.93	2.00	2.10	1.99
2.75	1.75	1.86	1.92	1.80
3.00	1.61	1.75	1.77	1.65

Table 4. Comparison of adaptive CUSUM plans for in-control ARL = 200.

Delta	$\alpha = 0.2$	$\alpha = 0.2$	$\alpha = 0.6$	$\alpha = 0.7$
	$h_{adj} = 1.2877$	$h_{adj}=0.9215$	$h_{opt} = 1.132637$	h_{opt} = 1.312637
	$k = SP_t/2$	$k = SP_{t-1}/2$		
0.00	199.979	200.897	200.328	200.006
0.50	17.009	18.291	15.380	15.641
0.75	9.996	9.971	9.122	9.255
1.00	6.944	6.662	6.453	6.488
1.25	5.240	4.948	4.996	4.948
1.50	4.179	3.949	3.990	3.984
1.75	3.472	3.303	3.367	3.325
2.00	2.968	2.864	2.928	2.855
2.25	2.594	2.541	2.580	2.510
2.50	2.306	2.303	2.317	2.231
2.75	2.085	2.126	2.116	2.024
3.00	1.904	1.984	1.952	1.852

Table 5. Comparison of adaptive CUSUM plans for in-control ARL = 300.

Delta	$\alpha = 0.2$	$\alpha = 0.2$	$\alpha = 0.6$	$\alpha = 0.7$
	$h_{adj} = 1.2877$	$h_{adj}=0.9215$	h_{opt} = 1.168285	h_{opt} = 1.351279
	$k = SP_t/2$	$k = SP_{t-1}/2$		
0.00	300.089	300.581	300.682	300.858
0.50	19.689	21.272	19.662	19.931
0.75	11.453	11.324	11.549	11.758
1.00	7.851	7.414	8.064	8.162
1.25	5.904	5.473	6.119	6.170
1.50	4.698	4.341	4.922	4.921
1.75	3.861	3.615	4.103	4.059
2.00	3.290	3.101	3.518	3.448
2.25	2.876	2.757	3.090	2.991
2.50	2.543	2.491	2.749	2.653
2.75	2.286	2.282	2.488	2.380
3.00	2.084	2.123	2.281	2.168

Table 6. Comparison of adaptive CUSUM plans for in-control ARL = 400.

Delta	$\alpha = 0.2$	$\alpha = 0.2$	$\alpha = 0.6$	$\alpha = 0.7$
	$h_{adj} = 1.386$	$h_{adj} = 0.9215$	h _{opt} = 1.267766	h _{opt} = 1.484168
	$k = SP_t/2$	$k = SP_{t-1}/2$		
0.00	398.492	399.897	400.127	400.369
0.50	21.831	23.357	21.662	22.120
0.75	12.875	12.201	12.670	12.999
1.00	8.896	7.991	8.776	8.992
1.25	6.663	5.902	6.644	6.745
1.50	5.269	4.648	5.306	5.345
1.75	4.333	3.872	4.413	4.401
2.00	3.674	3.326	3.776	3.726
2.25	3.187	2.941	3.302	3.233
2.50	2.815	2.649	2.938	2.845
2.75	2.512	2.421	2.648	2.558
3.00	2.288	2.249	2.416	2.316

Table 7. Comparison of adaptive CUSUM plans for in-control ARL = 600.

Delta	$\alpha = 0.2$	$\alpha = 0.2$	$\alpha = 0.6$	$\alpha = 0.7$
	$h_{adj} = 1.4311$	$h_{adj} = 0.907$	h_{opt} = 1.266595	h _{opt} = 1.47165
	$k = SP_t/2$	$k = SP_{t-1}/2$		
0.00	599.579	599.797	600.319	600.402
0.50	25.226	26.808	24.801	25.365
0.75	14.740	13.650	14.375	14.879
1.00	10.039	8.825	9.876	10.193
1.25	7.500	6.430	7.421	7.603
1.50	5.900	5.045	5.919	6.008
1.75	4.837	4.168	4.888	4.926
2.00	4.077	3.149	4.162	4.142
2.25	3.526	3.187	3.622	3.577
2.50	3.107	2.833	3.205	3.143
2.75	2.778	2.590	2.881	2.801
3.00	2.513	2.392	2.621	2.538

Delta	<i>α</i> = 0.2	<i>α</i> = 0.2	α = 0.6	$\alpha = 0.7$	
	$h_{adj} = 1.4311$	$h_{adj} = 0.909$	$h_{opt} = 1.3042$	$h_{opt} = 1.5196$	
	$k = SP_t/2$	$k = SP_{t-1}/2$			
0.00	799.979	800.213	800.279	800.312	
0.50	27.772	29.368	27.129	27.928	
0.75	16.047	14.722	15.608	16.195	
1.00	10.956	9.404	10.694	11.093	
1.25	8.158	6.823	7.998	8.265	
1.50	6.395	5.343	6.332	6.493	
1.75	5.216	4.139	5.212	5.289	
2.00	4.387	3.759	4.435	4.455	
2.25	3.783	3.305	3.840	3.821	
2.50	3.316	2.963	3.391	3.325	
2.75	2.961	2.708	3.043	2.981	
3.00	2.675	2.501	2.767	2.693	

Table 8. Comparison of adaptive CUSUM plans for in-control ARL = 800.

is only preferred when delta = 0.5. As such, selecting $k = SP_t/2$ is preferred if the in-control ARL = 100. However, its preference soon drops off as the in-control ARL increases from 200.

5.1. Attempts to improve on the adaptive plan of Sparks [12] in steady-state situations

Recall the adaptive CUSUM

$$AC_t^U(k) = \max(0, AC_{t-1}^U + (z_t - k_t)/h(k_t))$$
(5)

Now the Signal-to-Noise Ratio, SNR, $(z_t - k_t)/h(k_t)$ will be selected that will improve the detection performance of the plan. The EWMA smoothed trend in the z_t is given by

$$E_t = \alpha z_t + (1 - \alpha)E_{t-1} \tag{6}$$

Next, k_t is chosen such that the Signal-to-Noise Ratio $(z_t - k_t)/h(k_t)$ is a maximum, denote

$$SNR_t = max_k \left(\frac{z_t - k}{h(k)}\right) \tag{7}$$

for positive k values. The k is restricted to be greater than 0.22 in this paper which means we are less interested in location shifts less than 0.5 standard deviations. Note that $SNR_t < 0$ whenever $z_t < 0.22$. The new adaptive CUSUM statistic is now defined by

$$NC_t^U(k) = \max(0, NC_{t-1}^U + SNR_t)$$
 (8)

The threshold for this CUSUM is expected to be larger than 1. Therefore an increase in location is flagged when

$$NC_t^U(k) > h_{opt}$$
 (9)

where h_{opt} is selected to deliver a specified in-control ARL. The results in **Tables 3–8** outline the performance of this plan relative to the traditional adaptive CUSUM plan of Sparks [12] in the case where the in-control ARL = 100, 200, 300, 400, 600 and 800 (in the 3rd column).

Table 3 indicates that the user should select the EWMA weights to be 0.7 to improve on the traditional adaptive CUSUM plan when $0 < \delta \le 0.75$ and $\delta \ge 2.25$ for in-control ARL = 200, but for all in-control ARL tried (in-control ARL \ne 200) there is no advantage in using this plan in all cases except when $\delta = 0.5$.

6. Example of application

The example of application is the nitrogen dioxide (NO_2) values at Liverpool (a suburb in the western part of Sydney, Australia). Nitrogen dioxide primary gets into the air from the burning of fuel. High exposure to this can cause respiratory problems such as asthma (see WHO [17]). Nitrogen dioxide reacts with other chemicals in the air to form both particulate matter and ozone (see [2]). Both of these are harmful to humans and possibly animals when inhaled.

The data was downloaded from New South Wales (Australia) Heritage Foundation website on air pollution. Data ranged from the beginning of 2010 to the end of March 2017 and were daily averages.

The data up to the end of August 2016 were used as training data to fit both the (in-control) mean and standard deviation of the normal distribution using gamlss library in R [15]. The model had explanatory variables as time in days, day-of-the-week and harmonics. Harmonics are included because there were strong seasonal influences on nitrogen dioxide values at Liverpool. The qq-normal plot of standardised residuals of this model indicated that the normal assumption for the residuals was appropriate. This fitted model was then used to predict the mean and standard deviation for the period on 1 September 2016–31 March 2017 (taken as the expected value and standard deviation for in-control data).

The actual daily average nitrogen dioxide measures were standardised by subtracting their fitted mean and dividing by the fitted standard deviation. The adaptive CUSUM was then applied to these standardised scores to see if these values had increased significantly from expect during the period 1 September 2016–31 March 2017. The plan was designed to deliver an in-control ARL of 200. Whenever the chart flagged a significant increase the adaptive CUSUM was set equal to zero to see if the nitrogen dioxide levels remained significantly higher than expected.

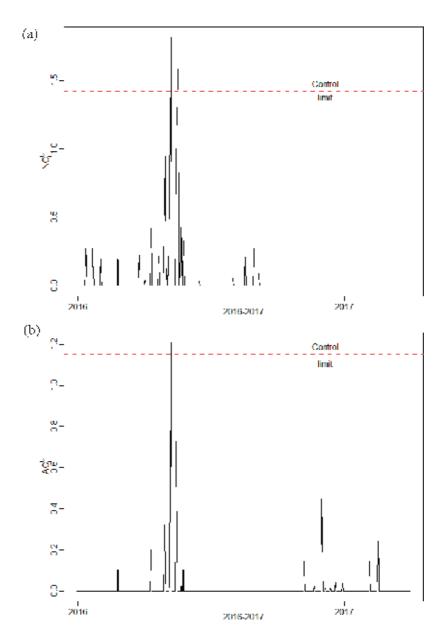


Figure 2. (a) The adaptive CUSUM $NC_t^U(k)$ advocated in this paper for in-control ARL = 200. (b) The adaptive CUSUM of Sparks [12].

Figure 2a adaptive CUSUM values as advocated in this paper for in-control ARL = 200 is plotted against the date for the period.

Figure 2b is the adaptive CUSUM of Sparks [12]. Both signal an increase in nitrogen dioxides on 8 May 2016, but the adaptive CUSUM values $NC_t^U(k)$ signals again on the 18 May 2016 after starting the CUSUM again at zero. The traditional adaptive CUSUM of Sparks [12] failed to signal a second time (**Figure 2b**).

7. Conclusions and further work

Although the new adaptive CUSUM has promise, the SNR_t proved too volatile to be efficient. There may be merit in establishing a smoother version of SNR_t that is less noisy. If future location shifts are known, then this paper offers the mean of selecting an optimal adaptive CUSUM plan.

A. Appendix

In-control ARL	Fitted model for $h(k)$
100	$h(k) = 0.3794337 - 2.9630562 \log(k) + 1.9600587k - 0.8024828k^2 + 0.9033659 \log(k)k$
200	$h(k) = -2.828476 - 4.867645\log(k) + 4.704948k - 1.827205k \times \log(k)$
300	$h(k) = -3.574586 - 5.639812\log(k) + 5.650032k - 2.177893k \times \log(k)$
400	$h(k) = -4.39191859 - 6.32066081 \log(k) + 6.67882498k - 0.06873969k^2 - 2.50144146k \times \log(k)$
500	$h(k) = -5.44288223 - 7.02105471\log(k) + 7.68319645k + 0.08688656k^2 - 3.22718165k \times \log(k)$
600	$h(k) = -6.602602 - 7.687670\log(k) + 8.825719k + 0.196071k^2 - 3.996312k \times \log(k)$
700	$h(k) = -8.0773942 - 8.4028196\log(k) + 9.9107572k + 0.6595734k^2 - 5.3895806k \times \log(k)$
800	$h(k) = -8.9383214 - 8.9021000 \log(k) + 10.7584243k + 0.7361421k^2 - 5.9389200k \times \log(k)$
900	$h(k) = -9.0757848 - 9.1040296\log(k) + 10.9300859k + 0.7607276k^2 - 6.0276468 \ k \times \log(k)$
1000	$h(k) = -8.84991553 - 9.31320632\log(k) + 11.10662579k + 0.40968650k^2 - 5.33730283k \times \log(k) + \text{as. factor} \\ (k < 0.675) \times (-0.11040543 + 0.09135357\ k + 0.11203402\ k^2)$

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Control Charts to Enhance Quality

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Additional information is available at the end of the chapter

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Abstract

Control charts are important tools of statistical quality control to enhance quality. Quality improvement methods have been applied in the last few 10 years to fulfill the needs of consumers. The product has to retain the desired properties with the least possible defects, while maximizing profit. There are natural variations in production, but there are also assignable causes which do not form part of chance. Control charts are used to monitor production; in particular, their application may serve as an "early warning" index regarding potential "out-of-control" processes. In order to keep production under control, different control charts which are prepared for dissimilar cases are established incorporating upper and lower control limits. There are a number of control charts in use and are grouped mainly as control charts for variables and control charts for attributes. Points plotted on the charts may reveal certain patterns, which in turn allows the user to obtain specific information. Patterns showing deviations from normal behavior are raw material, machine setting or measuring method, human, and environmental factors, inadvertently affecting the quality of product. The information obtained from control charts assists the user to take corrective actions, hence opting for specified nominal values enhancing as such quality.

Keywords: quality, quality improvement, control charts, upper and lower control limits, individual, variable, attribute, interpretation, corrective action

1. Introduction

Quality is regarded as an important build-in feature of a product, whose function is to fit ones needs, while showing no defects. In addition to this, the price has to be right, so that the product



may serve its designed life span. Another aspect of quality is that the product has to show the user a favorable characteristic while used other than the aim of the user to buy the product. When all the mentioned measures are met within the product, it may be regarded as a quality product.

Some types of production are done by one person, let us say a tailor; this person is responsible of every step of the product either machine performed, or by hand. As such, that person would take care of any defects as soon as these occur. In addition to this, that one person would add or deduct so-called "excitement" features in the product according to the consumer's taste. This kind of production is called the mentor-protege type. Henry Ford introduced and implemented mass production, where every step of the production is done by someone else with a different machine. Since many people and machines are involved in the production, the chance of deviations and defects increases and may cause quality-specific problems. Furthermore, since the operators do not know who the consumer they are producing for in mass production, research and development departments were created to fulfill the "excitement" features, since this work had to be done by other people than the operator; additionally, research and development departments serve to aim produced goods to different markets.

In order to effectively manage and eliminate quality-specific problems, a number of quality control methods were developed. The following encapsulates some of these:

- Quality control,
- Total quality control,
- Total quality management,
- Quality management,
- Quality improvement,
- Six-sigma quality management, etc.

Statistical quality control is used widely in the modern business world. Indeed, control charts are deemed as one of the primary techniques to enhance quality. Gathering data to prepare a control chart is done according to many national and international standards like British Standards (BS), American Standards (ASTM), German Standards (DIN), Turkish Standards (TSE), etc. Variations in due time or sample order are examined by control charts in order to keep production under control according to the product's desired properties. The purpose of this chapter is to highlight the arising benefits of using control charts and elaborate their impetus on industrial case studies such as to keep production under control, to eliminate defects, and to increase profit, if not, a full understanding of what is going on in production or service will not be conceived.

A process is a system of bonds worked altogether to produce a specific outcome or factors which affect the production and the quality of a product or a function. In order a process to achieve the intended result, the causes of the mentioned process have to be kept under control. To this end, control charts are used [1]. The latter is prepared with numerical data of a particular characteristic of the product, which is controlled. Additionally, control charts

provide visual support about the deviations in the characteristics [2]. In doing so, they prevent the formation of defects and increase and develop the efficiency of the processes.

1.1. Aims and objectives

Quality improvement tools are mainly process flow diagrams, cause-and-effect (fishbone) diagrams, check sheets, histograms, scatter plots, Pareto diagrams, and control charts. The aim of this chapter is to focus on the use of only the control charts and provide a qualitative and quantitative insight. As such, it will present industrial cases regarding their use and type. In addition to this, it will discuss on how they are designed, prepared, and interpreted together with research concerning control charts.

In doing so, this work will include:

- Presentation of control charts in the area of quality control;
- Design of a control chart;
- Types of control charts;
- General guidelines to prepare control charts;
- Control charts for variables, that is, individual measurements control charts, means control charts, ranges control charts, and standard deviation control charts with industrial applications;
- Control charts for attributes, that is, control charts for fraction nonconforming, control charts for the number of nonconforming items, control charts for conformities per unit, and control charts for nonconformities with industrial applications;
- Special cases for control charts;
- Interpretation of control charts;
- Research on control charts.

Control charts provide higher efficiency in production, decrease defects and faulty production, increase profit, and diminish costs. These are some of the reasons why control charts are widely used in industry. Indeed, their area of application is quite wide and covers nearly everything from service organizations and providers to financial consulting offices, as well as in various other applications in daily life.

2. Literature review

It is worth mentioning at this point that in nature as well as in service and production companies, no two products of the same substance are exactly the same. This implies that at least two of the same substance or characteristic are always different, or at least there is a small difference between them. This, however, is normal as long as it affects small variations. To produce every piece in a lot exactly to the specified nominal characteristic is both hard and costly. The measurements of some quality characteristic like length, width, temperature, weight, etc., vary slightly and maybe unavoidable. This variability depends on equipment, machinery, materials, equipment, environment, people, etc., and is acceptable. These types of variability are referred to as "normal", "random", or "natural".

In view of the above, it is preferred that the variability has to be reduced as much as possible in the process, if it is not eliminated. The distances of the points from the mean line give the user information about its variability. There are chance causes of variation in statistical control, but there are also assignable causes which are not a part of the chance causes. These show important, large, and unusual differences. The reasons for this may be:

- Material is taken from a different lot,
- The machine setter makes a new setting,
- Any kind of "operator error".

The above may cater for the "abnormal" or "unnatural" variations. In a production where the aim is to achieve quality and to meet the consumers' requirements, the presence of assignable causes may draw the process out-of-control. Since the objective of studied quality characteristic is to be stable and repeatable, the occurrence of assignable causes must be detected instantly and the investigation of the process and corrective action ought to take place before further nonconforming units are manufactured. Control charts are widely used in order to interpret the variability a characteristic possesses between nominal and actual settings. The differences between "normal" and "abnormal" variations are detected, and the characteristic is kept under control by taking all the necessary measures. The purpose of control charts in quality control is prevention, which is better than cure [3].

The amount of variation to be allowed in any manufacturing process is of paramount importance. It is impossible to examine the records of past data and evaluate data by looking and thinking without doing statistical calculations.

In some factories, technical staff checks out the data and estimates on an *ad hoc* level the limits of the process. These may be too wide or too narrow, which in turn, may be both affecting the production negatively causing it to go out-of-control. If the limits are too wide, the process will posses an excess of variation; if it is too narrow, extra work may be required so as to maintain set limits. It is worth noting at this point, both of them prevent corrective action to take place which is suitable for production. On the other hand, when the limits are calculated on a scientific basis, the exact amount of expected variation in a product will be determined and will be confidently used, so guesswork will be eliminated [4]. Examples for limits can be seen in **Figures 6–12**.

Shewhart developed the control charts first in 1924 and are as such called Shewhart control charts. The usage of control charts became common as its benefits were recognized in due time. Its benefits can be listed as:

- Knowing how the production proceeds,
- Diminishing costs,
- Increasing production by doing it right the first time so to prevent defects,
- Being aware of the effects of raw material, machine, worker, and environmental factors by analyzing the patterns occurring on the control chart
- Saving time by preventing the error of searching for special reasons that effect the processes even they do not exist;
- Making it easier to find the factors that negatively affect the process;
- Used to seek if the desired efficiency of a machine is achieved;
- Useful in decreasing the variations in a product or in a process;
- Useful in decreasing the number of rejected pieces or waste;
- Ensuring to decrease the cost of testing and control;
- Enabling the specifications and orders at a more realistic level;
- Helpful in making the processes more stable;
- Advantageous in preparation of reports near to real about the processes or operations to present to the managers;
- Expedient in keeping sensitive and reliable records;
- Used in deciding the renewal time of the production machines;
- Substantial reference in research and development practices;
- Helpful in cost and financial analysis;
- Used in stocks control [5].

The areas where control charts can be used are areas such as production-not least on say, count of the yarn or the weight of fabric in textiles, costs, sales, circulation of workers, material, chemicals, etc., in a certain period of time.

Quality control charts are statistical technique tools which have a wide application in scientific research, in industry, and even in daily life. This concept makes the use of control charts as important as cost control and material control. Information about the design and types of control charts and general guidelines to prepare control charts, and the likes are given below.

2.1. Design of a control chart

A control chart is a graph mainly derived from a normal distribution curve. The y-axis denotes a quality characteristic or a particular characteristic of the product or process, which is controlled and is marked in units, in which the test value is expressed. The x-axis consists of time intervals or sample number. There is a center line, which is the average of the value of the studied matter or may also indicate the nominal value. The upper boundary characterizes the upper control limit (UCL), while the lower designates the lower control limit (LCL), respectively. The gathered data are plotted in sequence, and then, the pattern occurring on the chart is interpreted. A sample of a control chart is given in **Figure 1**.

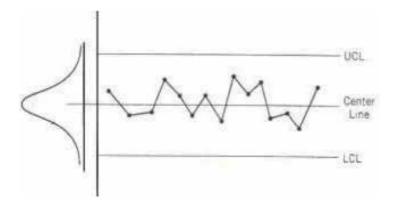


Figure 1. Sample of a control chart.

As can be seen from **Figure 1**, there is a close relationship between the normal distribution curve and the control chart. Control charts are constructed on the basis of expanding the sigma limits above and below of the mean. By taking a deeper look, it can be expressed that expansion of 1.962σ from the mean may be regarded as the "warning limit," and the expansion of 3.09σ from the mean is the "action limit" for large samples (**Figure 2**). Similarly, $2\sigma/\sqrt{n}$ and $3\sigma/\sqrt{n}$ are the same limits, respectively, for small samples (**Figure 3**) [6].

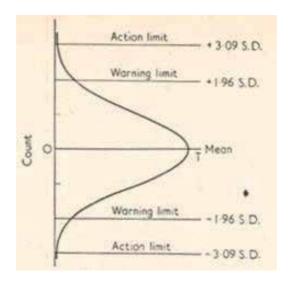


Figure 2. Warning and action limits for large samples.

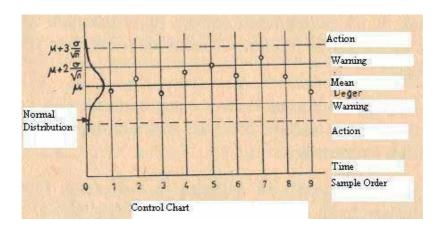


Figure 3. Warning and action limits for small samples.

The center line of a control chart stands from the past data or new data got from the measurements in the process or applied from what the consumer wants. If the clients have specified limits for their orders, production has to be done according to the specification limits of the client. In this case, the UCL and LCL have to be in the specification limits (**Figure 4**). If the control limits take place out of the specification limits (**Figure 4**), then that is an undesirable

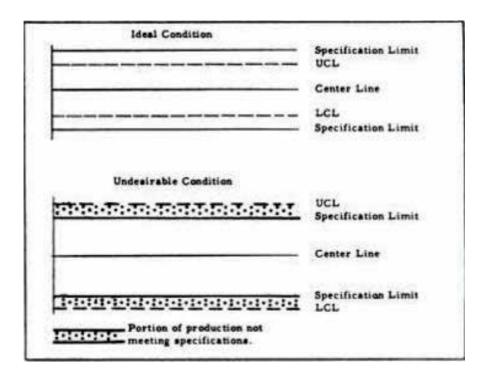


Figure 4. Placement of UCL and LCL according to specification limits.

condition because the product will be manufactured with a quality characteristic range that the client does not want, thus resulting in an inferior quality product.

 3σ expansion means 6σ expansion from the UCL and LCL in total. From a normal distribution diagram, it is known that the area under the diagram corresponds to a 99.73% of probability. This means that the points used in the preparation of control charts will be included in the study with a 99.73% probability (**Figure 5**).

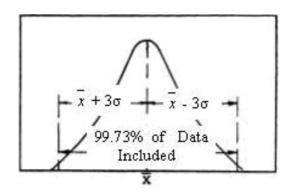


Figure 5. Representation of 99.73% probability.

Control charts are quality technique tools that may trigger an alarm. If a value exceeds the warning limit above or below, production may continue, but the reason for this variation must be investigated and corrective action must be taken.

In obtaining data from a process, sampling is performed by using small sample sizes. Concerning small samples, sensitivity of the control chart is increased by statistical methods, and the warning limit and the action limit are combined to be expressed as UCL and LCL. So, if a value gets close to one of these limits, it is understood that it is not needed to stop production but search for the reason of this variation and to correct it. Likewise, if a value crosses one of these limits, action has to be taken and production must be stopped before searching. Sensitivity, sample size, and sampling frequency (specific and equal time intervals) are important factors regarding the performance of the control chart. Sampling frequency must be in accordance with the production processes.

2.2. Types of control charts

Control charts have two main types according to the way the values used are obtained. Values can be obtained by measuring on a numerical scale, that is, counting, calculating, by using a testing instrument, or by deriving proportions of judgments. If they are conforming or nonconforming, one would look at their certain attributes they have to possess so as to express a case. If the values used are obtained by measuring, then they are called control charts for variables. If the values used are obtained by deriving proportions, then they are called control charts for attributes. These charts apply for different process-specific cases in processes, so that each can be evaluated on its own.

Each type has different kinds of control charts particularly for the case studied. The most important kinds of control charts for variables are mainly

- Individual measurements control chart (x),
- Means control chart (\overline{x}) ,
- Ranges control chart (R),
- Standard deviation control chart (s).

Others are s² control chart, moving range control charts, and regression control chart. The main kinds of control charts for attributes are foremost p-, np-, u-, and c-control charts. Others are standardized control charts, g control charts, and h control charts.

There are control charts for special uses in literature which can be listed as cumulative sum control charts, moving average control chart, x-bar and R-control charts for short production runs, attributes control charts for short production runs, modified and acceptance control charts, group control charts for multiple-stream processes, chi-square control chart, difference control charts, control charts for contrasts, run sum and zone control charts, adaptive control charts, moving average control charts, residual control charts, control charts for six-sigma processes, acceptance control charts, T² control charts, Hotelling T² control charts, Exponentially Weighted Moving Average (EWMA) control charts, exponentially weight means square control charts, multivariate EWMA control charts, one-sided EWMA control charts, moving centerline EWMA control charts, and one-sided CUSUM control chart [7].

2.3. General guidelines to prepare control charts

Steps to prepare control charts in general are as follows:

- 1. Obtain a set of values;
- 2. Decide which kind of a control chart to prepare;
- 3. Do the needed calculations;
- 4. Draw the control chart;
- **5.** Plot the values in Step 1 on the control chart;
- Continue to plot the new values collected in due time on the chart;
- Interpret the pattern occurring on the chart.

It is apparent from the last step, as the production proceeds, new values accumulate and these new values should be plotted on the same control chart with the UCL and LCL calculated from the first values of the same production. This procedure guarantees that the properties of the first products and the rest lie in the same control limits.

In the first preparation of the control chart, if an assignable cause is found in the data collected, that point is discarded and the trial control limits are recalculated, using only the remaining points.

2.4. Control charts for variables

Control charts for variables are widely used because they enable more effectual control and provide more information about the performance of the processes. These charts are preferred because they provide the user with an estimation of the central tendency and the distribution of the studied case [8]. The most commonly used ones as stated above are individual measurements control chart (x), means control chart (\overline{x}) , ranges control chart (R), and standard deviation control chart (S).

2.4.1. Individual measurements control charts (X control charts)

Control charts prepared with individual measurements are called individual measurements control charts. These charts are used in cases where only one value measured on a numerical scale is to be defined, that is, counting, calculating, or with a testing instrument. Examples would be the number of workers for successive months, paid taxes over years (in economics), effective staple length for similar fiber batches, fiber fineness obtained from air flow principle (in textiles), etc. [9].

Preparation steps for an X control chart are:

- 1. There has to be at least 10 values, 20 is better, but if there is a large time gap between obtaining the values 8 serves as well;
- **2.** Average value of $X(\overline{x})$ is calculated;
- 3. The absolute value of the differences between two consecutive values of X is called the moving range. Moving range (MR) is calculated and average of MR (\overline{MR}) is calculated;
- **4.** UCL and LCL are calculated by $\bar{x} \pm 2.66 \, \overline{\text{MR}}$ formula;
- **5.** Control chart lines are drawn with the center line (\bar{x}) , UCL, and LCL;
- **6.** The values used in calculation are plotted on the chart;
- 7. The values coming up in due time are plotted on the same chart and interpreted as will be explained later.

An application of the X chart to yarn irregularity quality characteristic (U%) of the Kaynak Group Cotton Yarn Factory's regular measurements is given in **Figure 6** [10].

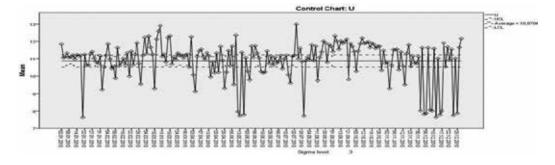


Figure 6. Application of X chart to yarn irregularity quality characteristic (U%) of the Kaynak group cotton yarn factory's regular measurements.

2.4.2. *Means control charts* (\overline{x}) $(\overline{x}$ *control charts)*

When sampling is done, n-repeats are taken at once to analyze the case under study in specified intervals. Control charts prepared with the means of the samples taken at once are called means control charts. These charts are used in cases where repeated measurements on a numerical scale of small sample sizes are done. Sample size is usually 5. Means of the samples possess a normal distribution. The basis of this system depends on finding how close the means of the samples measured are to the nominal or average value. Examples would be yarn count, fabric weight per unit area (in textiles), etc.

Preparation steps for an X-bar (\overline{x}) control chart are:

- 1. There has to be at least 10 different repeated measurement groups of a sample size of 5; 12 is better, but it should never be 8;
- **2.** Mean of sample size (usually 5) is calculated for each different repeated measurement group, where each mean of sample size is indicated as \bar{x} ;
- 3. Range is the difference between the maximum and the minimum value in a sample (like size of 5). Range (R) for each sample size is calculated;
- **4.** The averages of \overline{x} (\overline{x}) and R (\overline{R}) values are calculated;
- **5.** UCL and LCL are calculated by $\overline{X} + \overline{R}A_2$ formula. The constant A_2 is determined from the table in Appendix 1. The sample size is indicated in the column "n";
- **6.** Control chart lines are drawn with the center line (\overline{x}) , UCL, and LCL;
- 7. The values calculated in Step 2 (\overline{x}) are placed on the chart;
- **8.** The values coming up in due time are plotted on the same chart and interpreted as will be explained later.

An application of \bar{x} chart to yarn maximum breaking strength quality characteristic (gf) of the Kaynak Group Cotton Yarn Factory's regular measurements is given in **Figure 7**.

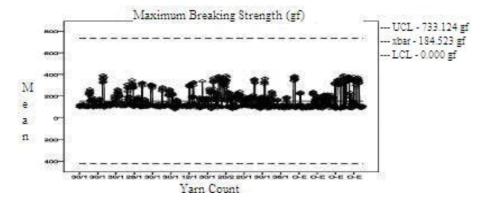


Figure 7. Application of \bar{x} chart to yarn maximum breaking strength quality characteristic (gf) of the Kaynak group cotton yarn factory's regular measurements.

2.4.3. Ranges control charts (R) (R-control charts)

Control charts prepared with the range values are called range control charts. These charts are used together with means control charts (\bar{x} charts). Some statistical information is lost, when small sample sizes (like 5 as stated above) are used and the mean of the values is used. The preparation of R chart becomes as such important in order to make the lost information somehow apparent. Ranges do not possess a normal distribution like the means of the samples. While a \bar{x} control chart gives information about the behavior of the mean values of a sample, a R-control chart gives information about the differences in the samples.

The preparation steps for a R-control chart are:

- **1.** The same R values obtained in Step 3 of \bar{x} chart are used;
- **2.** The same average of R (\overline{R}) in Step 4 of \overline{x} chart is used;
- **3.** The UCL is calculated by $D_4 \overline{R}$ formula, and the LCL is calculated by $D_3 \overline{R}$ formula. The constants D_4 and D_3 are determined from the table in Appendix 1. The sample size is indicated in the column "n";
- **4.** Control chart lines are drawn with the center line (\overline{R}), UCL, and LCL;
- The values used in Step 1 are plotted on the chart;
- 6. The values coming up in due time are plotted on the same chart and interpreted [9].

When interpreting the pattern occurring on the R-control chart, it is ideal when the points are located near to the LCL.

An application of R chart to yarn maximum breaking strength quality characteristic (gf) of the Kaynak Group Cotton Yarn Factory's regular measurements is given in **Figure 8**.

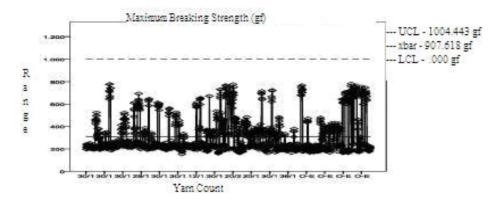


Figure 8. Application of R chart to yarn maximum breaking strength quality characteristic (gf) of the Kaynak group cotton yarn factory's regular measurements.

2.4.4. Standard deviation control charts (s) (s-control charts)

Control charts prepared with the standard deviation values are called standard deviation control charts. These charts are used together with the means control charts (\bar{x} charts). Some statistical information is lost when the mean of the values is used. When a sample size is large, it is preferred to use the s-control charts to make the lost information somehow apparent. Also, s charts are preferred to be used in cases, where there are missing data in the samples, in other words, the sample size varies. The s-control chart gives information about the overall variation of the values from the mean value of the samples.

It is suggested here to use \bar{x} , R, and s charts together so as to get a better understanding of the population that it is representing. Even the R chart and s charts have a similar pattern. In some cases, incidents are caught in the process which would alarm the user of an immediate problem. Range control chart shows the differences in individual measurements, but the scontrol charts depict the general behavior of the distribution in the population. In a sample of values, with the same R, s may be high or low or vice versa. This means that R gives a specific interpretation of a case, but s gives a general interpretation about it.

The preparation steps for a s-control chart are similar with range control charts, that is, average value of s (\bar{s}) is used instead of \bar{R} . The UCL is calculated by the B₄ \bar{s} formula, and the LCL is calculated by the B₃ \bar{s} formula. The constants B₄ and B₃ are determined from the table in Appendix 1. The sample size is indicated in the column "n".

An application of the s chart to yarn maximum breaking strength quality characteristic (gf) of the Kaynak Group Cotton Yarn Factory's regular measurements is given in **Figure 9**.

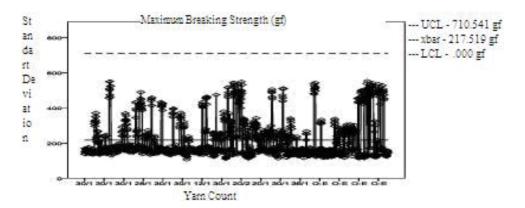


Figure 9. Application of s chart to yarn maximum breaking strength quality characteristic (gf) of the Kaynak group cotton yarn Factory's regular measurements.

2.5. Control charts for attributes

Control charts for attributes are used in cases, where the studied matter is not represented by measuring on a numerical scale but defined as a conforming (nondefective) or nonconforming

(defective) to specifications. Then, different proportions suitable to each case are obtained, and control charts are drawn. The most commonly used ones as stated above are control chart for fraction nonconforming (p), control chart for the number of nonconforming items (np), control chart for conformities per unit (u), and control chart for nonconformities (c).

2.5.1. Control charts for fraction nonconforming (p) (p-control charts)

Control charts are developed by dividing the amount of nonconforming pieces to the total production amount are called p-control charts. The p-control charts possess binomial distribution. Since the total amount will be changing from one lot, batch, or party to the other, proportions are used to bring all to the same denominator. In the case where p charts will be used, 100% of the production must be controlled, otherwise the nonconformities which are not controlled may reach the end user. Examples would be the proportion of number of defective skirts to total produced skirts in 1 day, the proportion of number of defective yarn cones to total produced cones in one shift (in textiles), etc.

The preparation steps for a p-control chart are:

- 1. There has to be at least 10 values;
- **2.** The proportions (p) are calculated by dividing the nonconformity amount to the total amount;
- **3.** The average value of p (\overline{p}) is calculated;
- **4.** The UCL and LCL are calculated by $\overline{p} \mp \sqrt{\frac{\overline{p}(1-\overline{p})}{n}}$ formula;
- **5.** The control chart lines are drawn with the center line (\overline{p}) , UCL, and LCL; and plotting is done as discussed above.

An application of the p chart to nonconforming pants in the Çağla Textile Ready-wear Factory's regular measurements is given in **Figure 10** [11].

2.5.2. Control charts for number of nonconforming items (np) (np-control charts)

Control charts prepared with the number of nonconforming items is called a np-control chart. A proportion is not done because the total production amount in these cases is the same in every day or shift, etc. There is no need to divide like in p-control charts every time. Examples would be the number of defective skirts in 1 day for a constant produced amount, the number of defective yarn cones in one shift for a constant produced amount (in textiles), etc.

The preparation steps for a np-control chart are similar with the p-control charts, that is, the average value of np $(n\overline{p})$ is used instead of \overline{p} , and the UCL and LCL are calculated by using the $n\overline{p} \mp 3\sqrt{n\overline{p}}(1-\overline{p})$ formula. \overline{p} is obtained by dividing $n\overline{p}$ to the constant produced amount.

An application of the np chart to the nonconforming skirts in the Çağla Textile Ready-wear Factory's regular measurements is given in **Figure 11**.

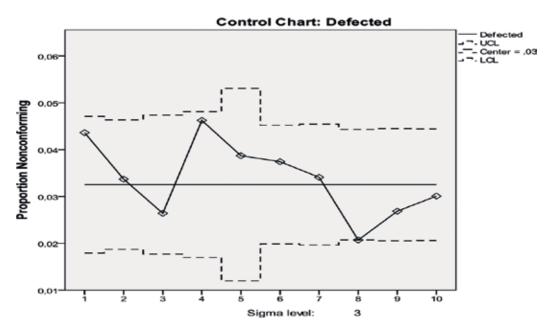


Figure 10. Application of p chart to nonconforming pants in the Çağla textile ready-wear Factory's regular measurements.

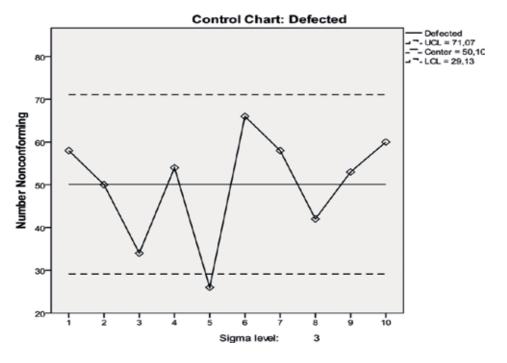


Figure 11. Application of np chart to nonconforming skirts in the Çağla textile ready-wear factory's regular measurements.

2.5.3. Control charts for conformities per unit (u) (u-control charts)

Control charts prepared with the number of nonconformities per unit are called u-control charts. The unit here is different from the production amount mentioned in the p- and np-charts, being changing or constant, respectively. The unit here is the restricting factor, where the main pronounced value is the nonconformity. A unit may be length, weight, etc. As such, it is mentioned as number of defects per unit length or number of conformities per unit weight, facilitating the status change of the unit.

The number of nonconformities is divided to the unit to find the "per unit" value of the defects to bring all to the same comparison ground. An example would be the number of defects per 100 m length of fabric (fixed width) (in textiles).

The preparation steps for a u- control chart are:

- 1. There has to be at least a set of 10 values;
- 2. The number of defects per unit is calculated for a specified unit for every value;
- **3.** The average value of $u(\overline{u})$ is calculated;
- **4.** The UCL and LCL are calculated by $\overline{u} \mp 3\sqrt{\frac{u}{n}}$ formula;
- 5. The control chart lines are drawn with the center line (\overline{u}) , UCL, and LCL; plotting the lines is done as depicted above.

When interpreting the pattern occurring on the u-control chart, it would be preferably when the points are located near to the LCL.

Applications of u charts to defects in fabrics of fixed width in the Özer Textile Weaving Factory's regular measurements are given in **Figure 12** [12].

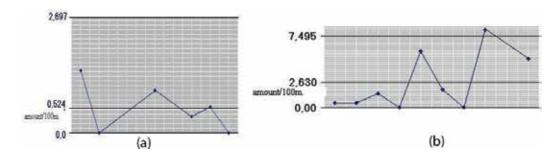


Figure 12. Application of u charts to defects in fabrics of fixed width in the Özer textile weaving factory's regular measurements. (a) Application of u chart to thin weft yarn defect calculated per 100 m. Of fabric (considered normal), (b) application of u chart to thick warp yarn defect calculated per 100 m of fabric (gives alarm).

2.5.4. Control chart for nonconformities (c) (c-control charts)

The control charts prepared with the number of nonconformities per constant unit are called ccontrol charts. The unit here is again the restricting factor, where the main pronounced value is the nonconformity. In these cases, the unit will be constant for all the data collected. There is no need to divide every time, since they are all on the same ground of comparison. Examples would be the imperfections (thick place in yarn, thin place in yarn, and neps) in yarn (number of an imperfection per 1 km. of yarn; in textiles).

The preparation steps for a c- control chart are similar with the u-control charts, that is, the average value of c (\overline{c}) is used instead of \overline{p} and UCL and LCL are calculated by $\overline{c} \mp 3\sqrt{c}$ formula.

The applications of c charts in the Gülçağ Textile Yarn Factory and the Yıldırımlar Printing & Dying Factory are given in **Figure 13**.

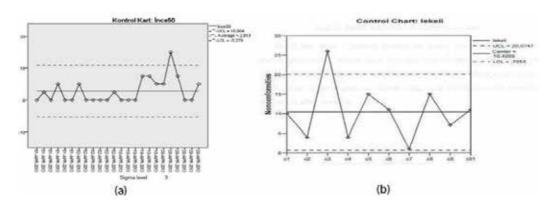


Figure 13. Application of a c chart. (a) Applications of c chart to thin place imperfection per 1 km, of yarn in the Gülçağ textile yarn Factory's regular measurements [13], (b) applications of c chart to spot defects per fixed fabric roll of 80 m. In the Yildırımlar printing & dying factory's regular measurements [14].

3. Results and analysis

This chapter will detail and analyze industrial applications of control charts for variables and attributes.

3.1. Industrial applications of control charts for variables

Control charts are widely used in industry nowadays. The information obtained from them helps production to be monitored effectively. Some examples of control charts for variables taken from industry are given in **Figures 14–17**.

Individual measurements control charts for number of rolls of nonwoven fabric and daily production weight of Sarıkılıç Textile Nonwoven Factory are given in **Figures 14** and **15**, respectively. By observing mentioned figures, one might see that at the beginning, both the number of rolls and production weight are high, but toward the end, even the number of rolls are near to average and production weight is high. This is because the weight of the unit area of nonwoven fabric increased. This is a typical case seen in textile factories, and as such, it can be said that production is under control.

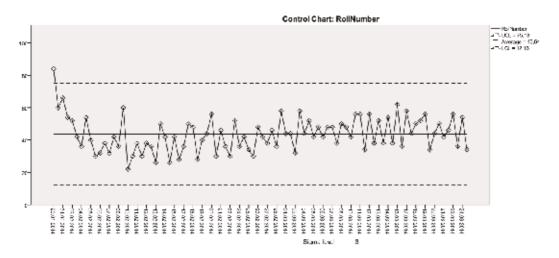


Figure 14. Individual measurements control chart for the number of rolls daily of Sarıkılıç.

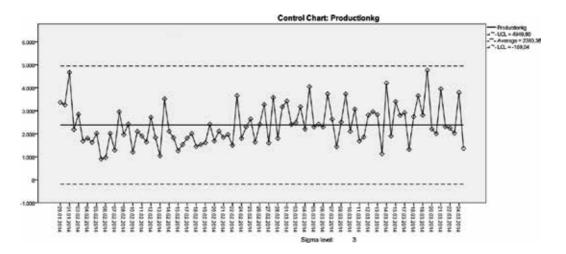


Figure 15. Individual measurements control chart for the production weight daily of Sarıkılıç textile nonwoven factory.

In **Figure 16**, the means control chart, ranges control chart, and standard deviation control chart are given for open-end yarns' hairiness values, which are supplied from Kaynak Group Yarn Factory. A closer look at the charts may reveal an improvement in hairiness values, as the production proceeded but for a short time. The factory searched for the reason of this improvement and found out that it was because of the better condition of air suction and applied that condition afterward.

In **Figure 17**, means control chart, ranges control chart, and standard deviation control chart are given for nonwoven thickness of nonwoven fabric values of the Sarıkılıç Textile Nonwoven Factory. It is seen in the charts that the thickness values have increased. The same applies to the range and standard deviation values too. The factory searched for the reason, and it was

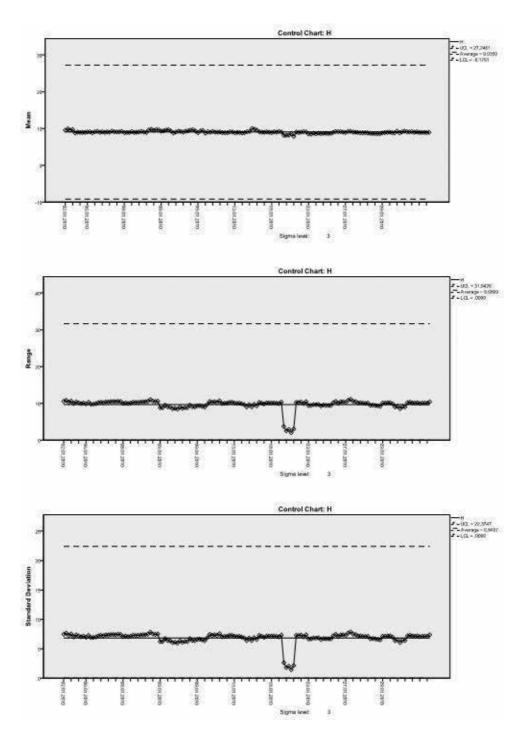
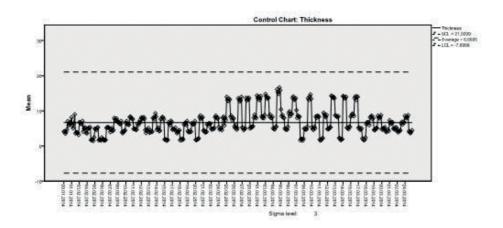
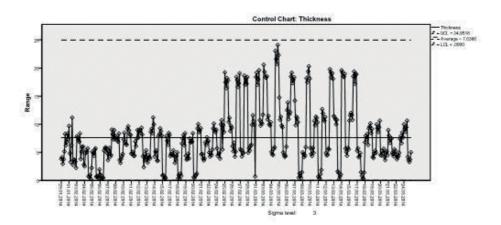


Figure 16. Means control chart, ranges control chart, and standard deviation control chart for open-end yarns' hairiness values of the Kaynak group yarn factory.





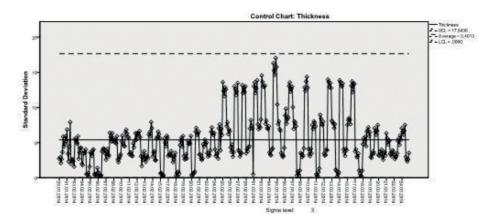


Figure 17. Means control chart, ranges control chart, and standard deviation control chart for nonwoven thickness values of the Sarıkılıç textile nonwoven factory.

determined that different unit weights of nonwoven rolls were plotted on the same charts and were corrected.

3.2. Industrial applications of control charts for attributes

Some examples of control charts for attributes applied in industry are given in Figures 18-21.

In the Tekstüre Textile Socks Factory in İstanbul, there are nonconforming socks produced during manufacturing. A p-control chart for nonconforming socks in different amounts of production is given in **Figure 18**. As can be seen in the figure, there is an increase in nonconformities toward the end. The factory searched for the underlying reason and found out that new employees had not taken enough training regarding socks production. A np-control chart for nonconforming socks in constant amount of production is given in **Figure 19**. As depicted in the figure, there is a decrease in nonconformities toward the end. The factory searched for its reason and found out that new machines were bought, which had started production.

In the Ne-Ke Textile Weaving Factory, there is a double weft fault in weaving of bed placemats. A u-control chart for different lengths of fabric rolls is given in **Figure 20**. As seen in the figure,

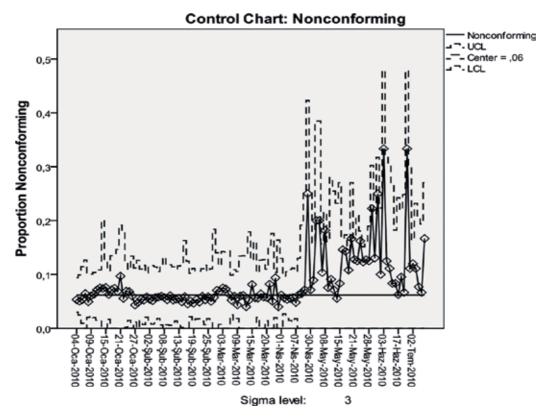


Figure 18. p control chart for nonconforming socks in different amounts of production in the Tekstüre textile socks factory.

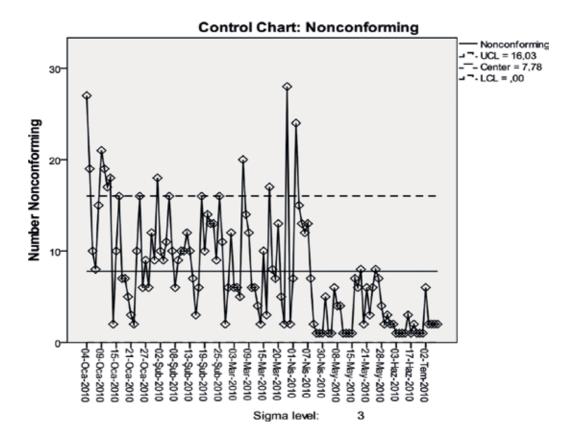


Figure 19. np-control chart for nonconforming socks in constant amount of production in the Tekstüre textile socks factory.

the pattern seemed normal, and the factory did not take any action for this case. In **Figure 21**, a c-control chart is given for the cracks occurred in the dying department of the Ozer Textile Weaving Factory. By observing the corresponding figure, it can be seen that there is a sharp increase and then a fall. The factory searched for its reason and found that the worker had forgotten to add the anticrack chemical into the dying bath in the night shift and gave more training to the worker.

3.3. Special cases for control charts

Some special cases for control charts are listed below:

- The formulae for calculation of the UCL and LCL change in \bar{x} , R, and S charts, when standard values for μ and σ are known from past data
- If there are variable sample sizes, then the UCL and the LCL will be varying also and another approach to dealing with variable sample size is to use a "standardized" control chart

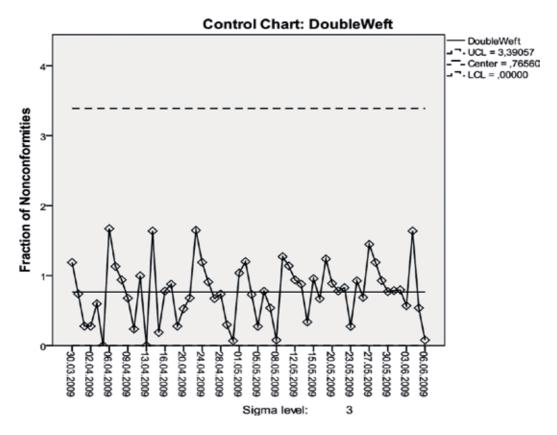


Figure 20. u-control chart for double weft fault in different lengths of fabric rolls in the Ne-Ke textile weaving factory.

- There can be subgroups for a case studied in the control chart. An example would be
 individual machines producing the same lot, yarn producing machines or fabric producing machines. In this case, there may be different control charts to control every machine
 under control even if they produce the same lot
- Process capability analysis can be done using a control chart
- There may be variable sample sizes on control charts
- There may be variable sampling interval on control charts

The details for these special cases are not included here.

3.4. Interpretation of control charts

The distribution of the points on a control chart is important, and the patterns occurring on the control chart have to be examined and interpreted. Since the values distribute at a distance around the mean value and support visually the variation in the spread of the test results, they provide useful information about the process so as to make modifications in order to reduce variability. For interpreting the control charts, the principles of the control charts have to be

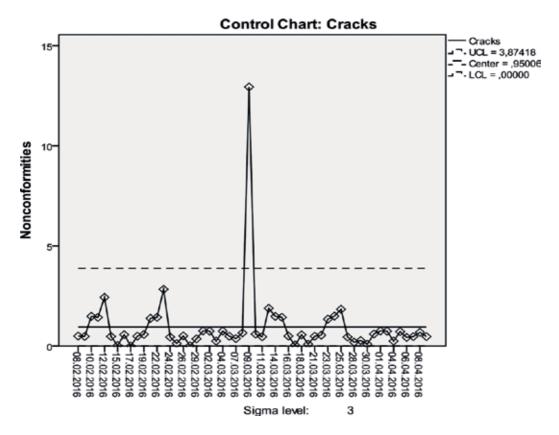


Figure 21. c-control chart for cracks in dying department of the Özer textile weaving factory.

known, and their users must be familiar with the process. It is the author's view that during the interpretation of control charts, not only statistics but also experience and common sense have to be combined with it. If there is a run toward the warning limit, this may suggest that a change has to be made. On the other hand, a similar run would also mean that a change in time may prevent the next item from lying outside the limits. This has to be evaluated for every occasion on its own.

Two examples of a typical control chart where production is under control or a normal behavior is noticed is seen in Figure 22.

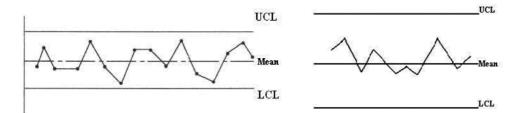


Figure 22. Two examples of a typical control chart.

The main interpretation of control charts is that all the points should lie in between the UCL and LCL. If sample points fall in between the control limits in a continued production, then the process is in control, and as such, no action has to be taken. If a point falls out of them, then the process is out-of-control, and further investigative and corrective action ought to be taken. If, however, points get close to the UCL and LCL's, one has to search for the root of the problem and solve it without stopping production. If on the other hand, points cross the UCL and LCL's, production must be stopped and the problem must be investigated and solved. Faulty production is worse than no production.

On the other hand, even if none of the points lie out of the control limits, this does not mean that the chance factor had played a role. All the points on the control chart may lie in between the UCL and LCL's like a typical chart in Figure 22, but this does not mean that production is under control. Incidentally, they may well be out-of-control soon. The reason for this is the pattern occurring on the control chart. Patterns give information about the condition of the process, and their early identification may trigger the alarm for the user to investigate their causes and to prevent any faults before they occur. Patterns having deviations from normal behavior are indicators of raw material, machine (setting, adjustment, tool abrasion, and systematic causes of deterioration) or measuring method, human, and environmental factors starting to change the quality characteristic of the product. To interpret control charts, every cause has to be studied one by one and investigated and corrective action ought to be taken.

 \overline{x} and R charts are interpreted together. If the underlying distribution is normal, then the two charts are statistically independent, and their joint consideration gives the user more information about the process. If there is an assignable cause in the process, it will show itself in both of them. If the underlying distribution is not normal, this nonnormality effects the \bar{x} and R charts, leading corrective action not to be taken on time. As such, normality tests have to be done at the beginning. \bar{x} and s charts are also interpreted together.

3.5. Patterns occurring on control charts

Cyclic patterns: Two examples of control charts showing a cyclic pattern are given in Figure 23. An \bar{x} control chart having a cyclic pattern between the UCL and LCL may result from systematic environmental changes, such as temperature or heat or stress buildup, raw material

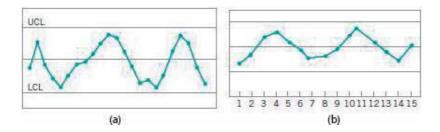


Figure 23. Two examples of control charts showing a cyclic pattern.

deliveries, operator fatigue, regular rotation of operators and/or machines, and fluctuation in voltage or pressure. An R-control chart having a cyclic pattern may result from maintenance schedules, fatigue, or tool wear. It is clear that the process is not out-of-control, but elimination or reduction of the source of variability will improve the product.

Mixture: An example of a control chart showing a mixture pattern is given in Figure 24. In a mixture pattern, the plotted points gather around the UCL and LCL, but few points fall near the center line. In this outline, there are two or more overlapping distributions generating the process output. An \bar{x} control chart having a mixture pattern may be the result of "overcontrol," where process adjustments are done too often, or if many machines do the same production, but are adjusted wrongly.

Shift in process level: An example of a control chart showing a shift in process level pattern is given in **Figure 25**. An \bar{x} control chart having a shift in process level pattern may result from introduction of new workers, methods, raw material, machine, change in the inspection method or standards, change in the either skill, attentiveness, or motivation of the operators.

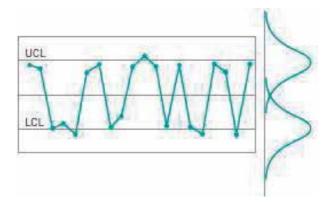


Figure 24. Example of a control chart showing a mixture pattern.

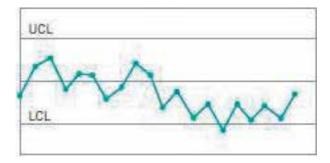


Figure 25. Example of a control chart showing a shift in process level pattern.

Trend: An example of a control chart showing a trend pattern is given in Figure 26. In a trend pattern, the plotted points continuously move in one direction. An \bar{x} control chart having a trend pattern may result from gradual wearing or deterioration of a tool or component, human causes, such as operator fatigue or the presence of supervision, and seasonal influences like temperature.

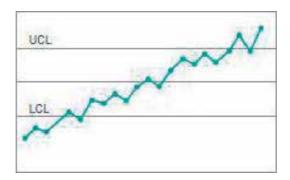


Figure 26. Example of a control chart showing a trend pattern.

Stratification: An example of a control chart showing a stratification pattern is given in Figure 27. In a stratification pattern, the plotted points tend to cluster around the center line, and there is a lack of natural variability in the pattern. An \bar{x} control chart having a stratification pattern may result from incorrect calculation of the control limits, or if there are subgroups, several different underlying distributions might be collected in the sampling process.

Approaching LCL: An example of a control chart showing an approach to LCL pattern is given in Figure 28. A p-control chart having an approach to LCL pattern may represent a real improvement in process quality. But, downward shifts are not always attributable to improved quality. This is due to the fact that errors in the inspection process may be resulting from inadequately trained or inexperienced inspectors or from improperly calibrated test and inspection equipment during that particular shift. Besides, inspection may pass nonconforming units owing to a lack in training. The same interpretation is valid for np-control charts also.

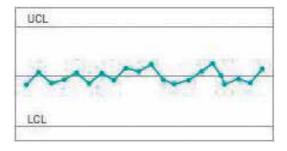


Figure 27. Example of a control chart showing a stratification pattern.

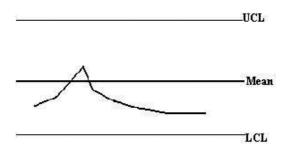


Figure 28. Example of a control chart showing an approach to LCL pattern.

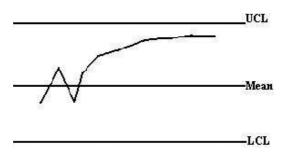


Figure 29. Example of a control chart showing an approach to UCL or LCL pattern.

Approaching UCL or LCL: An example of a control chart showing an approach to UCL or LCL pattern is given in **Figure 29**. A c-control chart having approaching the UCL line may be because of temperature control and an approach to the LCL may be due to inspection error.

3.6. Categorical guidelines other than patterns

Some definitive guidelines are developed to interpret control charts. Keeping in mind that the main principle is none of the points should cross UCL or LCL, the developed standards can be grouped as follows showing that process is out-of-control:

Point/Points crossing the control limits: Examples of control charts showing point/points crossing the control limits are given in **Figure 30**. If there is an assignable cause in the \bar{x} control chart, this is related with either raw material, erratic method, or human error. The latter may be attributable to either changes in raw material lot, changes in microstructure, changes in measuring and control methods, changes in machine adjustments, or wrong reading by the

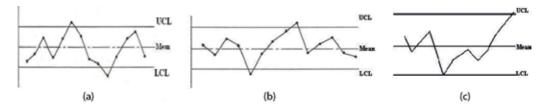


Figure 30. Examples of control charts showing point/points crossing the control limits.

operator. If there is an assignable cause in the R-control chart, this is related with either machine or measuring instruments. Some noteworthy cases are, say, not calibrated measuring instruments, showing as such a low sensitivity value, the systematic causes of deterioration of production machines, as well as low machine maintenance. If there are points lying out of the control limits in both the \bar{x} and R chart, this means that the calculation of the UCL and LCL would have been either wrong, or that the points were placed erratically. In addition to this, the process would have been out-of-control, the measuring system might have changed, or the measuring instrument may not be working properly. If one or more points fall sharp beyond or get close to the UCL or LCL, this is evidence that the process is out-of-control. A detailed investigation of the current circumstance has to be done, and corrective action has to be taken.

Many points very near to the control limits: An example of a control chart showing many points that are very near to the control limits is given in **Figure 31**. This pattern may be toward UCL or LCL.

Points gather around a value: An example of a control chart showing points gathering around a value is given in **Figure 32**.

Consecutive points: All the consecutive seven points which are placed on one side of the center line is given in **Figure 33**. About 10 out of 11 consecutive points that are placed on one side of the center line is shown in **Figure 34**.

This expression can be widened as 12 out of 14 consecutive points, 14 out of 17 consecutive points, 16 out of 20 consecutive points, and 19 out of 25 consecutive points (**Figure 35**) are placed on one side of the center line. They all indicate very nonrandom appearance and an out-of-control production.

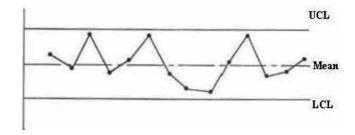


Figure 31. Example of a control chart showing many points that are very near to the control limits.

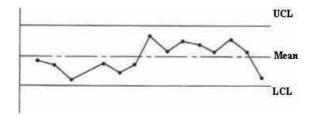


Figure 32. Example of a control chart showing points gathering around a value.

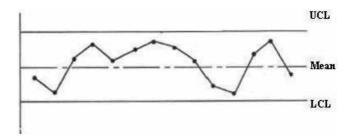


Figure 33. All of the consecutive 7 points are placed on one side of the center line.

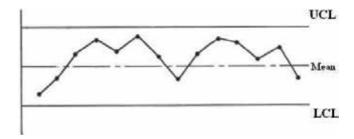


Figure 34. 10 out of 11 consecutive points that are placed on one side of the center line.

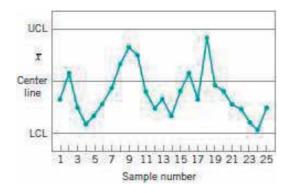


Figure 35. 19 out of 25 consecutive points are placed on one side of the center line.

Runs: Average run length is the average number of points that must be plotted assignable before it can be said that it is an out-of-control condition. They describe the performance of the control charts. Some examples are:

A run of 2 points out of 3 near the control limits is given in **Figure 36**.

Others may be a run of 4 points out of 5 at a 1σ distance from the center line, a run of 8 points lie at one side of the center line, and a run of 7 points rises or falls (**Figure 37**).

The placement of the points according to the center line is also important. 2/3 of the points have to lie between the inner 1/3 distance between the UCL and LCL's and 1/3 of the points

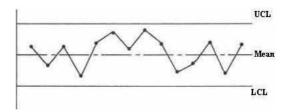


Figure 36. A run of 2 points out of 3 is near the control limits.

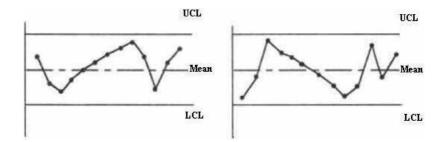


Figure 37. A run of 7 points rises or falls.

have to lie between the outer 2/3 distance between the limits. If more or less of the 2/3 of points lie near the center line, then this means either the limits were calculated wrong or the points are placed erratically on the chart, successive measurements may have been from different parties in production but located on the same chart by fault, or the machine adjustments have changed but the control operator was not aware of it and located the points on the same chart by fault instead of preparing a new chart.

Examples of less than 2/3 of points lie in the middle 1/3 of the control limits are given in **Figure 38**.

An example of clear shifts for different periods is given in **Figure 39**. The reason for these shifts would be that the process is changing periodically, and so, different limits have to be calculated for different periods. Another reason would be that the lot had been changed, but the person in charge is not aware of it and continues to plot two different lots on the same chart rather than preparing a new one for the new lot.

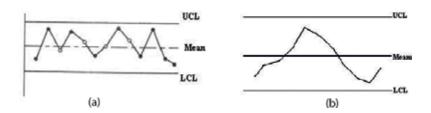


Figure 38. Less than 2/3 of points lie in the middle 1/3 of the control limits.

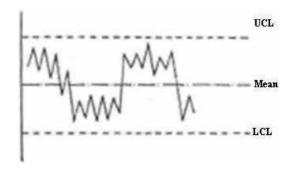


Figure 39. Example of clear shifts for different periods.

4. Discussion

A number of researches have been performed on the topic of control charts. Indeed, the majority of studied works emphasize the early prediction of defects and on different areas like poultry, health, etc., other than manufacturing which is the main area these are used. A short survey of new developments in control charts is given below.

There are some statistics software packages which also include preparations of control charts like SPSS, MATLAB, STATISTICA, etc. These software packages utilize the usage of control charts in companies, service, and official applications. With the help of computers, much of the work done by hand is performed very quickly, and results are obtained right away. The results are interpretated fast, and corrective action is taken to increase efficiency and profit in the enterprise. Furthermore, new techniques like artificial neural networks are applied in modern quality control methods and techniques.

4.1. Research on control charts done in Turkey

The authors use Shewhart control charts to maintain the quality of raisins (dried grapes) and dried figs within acceptable limits and make it possible to readjust storage conditions, if the acceptable limits should be violated. This occurs since the Shewhart control charts they use are constructed by using the Hunter *Lab* color scale parameters to assure maintenance of the color and flavor of raisins and dried figs during storage in modified atmosphere packages, vacuum packages, or nylon bags. Changing the storage conditions after the fruits have deteriorated cannot improve quality because deterioration of raisins or figs is irreversible. In the early stages of storage, violation of the control limits will warn the operators, and the storage conditions will be improved [15].

The authors used the program which was designed by Montgomery to prevent errors and wastage of resources during sampling process in order to determine the economic design of parameters. The economical design of Shewhart control charts improves the principle of balancing between control efficiency and its costs. They did an application in a fruit soda producing factory. It is worth noting at this point that although staff was trained about total

quality control, they were not adequately trained in statistical quality control. After the work of the authors, with this program and by paying attention to the lost functions and unit costs, design parameters, sample size, sampling interval, and the control limits were determined, resulting in a reduction of errors [16].

It is the author's view that coal properties are variable even within a single coal seam due to coalification history, mining method, etc. To control the variability of coal quality is important from the points of efficiency and production costs of power plants. These are negatively affected by nonconsistent coal characteristics such as calorific value, moisture content, and ash content and profitability of the coal producer. Variations in coal properties of the Tuncbilek Power Plant were studied by means of control charts, and process capability analysis of the statistical quality control methods was found to be very high. The latter showed variation within short intervals and away from contract specifications. It was suggested that the coal should be blended to reduce the variability in coal characteristics before selling to power plants, so that the efficiency of the power plant and the income of the coal producer can be increased [17].

The authors obtained the control limits of \bar{x} and R-control charts for skewed distributions by considering the classic, the weighted variance (WV), the weighted standard deviations (WSD), and the skewness correction (SC) methods. They compared these methods by using Monte Carlo simulation, Type I risk probabilities with respect to different subgroup sizes for skewed distributions, which are Weibull, gamma, and log-normal. They concluded that Type I risk of SC method is less than that of other methods, the Type I risks of Shewhart, WV, WSD, and SC $^{\rm X}$ charts are comparable when the distribution is approximately symmetric, and the SC R chart has a smaller Type I risk [18].

It is worth noting however that statistical quality control charts (SQCCs) are widely used in manufacturing processes so as to keep fluctuations within the acceptable limits; nonetheless, no application is done to weight management studies. In this paper, the author proves that using the mean Body Mass Index (BMI) values as the only indicator to assess the weight status of populations might be misleading in clinical weight management studies. For healthy aging, the author suggests to introduce a powerful tool, SQCCs, to keep fluctuations in BMIs within acceptable limits in a given population and makes a cross-sectional design. The distributions of individual BMIs and the pattern of BMI which change by age were studied using X charts, tolerance charts, and a capability analysis was performed. It is concluded by the author that the mean BMI increased in both genders by age as seen in Figure 40. Likewise, the individual weights were out-of-control limits, the mean BMI values were within the limits, and although the number of overweight individuals was greater in some groups, their mean BMIs were lower compared to the groups with fewer overweight individuals. Capability tests concluded that each group, even the groups with a mean BMI in the normal weight ranges and also the groups which are referred as being "under control" according to the X charts, was not within the so-called energy balance (Cp < 1 and $Cp_k < 1$). The results suggest that by using the mean BMIs as the only indicator might be misleading in weight management studies. This work introduces SQCCs as a potential tool for clinical nutrition studies to maintain the fluctuations of individual BMIs within acceptable limits for healthy aging populations [19].

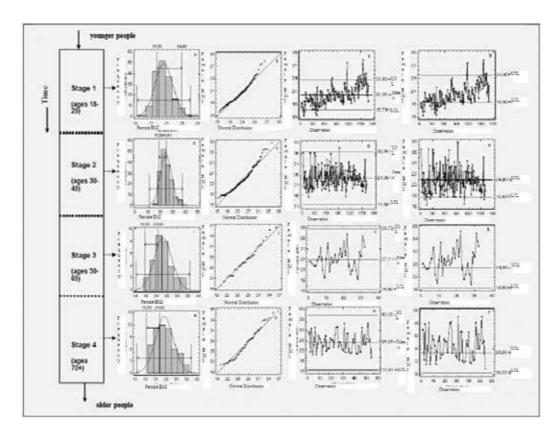


Figure 40. Mean BMI increase in females by age.

The authors constructed modified Shewhart charts incorporating weight loss, Haugh units and yolk index for storage of untreated, soda lime, water glass, or oil coated and thermostabilized eggs. The data obtained showed differences between particular treatments. Control charts derived from them illustrate that maintenance lies within the limits of the inevitable quality loss, and this comes from the storage of eggs. Knowing the trends made it possible to readjust the storage conditions so as to prolong the period before the violation of acceptable limits [20].

In determining the quality of the egg shell, broken or cracked eggs are important factors. The manufacturers need control charts throughout production to keep the number of broken or cracked eggs under control. The authors in this paper used p-control charts prepared with 52 weeks data in poultry business. They used three methods to draw control charts and concluded that the process was not under control because the number of broken or cracked eggs often crossed the upper control limit [21].

4.2. Research on control charts done in Greece

When the vector of means of several quality characteristics are monitored, the most widely used multivariate control chart is the Hotelling's $\chi 2$ control chart, which is a Shewhart-type control chart, and it is relatively insensitive to detect small magnitude shifts quickly. The

authors study the performance of the Hotelling's $\chi 2$ control chart supplemented with a rout-of-m runs rule. Their new control chart exhibits an improved performance over other competitive runs rules based control charts [22].

When the quality characteristics cannot be measured on a continuous scale, attribute control charts are very useful for monitoring different processes. Some cases involve the monitoring of multiple attributes simultaneously. This leads to multinomial and multiattribute quality control methods, which are better than the simultaneous use of multiple uniattribute methods. The authors equally studied research previously conducted on multiattribute quality control, regarding the design, performance, and applications of multiattribute control charts (MACCs), as well as multiattribute sampling plans. They also reviewed comparisons of the MACCs, as well as MADM research. They also emphasized the need of neural networks, the design of artificial neural network in attributes monitoring for an out-of-control signal, the detection of the magnitude of the shifts in parameters, the determination of the shape of the membership functions in linguistic terms, the appropriate degree of fuzziness of the membership functions, the exact relationship between the degree of fuzziness and sensitivity of control charts, and in nonhomogenous cases, where the distribution is no longer binomial what the properties of the process *p* chart should and as such may form a subject for further investigation [23].

The authors have examined the problem of the statistical and economics-based design of fully adaptive Shewhart control charts for monitoring finite-horizon processes, where the production horizon for a specific product can be limited to a few hours or shifts. They propose a Markov chain model to design a fully adaptive Shewhart control chart for such cases. Their Markov chain model allows the exact computation of several statistical performance metrics, as well as the expected cost of the monitoring and operation process for any adaptive Shewhart control chart with an unknown but finite number of inspections. The implementation of the Vp *X* chart in short runs shows the production of a finite batch of products. They also support two models, namely one that is economics based and one that is aimed for the statistical design. These charts can also be used to optimize the performance of any adaptive control chart (VSSI, VSI, VSS, and Vp) in a finite-horizon context. They derived some properties of the economics-based model, which facilitates economic optimization and CUSUM adaptive control charts can also be developed [24].

The authors presented the economic design of \overline{x} control charts for monitoring a critical stage of the main production process at a ceramic tiles manufacturer in Greece. They developed two types of \overline{x} charts:

- A Shewhart-type chart with fixed parameters and,
- An adaptive chart with variable sampling intervals and/or sample size.

They aimed to improve the statistical control scheme employed for monitoring quality characteristics and minimize the relevant costs. They also tested and confirmed the applicability of the theoretical models supporting the economic design of control charts with fixed and variable parameters and evaluated the economic benefits of moving from the broadly used static charts to the application of the more flexible and effective adaptive control charts. They concluded that by re-designing the currently employed Shewhart chart using economic criteria, the quality-related cost is expected to decrease by approximately 50% without

increasing the implementation complexity. It is the author's view that by monitoring the process by means of an adaptive \bar{x} chart with variable sampling intervals will increase the expected cost savings by about 10% compared with the economically designed Shewhart chart at the expense of some implementation difficulty [25].

The author studied the factors that affect the Brix value and the volatile acidity of the final product in the bio-production of grape molasses, considering the ground used for cultivation and the variety of grapes. The author applied off-line statistical quality control techniques and discussed the outcomes in detail, concluding that Corinthian and Camborne varieties of grapes seemed to lead to the optimum result because the Brix value is optimum and grape molasses, while Phocean and Corinthian varieties of grapes were the best choices in order to decrease their volatile acidity, and mountain ground was better [26].

The author indicates that Statistical Process Control procedures are based on the assumption that the process subject to monitoring consists of independent observations. Many nonindustrial processes besides chemical processes exhibit autocorrelation, where the assumption is not valid. The author has developed a methodology for monitoring autocorrelated processes. The main idea here is to compare the performance of the time series model against an alternative which works with departures from it. A phase II control procedure is proposed, which is a time-varying auto-regressive (AR) model for autocorrelated and locally stationary processes. That model is optimized during phase I, and as a result, the model describes the process accurately. The phase II control procedure is based on a comparison of the current time series model with the alternative model which is measuring deviations from it, using Bayes factors where its threshold rules enable a binomial-type control procedure. This model can equally be used in local nonstationarities via the dynamic evolution of the AR coefficients, and so it describes stable and nonstable processes. In particular, this method can be used in nonindustrial process monitoring, where nonstable or nonstationary processes are typical (finance, environmentrics, etc.). Temperature measurements at two different stages in the manufacturing of a plastic mold are used as data sets [27].

In statistical quality control, control charts are the most widely used and are regarded as an effective tool. This work presented recent developments in the design of the adaptive control charts, especially in univariate control charts because they allow some of their parameters to change during production. They also act as an extension of the study of Tagaras. Based on performed literature review, it may be stated that the adaptive control charts may result to faster detection of a process shift and thus may contribute to improving overall economic performance. However, they are harder to administer, and their application may run up against technical difficulties. The design parameters which are the sample size, the sampling interval, and the control limit coefficient can be changed in adaptive control charts, while warning limits are added and improvements are gained. This study has equally shown that the more parameters are adaptive, the more improvement is obtained, hence, making the implementation of the control chart more difficult. The performance measures of the adaptive control charts which are derived from the Markov chain approach are discussed in this paper. The authors are interested in monitoring the process dispersion instead of the process mean. They indicate that in the S or R chart and the conforming run length chart, modification can be applied in order to detect variance shifts, and these shifts prove to detect increase in σ better than the decrease and are useful to monitor both the process mean and the process variance shift. It is the author's view that users may misuse the cause-selecting chart in production steps because of unsatisfactory training, and this may lead to unnecessary adjustment that could increase the variability and as such the cost of the products. In view of the above, the dependent processes can be extended to the VP charts as well as to multiple process steps, multiple assignable causes, and dependent assignable causes. EWMA and the CUSUM charts are more effective than the standard Shewhart charts because they take into account both the present and previous samples. The adaptive control charts for attributes are also studied in this paper, and it is shown that by adding the adaptive feature, the detection ability of the charts is increased [28].

4.3. Research on control charts done in Bulgaria

In today's world, the pursuit of high quality production is one of the main topics. The need for use of the specific software products so as to control the production process quality is the result of the variety and complexity of the production characteristics. SPSS is the most widely used software, which provides increased deliverables for a basic quality control analysis. A critical review of SPSS quality control functions and features is done, which contributes to enhanced quality management. It is worth mentioning at this point though, that aforementioned software package is facing competition from Minitab and Statistica to name but a few. In the future, it is hoped to find a universal all-in-one tool for the data processing without any insufficiencies concerning quality control functions and statistical analyses [29].

4.4. Research on control charts done in China

Performed literature research indicates that pattern recognition technology is used to automatically judge the changing modes of control chart, which reveal potential problems. They propose a neural network-numerical fitting (NN-NF) model to recognize different control chart patterns with the purpose of improving the recognition rate and the efficiency of control chart patterns. They first use a back propagation (BP) network and then Monte Carlo simulation to generate training and testing of the data samples. If the control chart patterns are recognized with the general run rules, the abnormal report is directly generated, if not, the NN-NF model is activated. Training time of their NN-NF model is less, and the recognition rate is also improved [30].

In addition to the above, a skewness correction (SC) method is proposed for constructing the \overline{X} and R-control charts. The latter are adjustments of the conventional Shewhart control charts for skewed process distributions. Their asymmetric control limits are based on the degree of skewness estimated from the subgroups, and no parameter assumptions are made on the form of process distribution. The new developed charts are compared with the Shewhart charts and weighted variance (WV) control charts. It is concluded that when the process distribution is in the proximity of a Weibull, log-normal, Burr, or binomial family, performed simulation showed that the SC control charts had a Type I risk closer to 0.27% of the normal case. Also, in the case where the process distribution is exponential with a known mean, both the control limits and the Type I risk, as well as the Type II risk of the SC charts, are closer to those of the exact \overline{X} and R charts than those of the WV and Shewhart charts [31].

4.5. Research on control charts done in Tunisia

This paper emphasizes that control chart pattern recognition (CCPR) is a important task in statistical process control (SPC). Abnormal patterns in control charts can be associated with certain assignable cause adversely affecting the process stability. Work is aimed at reviewing and analyzing research on CCPR. In conjunction with this, a new conceptual classification scheme emerges, based on a content analysis method, so as to classify past and current developments in CCPR research done in more than 120 papers within the period 1991–2010. It was found that most of the CCPR studies dealt with independently and identically distributed process data; some recent studies pertaining to the identification of mean shifts or/and variance shifts of a multivariate process were based on innovative techniques. It is worth mentioning at this point though that there is an increase in the percentage of studies that address concurrent pattern identification as well as in Artificial Neural Network (ANN) approaches for improving the recognition of pattern together with hybrid, modular, and integrated ANN recognizer designs. The latter may be combined with decision tree learning, particle swarm optimization, etc. There are two main categories of performance criteria used to evaluate CCPR approaches: statistical criteria that are related to two conventional average run length (ARL) measures and recognition-accuracy criteria, which are not based on these ARL measures mainly for ANN-based approaches. Performance criteria with ARL measures are insufficient and inappropriate in the case of concurrent pattern identification. The authors also discuss some future research directions and their perspectives [32].

5. Conclusion and further work

Control charts are important tools of statistical quality control that enhance quality. Quality improvement methods like flow diagrams, cause-and-effect (fishbone) diagrams, check sheets, histograms, scatter plots, and Pareto diagrams have also been applied so as to fulfill the needs of consumers with the desired properties and the least possible defects in the output, while maximizing producers' profit. There are natural variations in production but also assignable causes which are not a part of chance but may be attributable to a number of internal and/or external factors like raw material, machine setting (or adjustment, tool abrasion, systematic causes of deterioration) or measuring method, human, and environmental effects.

This paper provided a qualitative and quantitative insight into the use of only the control charts. Based on a number of industrial cases, it showed that the implementation of control charts can indeed contribute to defects minimization and, hence, reduce warranty and other costs.

Control charts mainly used are control charts for variables, that is, individual measurements control chart (x), means control chart (\bar{x}), ranges control chart (R) and standard deviation control chart (s), and control charts for attributes, that is, control chart for fraction nonconforming (p), control chart for the number of nonconforming items (np), control chart for conformities per unit (u), and control chart for nonconformities (c). Sensitivity, sample size, and sampling frequency (specific and equal time intervals) are important effectors on the performance of the control chart. Upper and lower control limits are calculated by using different equations for each control chart. Points are plotted on the charts, and they have to be in between the UCL and LCL for a normal production. This, however, is not deemed to be enough to keep production under control. The pattern made by the points on the chart needs

to be interpreted. Corrective actions are taken to keep production under control and bring the points back in between the control limits for the product to be at tolerable distance to the specified nominal values. The performance of a control chart is precise, even if it is the result of small sample sizes in production for tests done everyday.

The case studies presented herein showcase that control charts result in higher production efficiency and are as such used widely in industry. This work has equally highlighted performed research in the area of control charts. Indeed, research on control charts is done on a global basis, and from the findings discussed in this work, statistical methods and techniques are further empowered by the use of computer technology and, in particular, dynamic software packages and artificial neural networks, to name a few. In view of the above, it may be stated that Statistics may further assist its users by refined and selected methods to improve quality in a modern way besides control charts.

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Appendix 1 [7]

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Quality management systems form an integral part of modern corporations. Acknowledging current socio-economic and environmental challenges, quality standards ought to be dynamic and flexible so as to cater for different markets and requirements.

This book portrays a collection of international papers addressing current research and practice within the areas of engineering and technology, health and education.

Amidst striving for "zero defects", "cost-effectiveness" and "tight financial budgets", quality management systems ought to embrace the creator of them all: humans; as the ancient Greek Sophist Protagoras said, "Of all money, Man is the measure" «Πάντων χρημάτων Μέτρον Άνθρωπος» (Plato, Theaetetus 166d).

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