Use of IT in ISO 9001 Systems for Better Process Management

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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

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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;

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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].

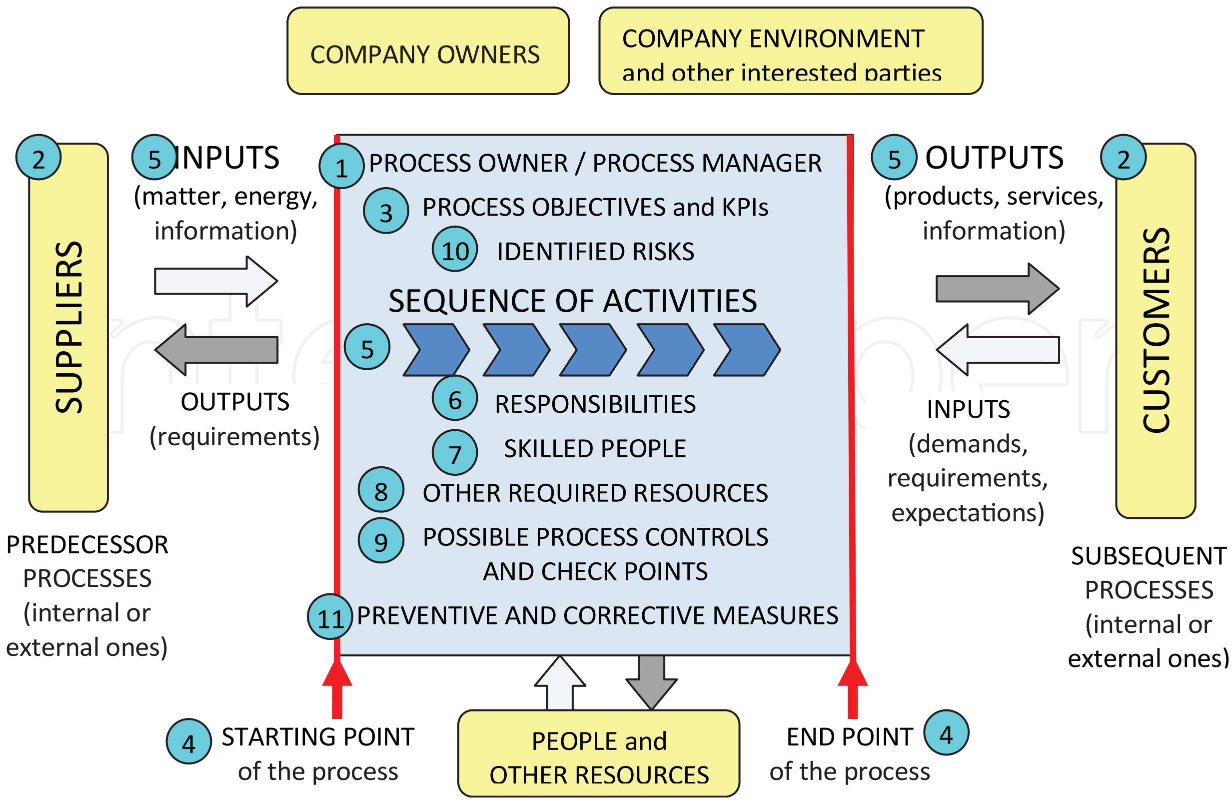

Figure 1. Schematic representation of the elements of a single business process.

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.

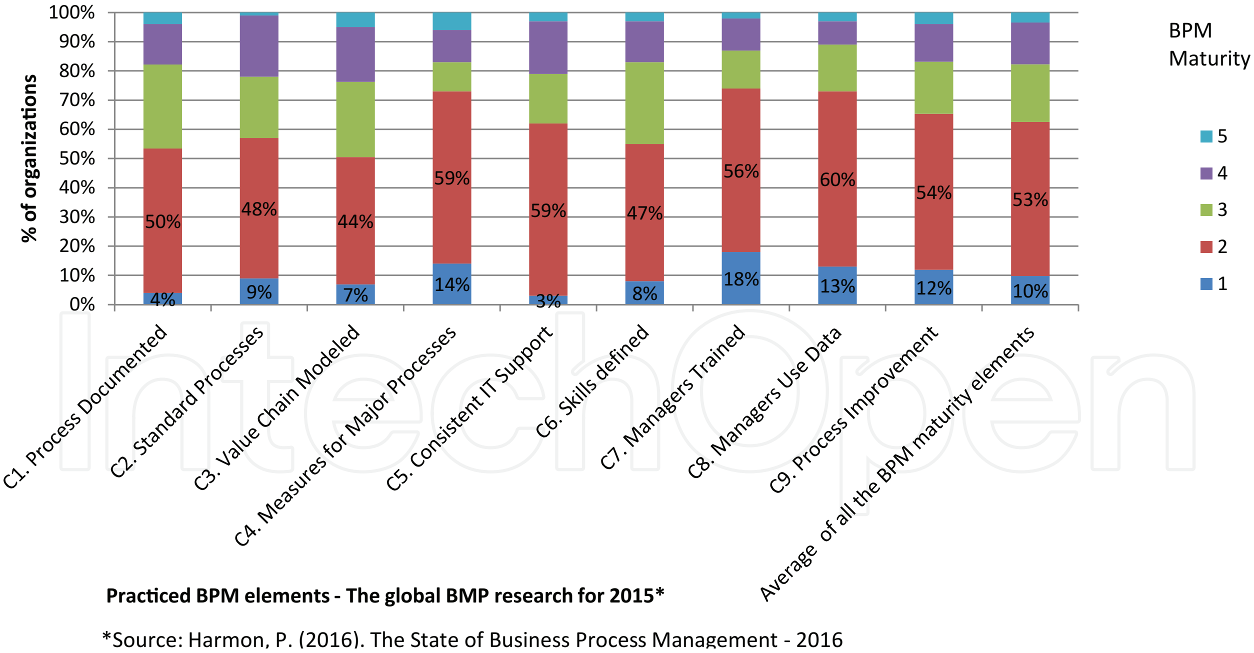

Figure 2. Global BPM maturity survey results for 2015.

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 QMS.

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].

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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
Trade	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
IT-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**.

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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 level							
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].

Table 3. BPM maturity level of ISO 9001 audited organizations compared with results of global BMP research.

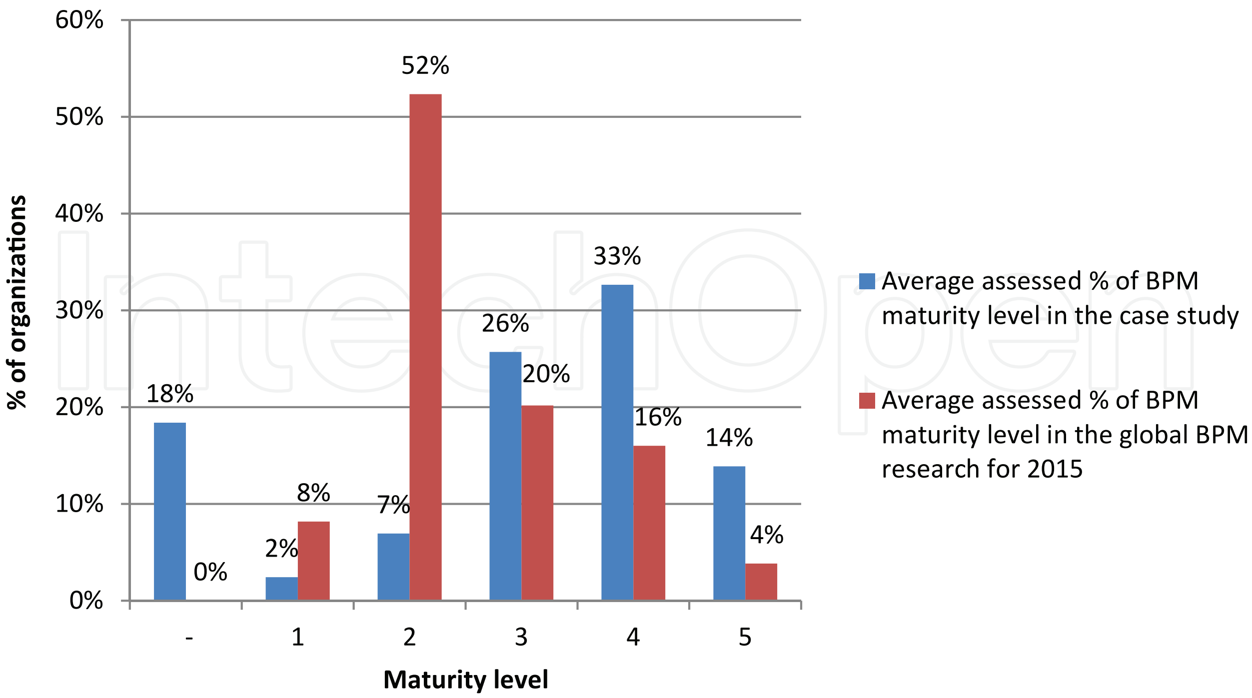

Figure 3. Practiced BPM elements of ISO 9001 audited organizations compared with results of global BMP research.

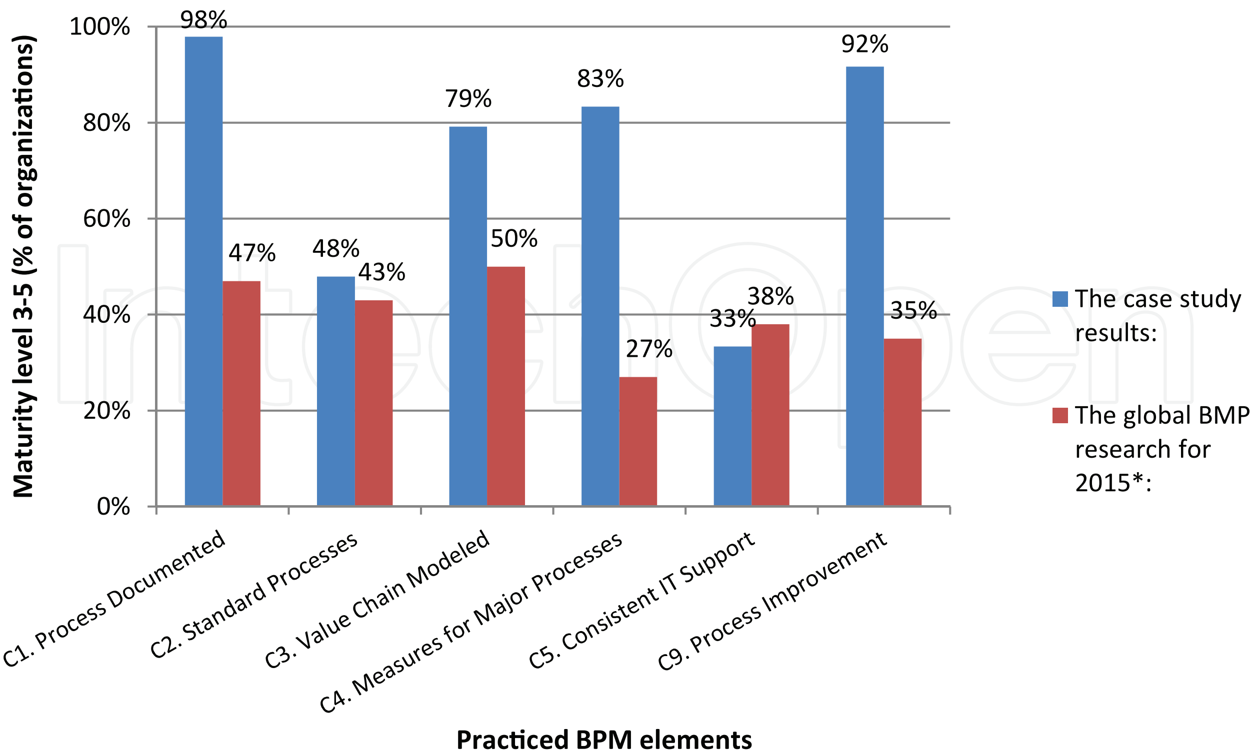

Figure 4. ISO 9001 audited organizations at BPM maturity level 3–5 compared with results of global BMP research.

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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Abstract

There is ample historical and scientifically proven information regarding the health benefits of spice paprika, including favourable physiological effects, anti-oxidant and anti-inflammatory 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.

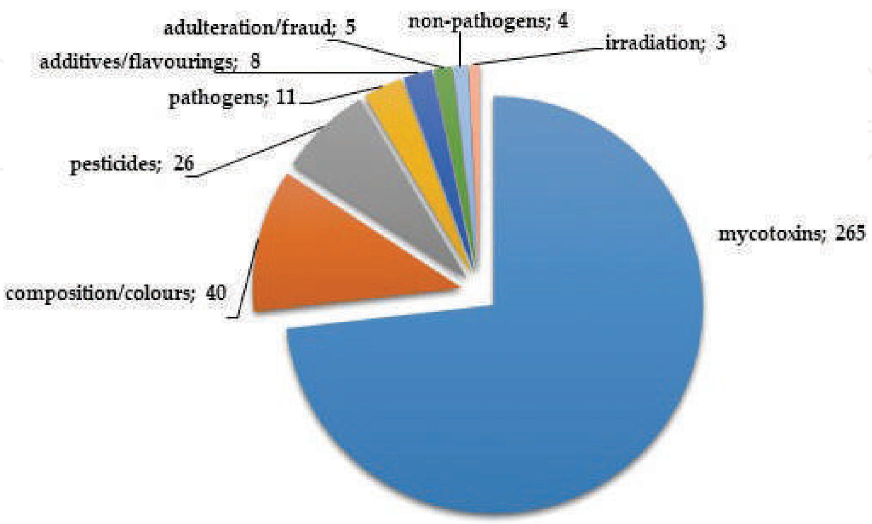

Figure 1. The number of notifications in RASSF between 2007 and 2016 regarding contamination of spice paprika.

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 mid-early (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 R^2 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 non-target 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

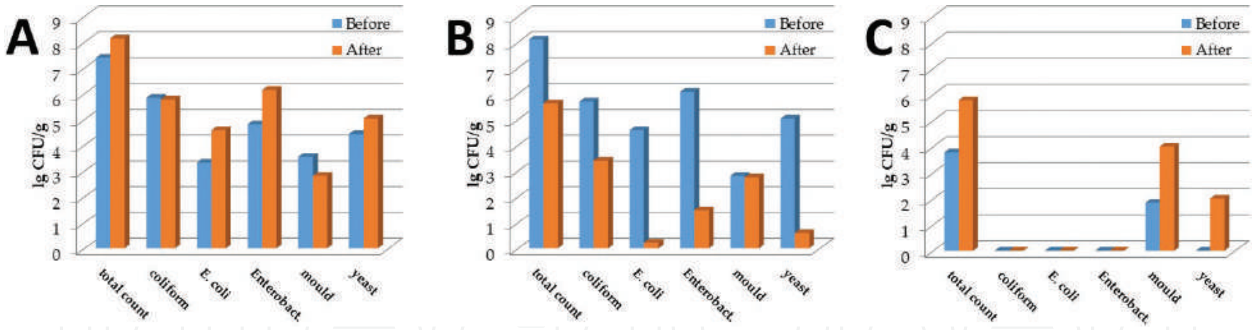

Figure 2. The effect of technology steps on the microbial status of the paprika half-product. **A**: slicing, **B**: drying, **C**: grinding.

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, 10^8–125°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 $6.3*10^4$-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 ($^{87}Sr/^{86}Sr$ 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 class-modelling 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 δ18O elemental analysis of source and paprika fruit water, and on compound-specific, n-alkane, δ2H 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 μg/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 10^2 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

Ross Sparks

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	13.219

(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	10.384

(c)

k	0.3	0.3125	0.325	0.3375	0.35	0.375	0.3875	0.4	0.4125
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

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δ									
1.00	6.6253	**6.619**	6.620	6.641	6.655	6.713			
1.05	6.233	6.195	**6.187**	6.188	6.203	6.229	6.280		
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	2.796	2.795	**2.794**	2.795	2.799	2.806	2.804		
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	10.092

(e)

k	0.375	0.4	0.425	0.45	0.475	0.5	0.525	0.55	0.575

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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	5.308	5.254	5.233	**5.223**	5.228	5.252		
1.50	5.143	5.076	4.983	4.979	4.980	**4.969**	4.981	4.992	
1.55	4.913	4.831	4.756	4.747	4.726	4.725	**4.717**	4.725	4.738

(h)

k	0.65	0.70	0.725	0.75	0.775	0.80	0.825	0.85	0.875
δ									
1.60	4.512	4.499	4.504	**4.498**	4.499	4.509			
1.65	4.316	4.284	4.287	4.280	4.294	**4.274**	4.302		
1.70	4.159	4.114	4.097	4.099	4.099	4.096	**4.083**	4.098	
1.75	3.986	3.945	3.931	3.932	3.916	3.911	3.913	**3.910**	3.928

(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

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

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

$$C_t^U(k) > h(k) \quad (2)$$

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:

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

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 $k = 0.25$.

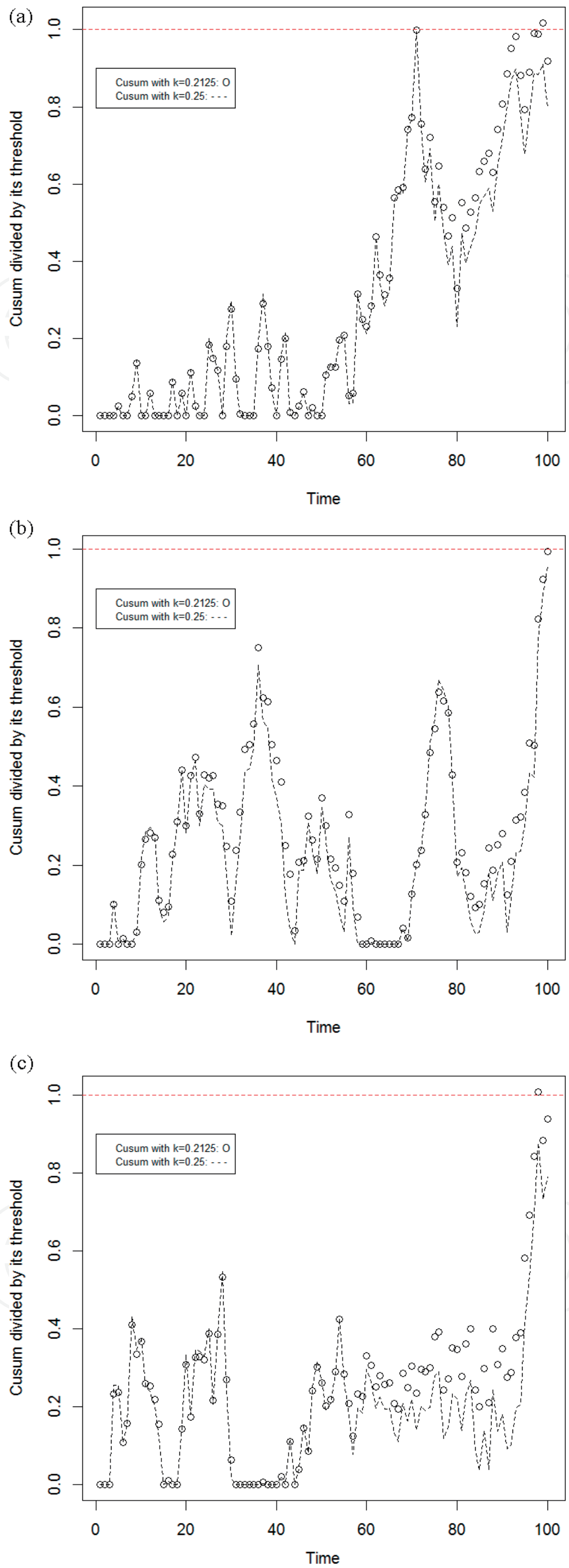

Figure 1. (a) Example 1 of when zero state optimal $k = 0.25$ does not do better than $k = 0.2125$. (b) Example 2 of when $k = 0.2125$ resets the CUSUM to zero than $k = 0.25$ and there has a better chance of detecting small shifts early. (c) Example 2 of when zero state optimal $k = 0.25$ does not do 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 in-control ARL = 200 and a location shift of $\delta = 0.5$ 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 $k = \delta/2$ is never the plan with the smallest out-of-control ARL—the k with the smallest out-of-control ARL is always smaller than $\delta/2$; 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 $\delta = 0.5$ 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**, $k = \delta/2$ 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 $\delta/2$ but now the difference between the k with the smallest out-of-control ARL and $\delta/2$ 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.,

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

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	$\alpha=0.2$	$\alpha=0.2$	$\alpha=0.6$	$\alpha=0.7$
	$h_{adj}=1.2271$	$h_{adj}=0.9215$	$h_{opt}=1.005$	$h_{opt}=1.172$
	$k=SP_t/2$	$k=SP_{t-1}/2$		
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	α **= 0.2**	α **= 0.2**	α **= 0.6**	α **= 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	α **= 0.2**	α **= 0.2**	α **= 0.6**	α **= 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

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

Delta	$\alpha = 0.2$	$\alpha = 0.2$	$\alpha = 0.6$	$\alpha = 0.7$
	$h_{adj} = 1.4311$	$h_{adj} = 0.909$	$h_{opt} = 1.3042$	$h_{opt} = 1.5196$
	$k = SP_t/2$	$k = SP_{t-1}/2$		
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

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

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

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

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

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

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

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

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

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

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

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 $0 < \delta \leq 0.75$ and $\delta \geq 2.25$ for in-control ARL = 200, but for all in-control ARL tried (in-control ARL≠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.

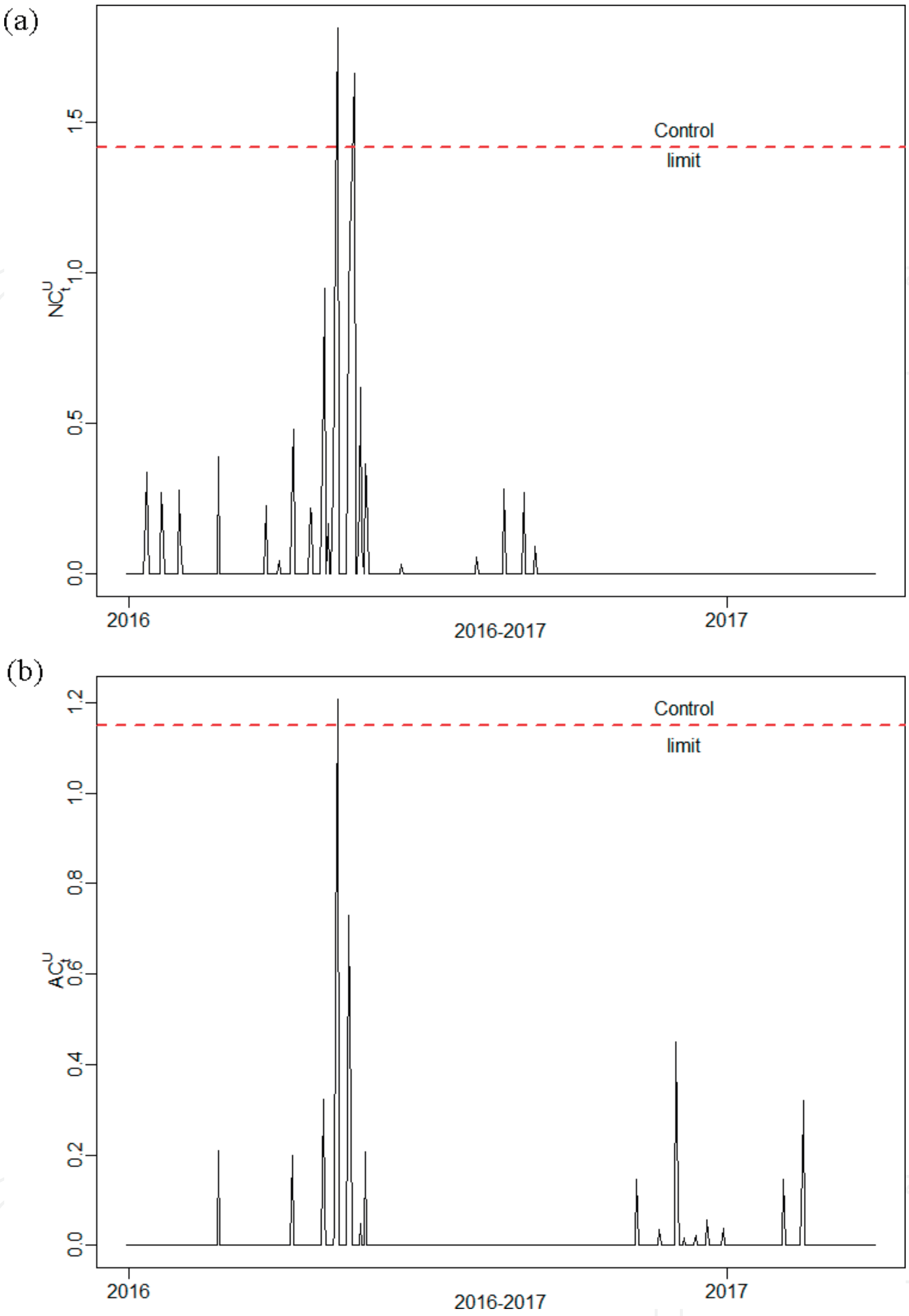

Figure 2. (a) The adaptive CUSUM $NC_t^U(k)$ advocated in this paper for in-control ARL = 200. (b) The adaptive CUSUM of Sparks [12].

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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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**.

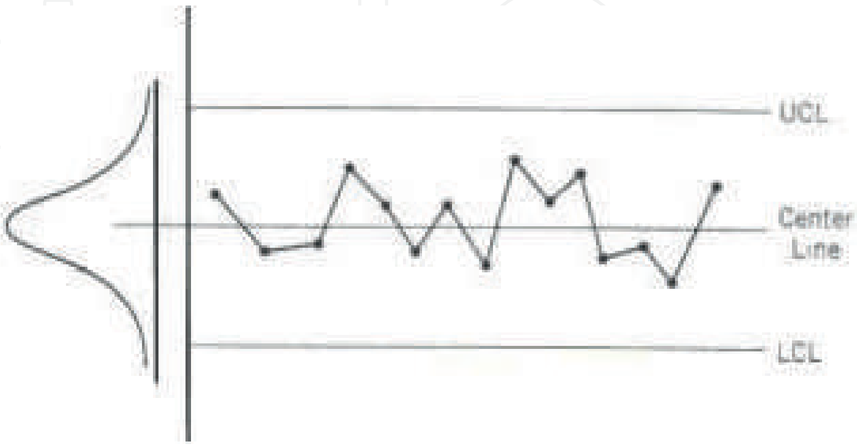

Figure 1. Sample of a control chart.

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].

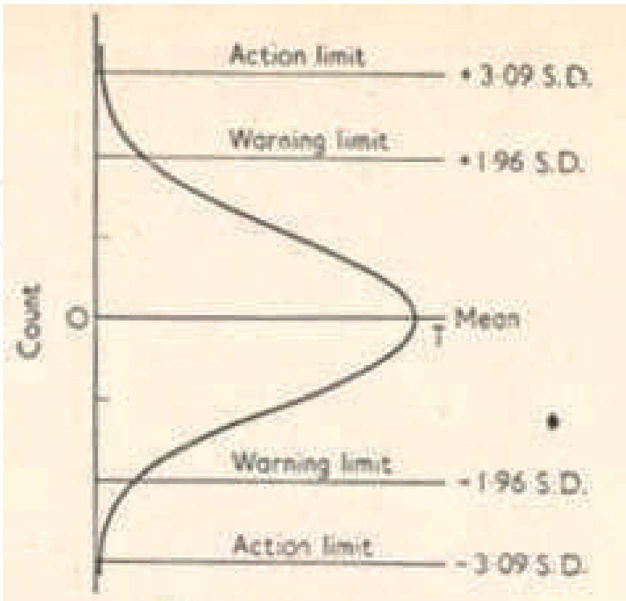

Figure 2. Warning and action limits for large samples.

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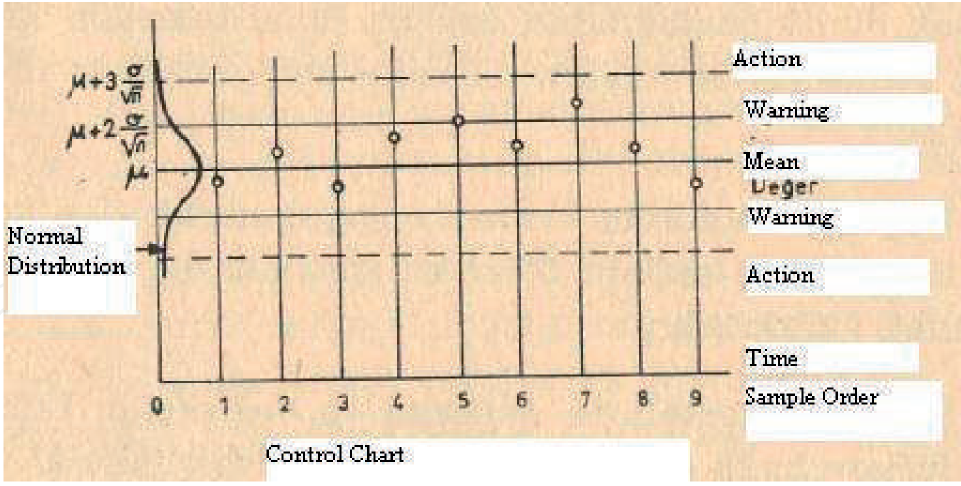

Figure 3. Warning and action limits for small samples.

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

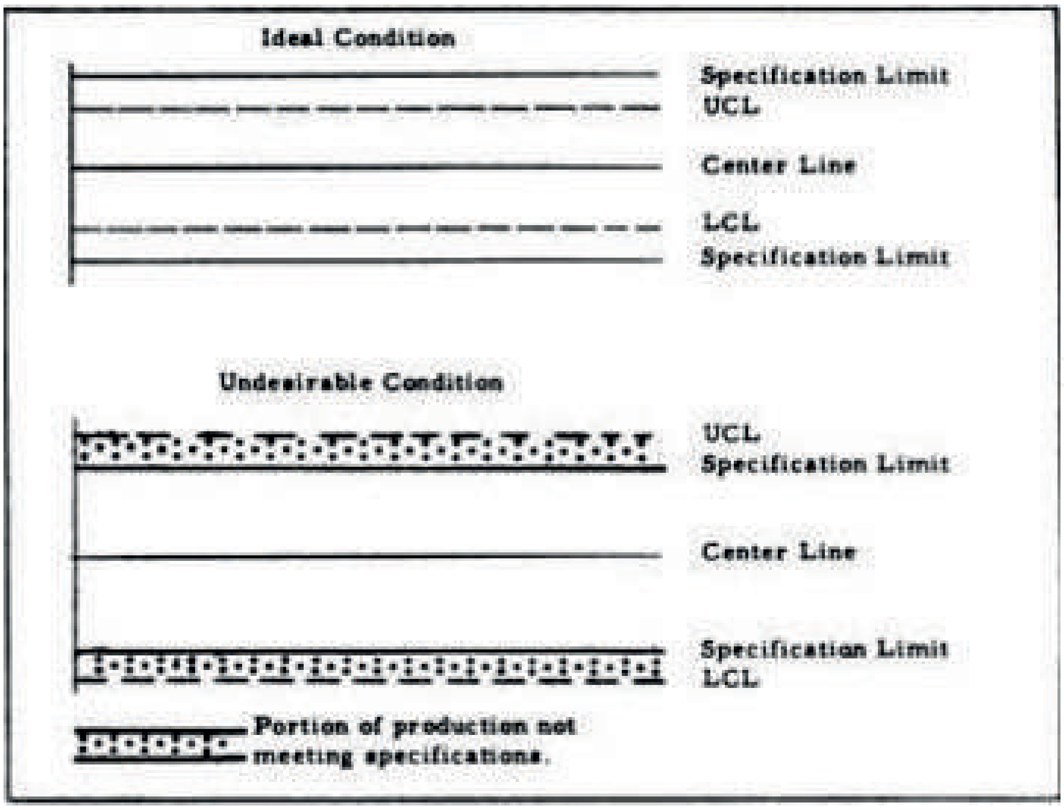

Figure 4. Placement of UCL and LCL according to specification limits.

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**).

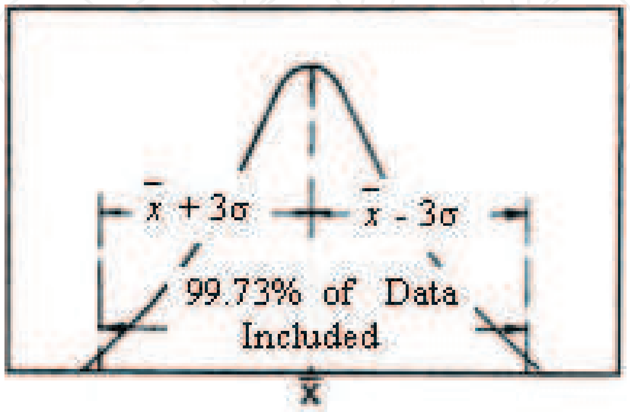

Figure 5. Representation of 99.73% probability.

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 ($\bar{x}$),
- Ranges control chart (R),
- Standard deviation control chart (s).

Others are s^2 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, T^2 control charts, Hotelling T^2 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;
6. Continue to plot the new values collected in due time on the chart;
7. 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 ($\overline{\mathrm{MR}}$) is calculated;
4. UCL and LCL are calculated by $\overline{x} \pm 2.66\ \overline{\mathrm{MR}}$ formula;
5. Control chart lines are drawn with the center line ($\overline{x}$), 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].

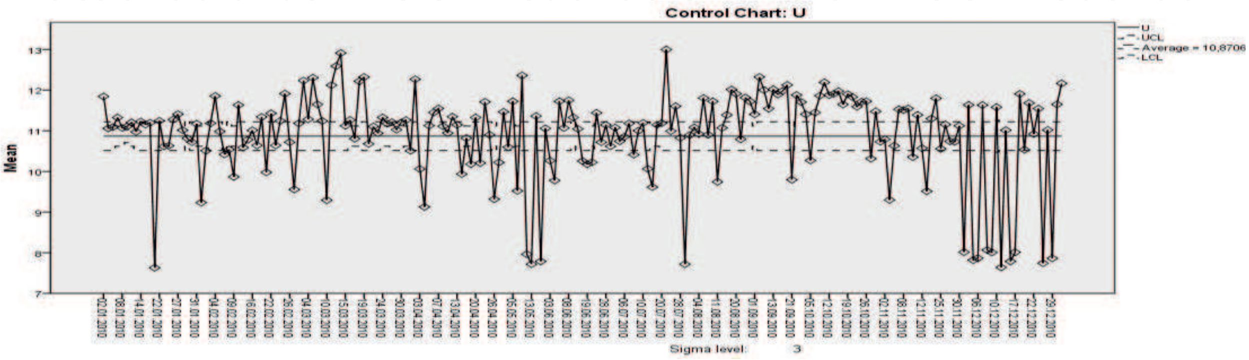

Figure 6. Application of X chart to yarn irregularity quality characteristic (U%) of the Kaynak group cotton yarn factory's regular measurements.

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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 $\overline{x}$;
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 $\overline{x}$ ($\overline{\overline{x}}$) and R ($\overline{R}$) values are calculated;
5. UCL and LCL are calculated by $\overline{\overline{X}} \mp \overline{R}A_2$ 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 ($\overline{\overline{x}}$), UCL, and LCL;
7. The values calculated in Step 2 ($\overline{\overline{x}}$) 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 $\overline{x}$ chart to yarn maximum breaking strength quality characteristic (gf) of the Kaynak Group Cotton Yarn Factory's regular measurements is given in **Figure 7**.

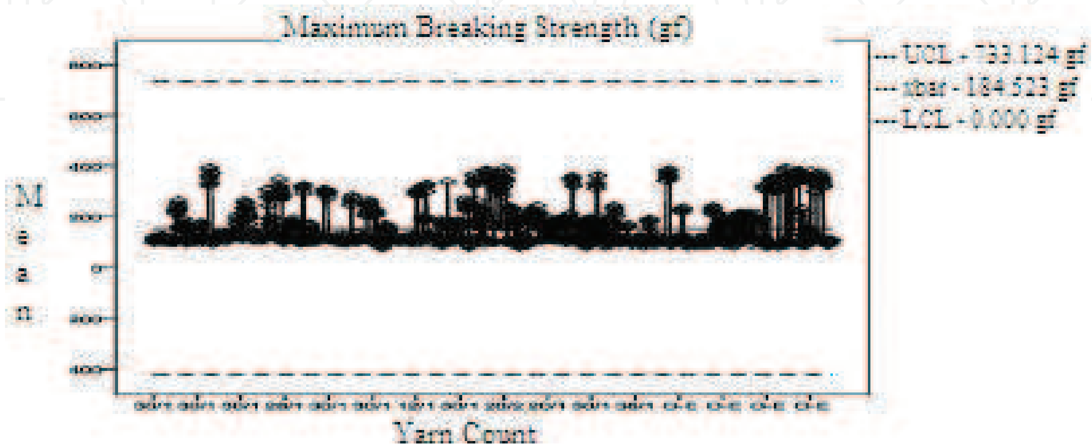

Figure 7. Application of $\overline{x}$ chart to yarn maximum breaking strength quality characteristic (gf) of the Kaynak group cotton yarn factory's regular measurements.

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 ($\bar{R}$) in Step 4 of $\bar{x}$ chart is used;
3. The UCL is calculated by $D_4\,\bar{R}$ formula, and the LCL is calculated by $D_3\,\bar{R}$ 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 ($\bar{R}$), UCL, and LCL;
5. 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**.

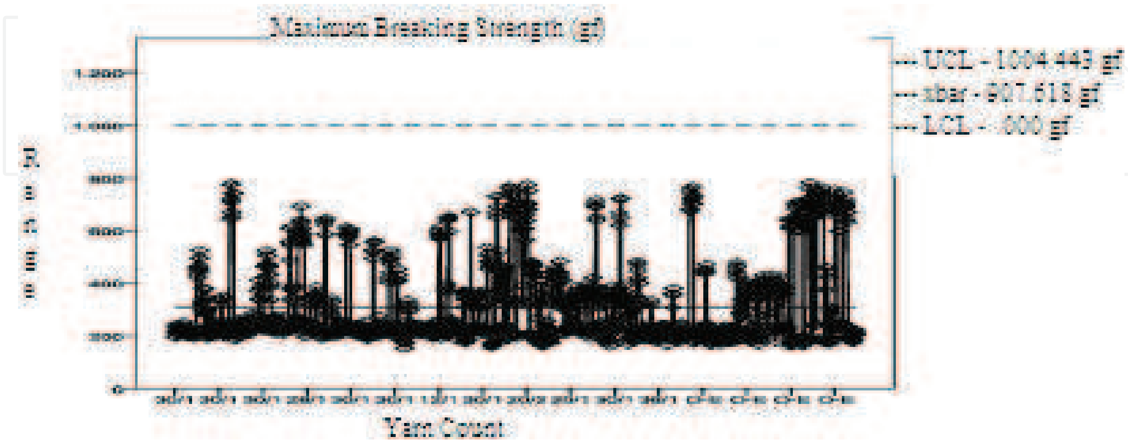

Figure 8. Application of R chart to yarn maximum breaking strength quality characteristic (gf) of the Kaynak group cotton yarn factory's regular measurements.

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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 s-control 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 $\overline{R}$. The UCL is calculated by the $B_4\,\bar{s}$ formula, and the LCL is calculated by the $B_3\,\bar{s}$ formula. The constants B_4 and B_3 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**.

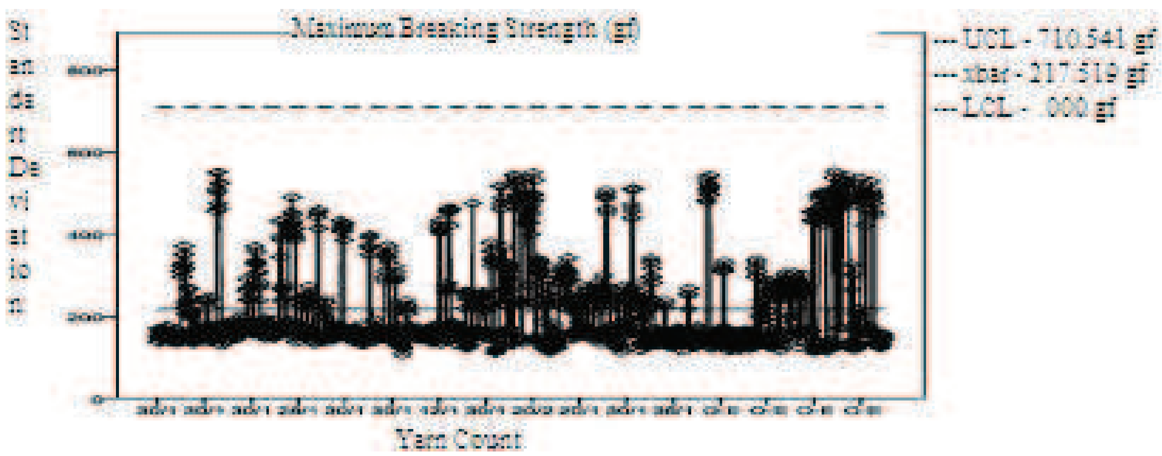

Figure 9. Application of s chart to yarn maximum breaking strength quality characteristic (gf) of the Kaynak group cotton yarn Factory's regular measurements.

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 $\overline{\mathrm{p}} \mp \sqrt{\frac{\overline{\mathrm{p}}(1-\overline{\mathrm{p}})}{\mathrm{n}}}$ 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**.

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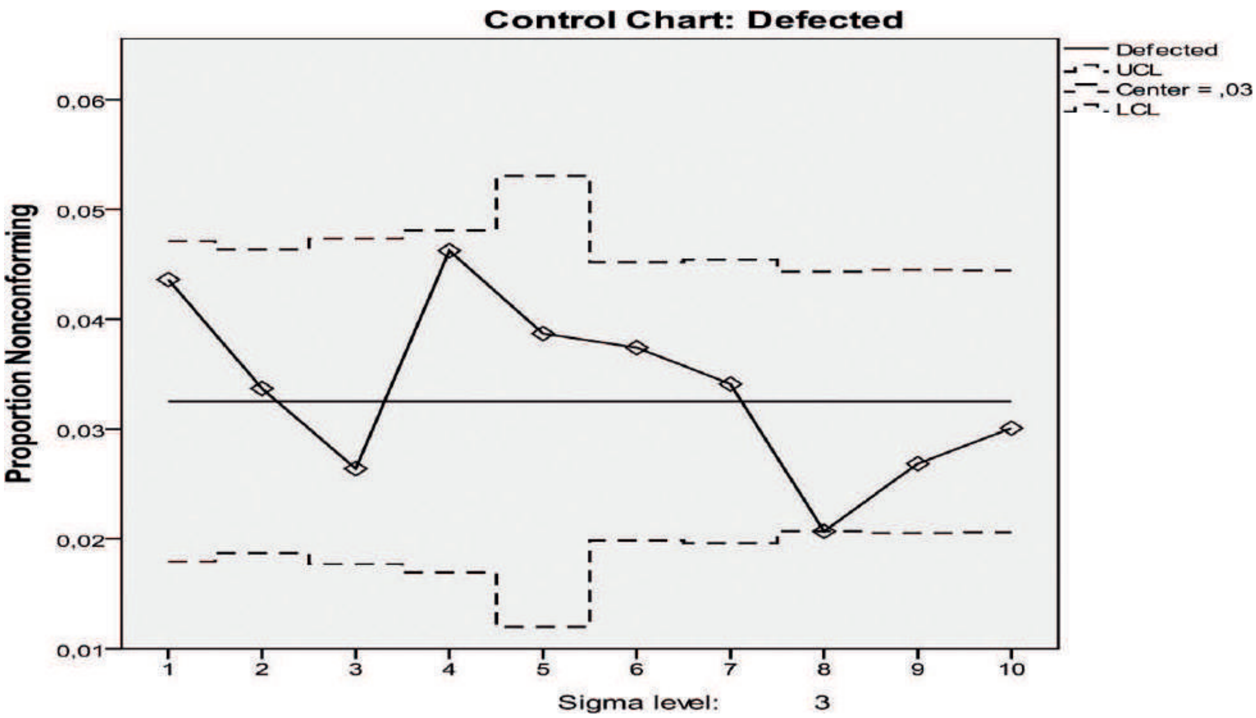

Figure 10. Application of p chart to nonconforming pants in the Çağla textile ready-wear Factory's regular measurements.

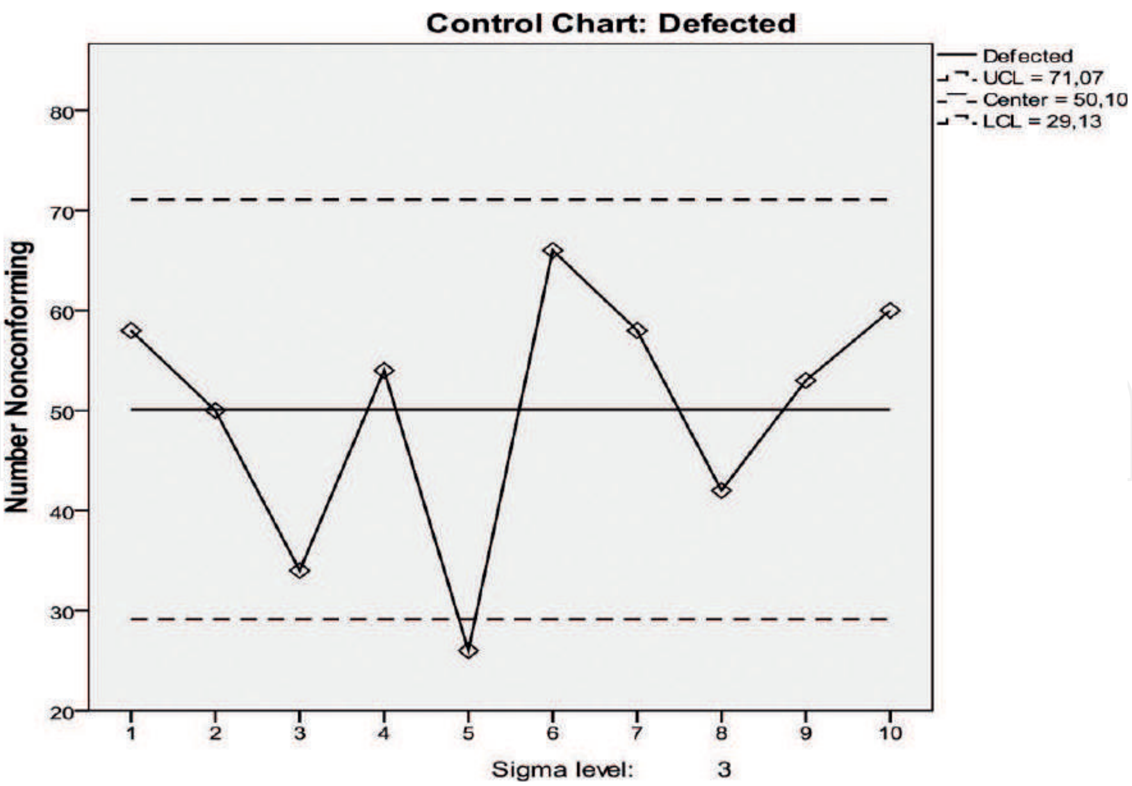

Figure 11. Application of np chart to nonconforming skirts in the Çağla textile ready-wear factory's regular measurements.

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 $\overline{u} \mp 3\sqrt{\frac{\overline{u}}{n}}$ 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].

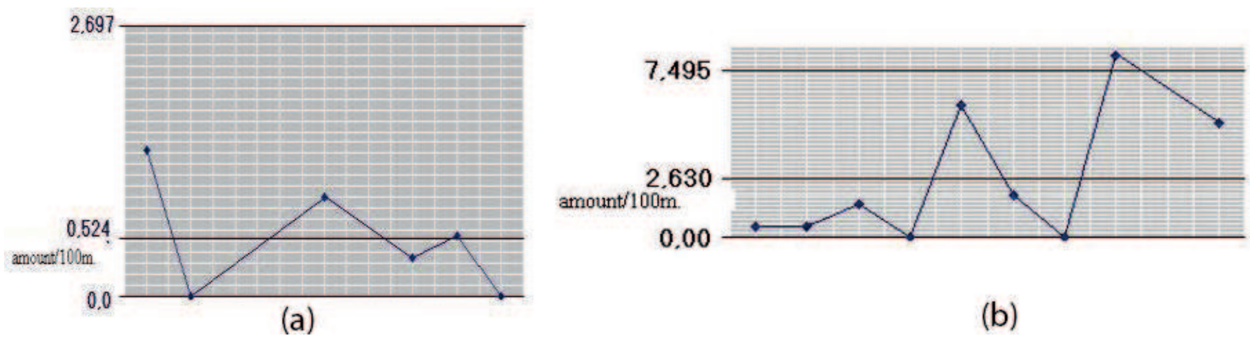

Figure 12. Application of u charts to defects in fabrics of fixed width in the Özer textile weaving factory's regular measurements. (a) Application of u chart to thin weft yarn defect calculated per 100 m. Of fabric (considered normal), (b) application of u chart to thick warp yarn defect calculated 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 c-control charts. The unit here is again the restricting factor, where the main pronounced value is

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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 $\overline{c} \mp 3\sqrt{\overline{c}}$ formula.

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

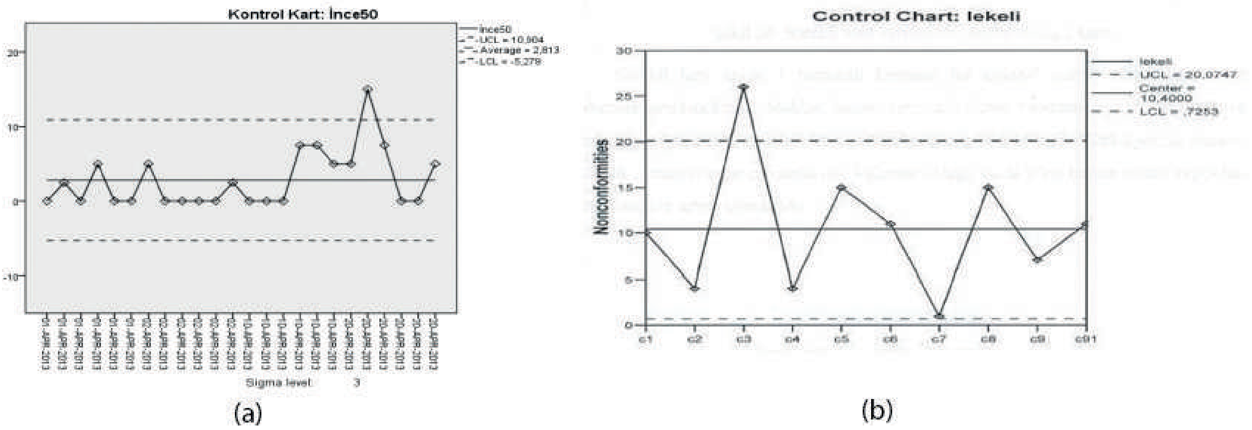

Figure 13. Application of a c chart. (a) Applications of c chart to thin place imperfection per 1 km, of yarn in the Gülçağ textile yarn Factory's regular measurements [13], (b) applications of c chart to spot defects per fixed fabric roll of 80 m. In the Yıldırımlar printing & dying factory's regular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

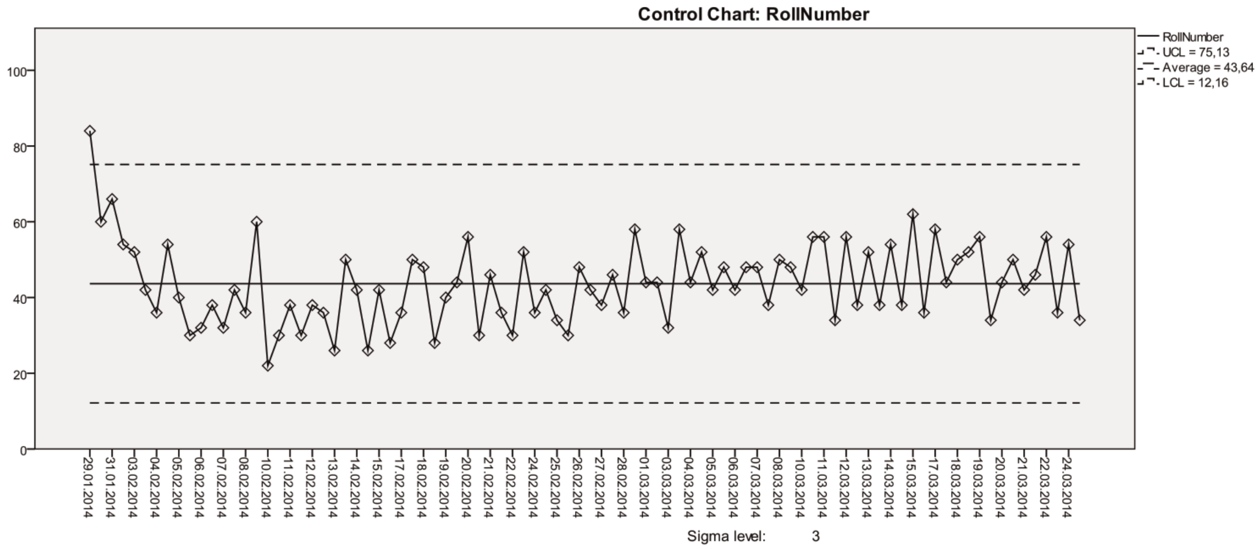

Figure 14. Individual measurements control chart for the number of rolls daily of Sarıkılıç.

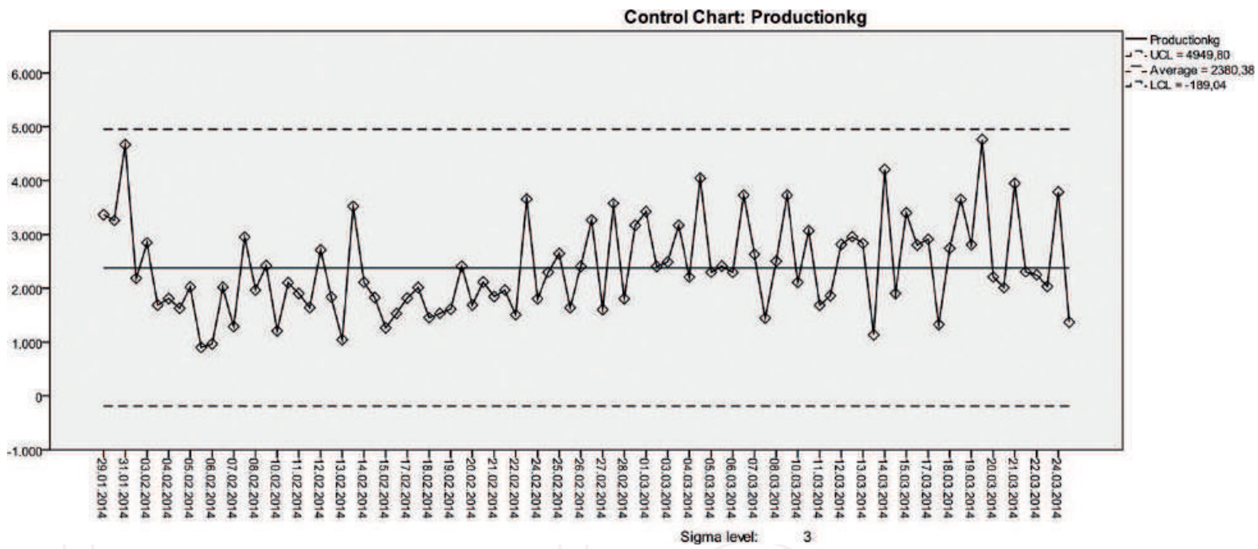

Figure 15. Individual measurements control chart for the production weight daily of Sarıkılıç textile nonwoven factory.

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

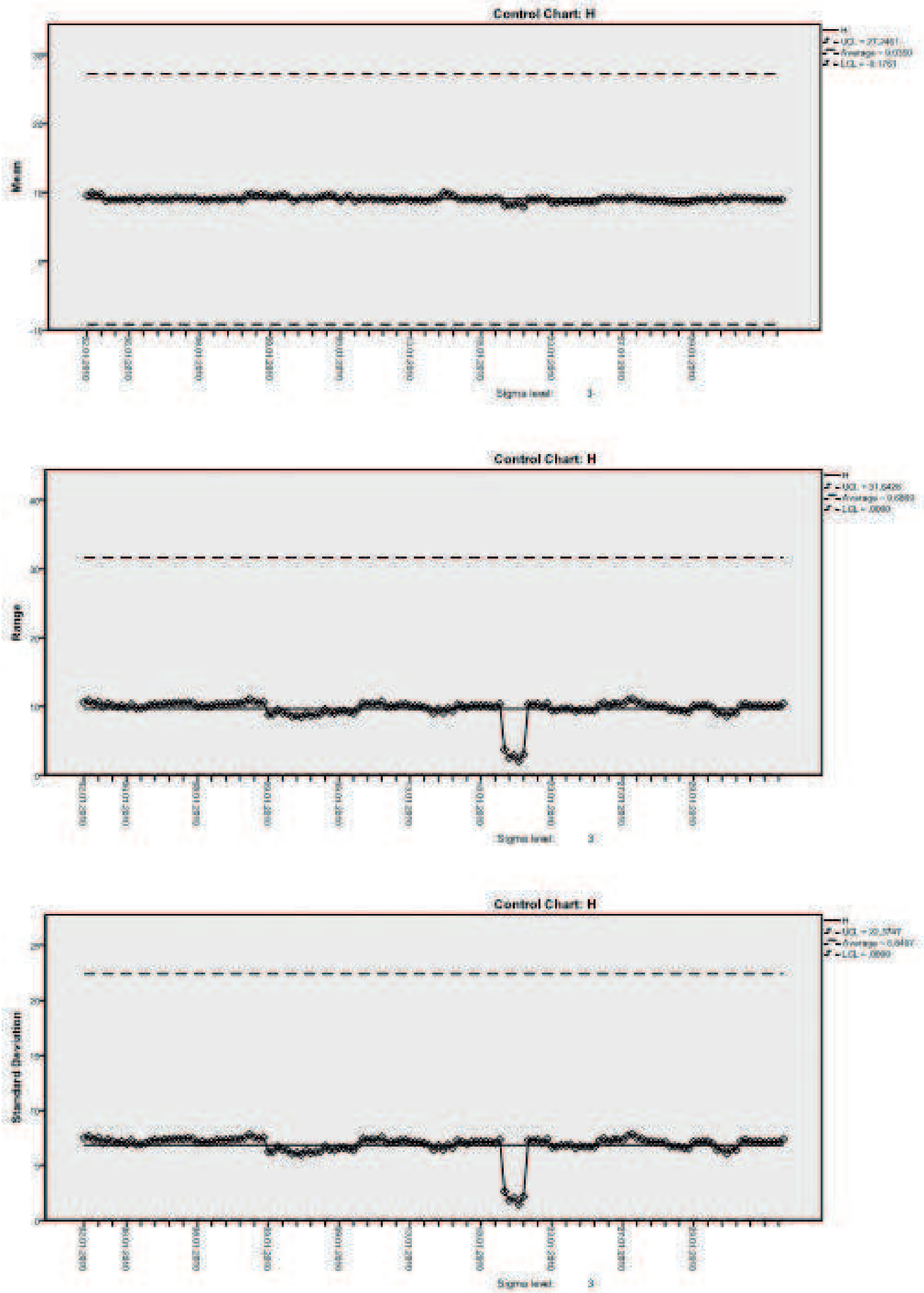

Figure 16. Means control chart, ranges control chart, and standard deviation control chart for open-end yarns' hairiness values of the Kaynak group yarn factory.

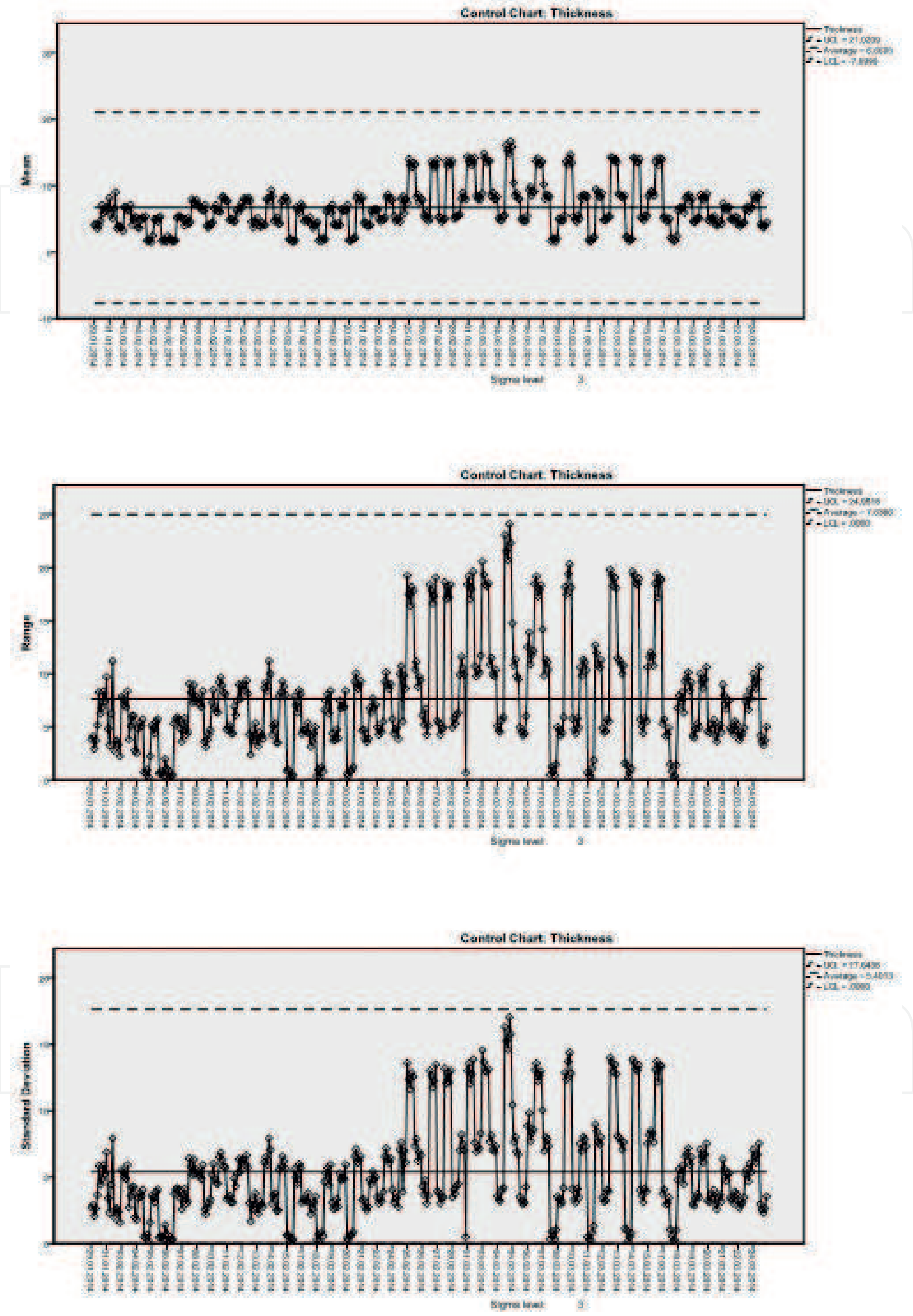

Figure 17. Means control chart, ranges control chart, and standard deviation control chart for nonwoven thickness values of the Sarıkılıç textile nonwoven factory.

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 non-conformities 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,

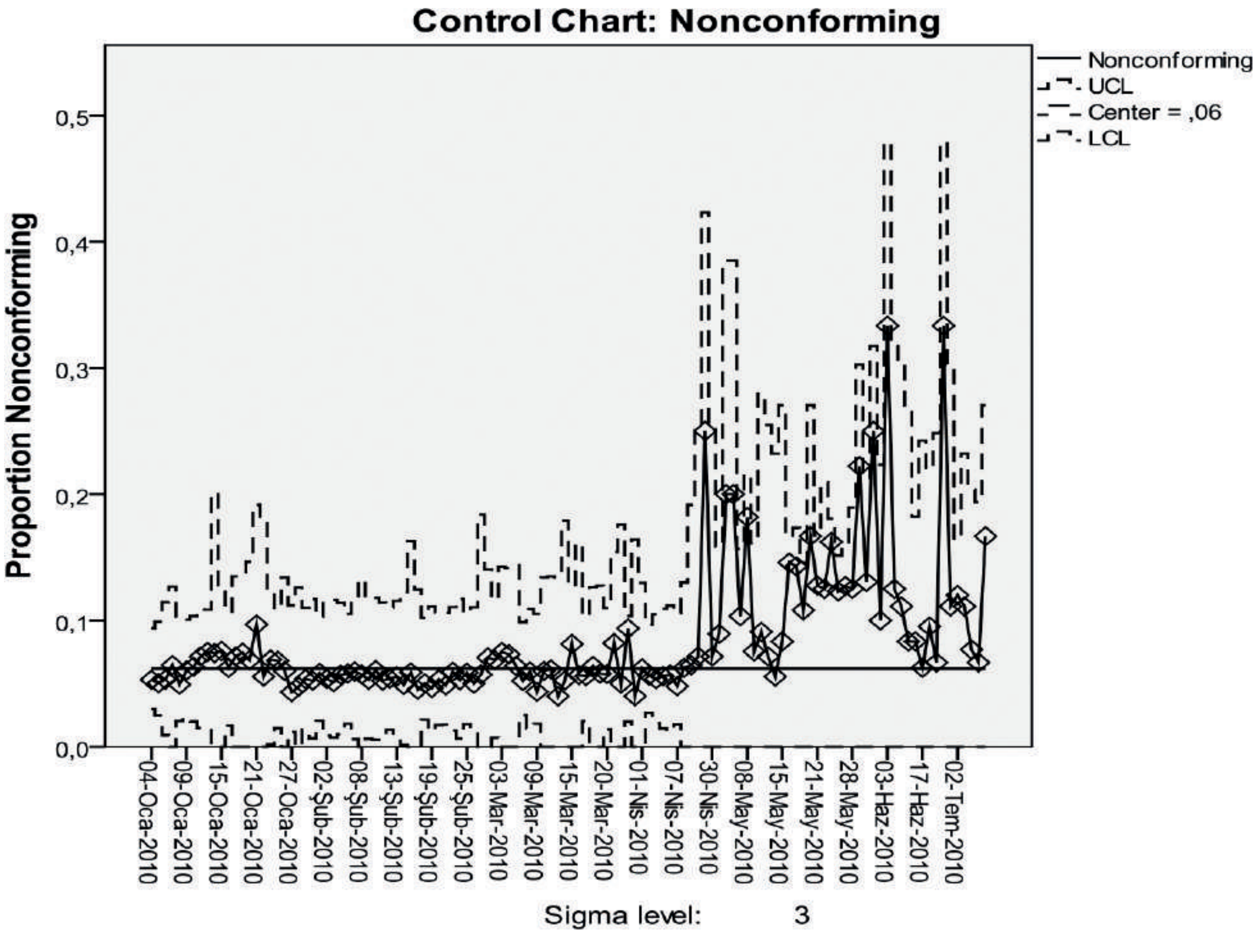

Figure 18. p control chart for nonconforming socks in different amounts of production in the Tekstüre textile socks factory.

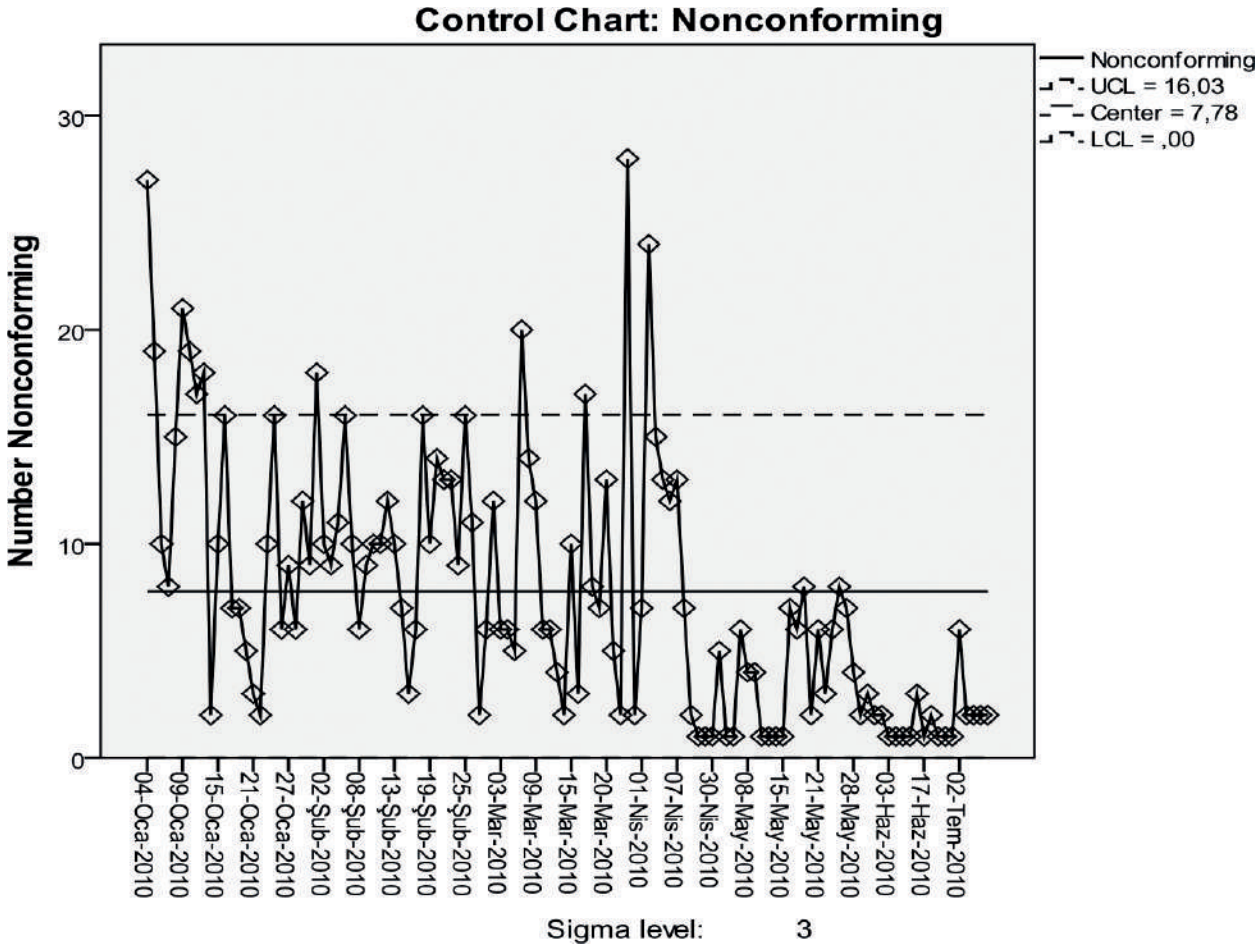

Figure 19. np-control chart for nonconforming socks in constant amount of production in the Tekstüre textile socks factory.

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 Özer 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 $\overline{x}$, 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

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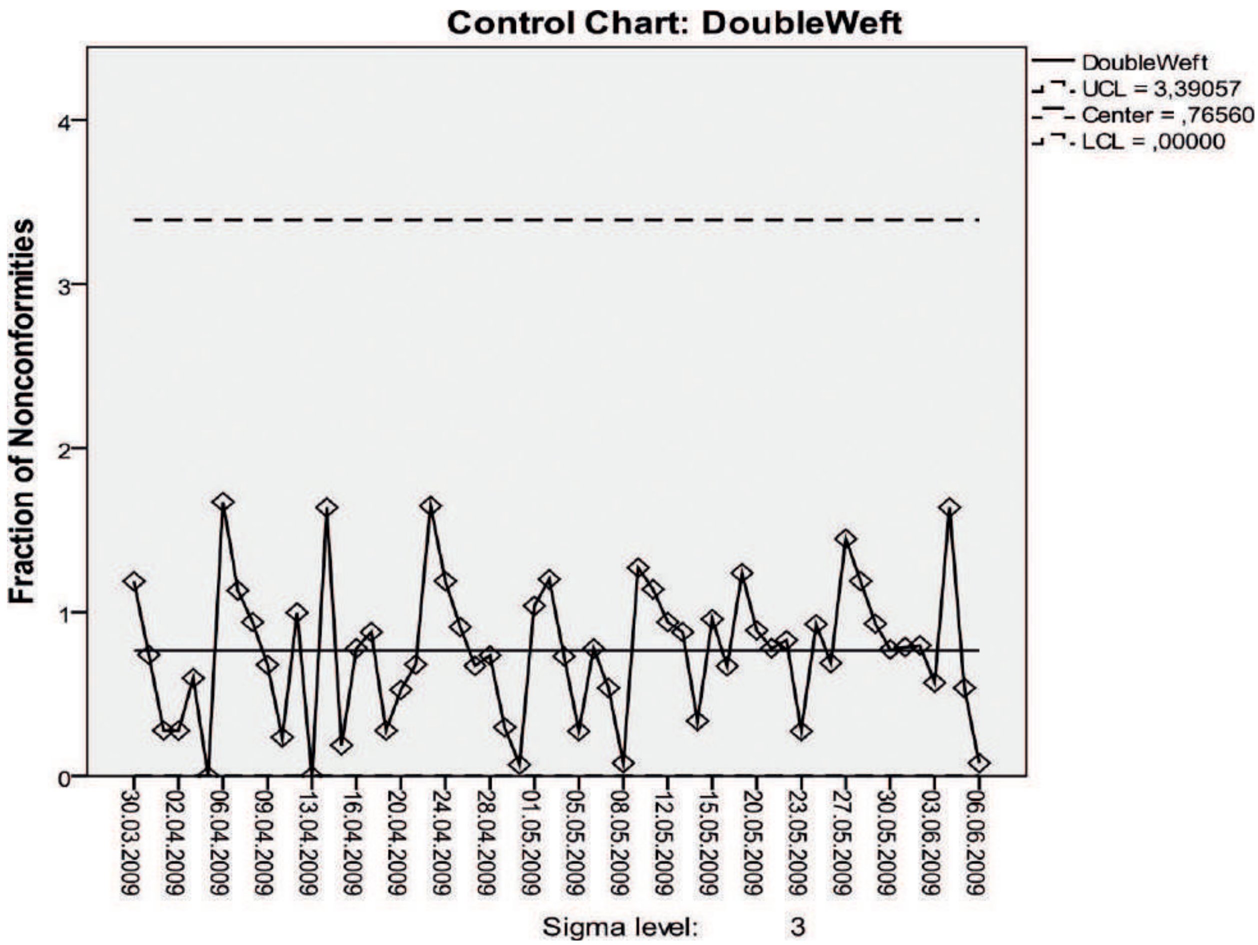

Figure 20. u-control chart for double weft fault in different lengths of fabric rolls in the Ne-Ke textile weaving factory.

- 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

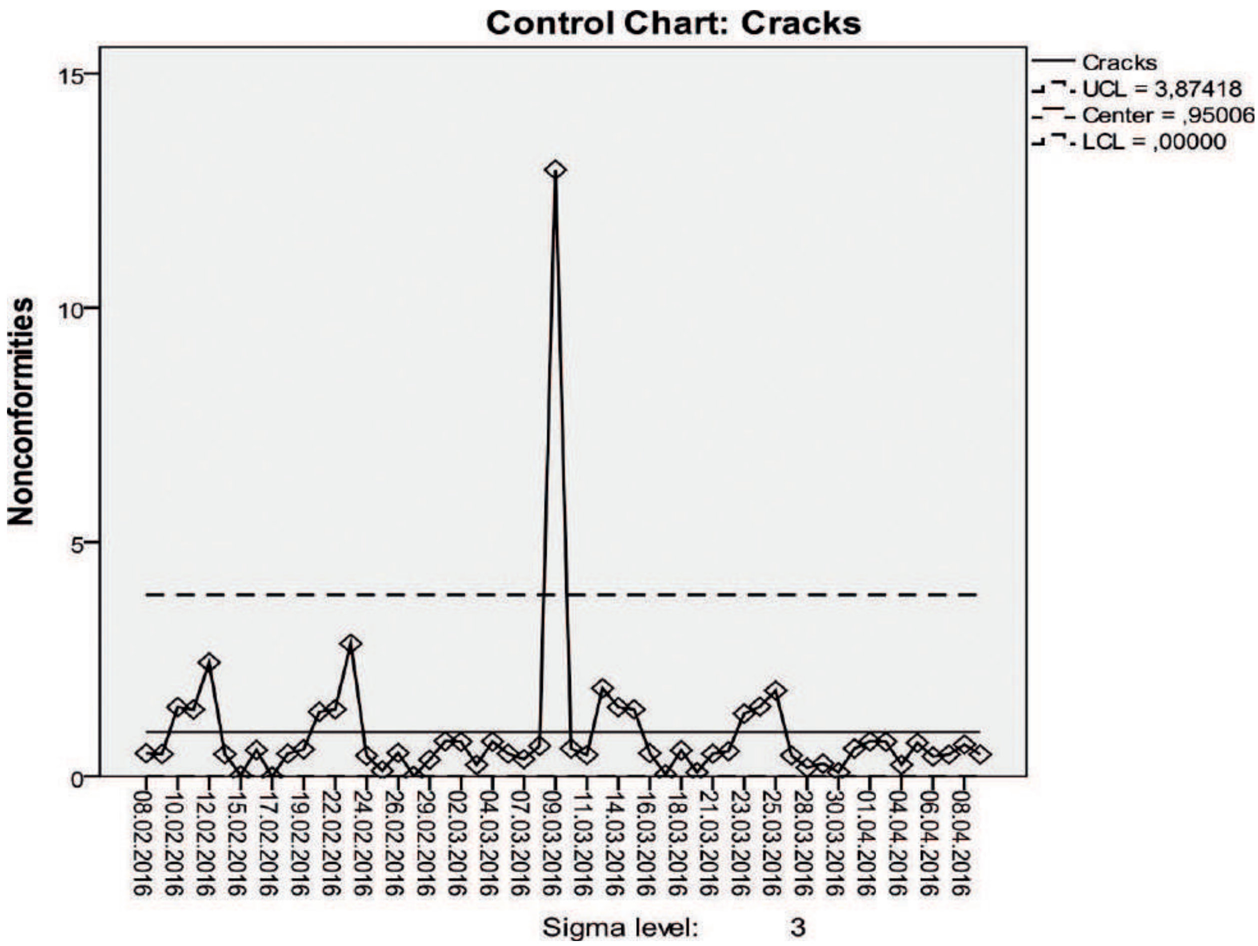

Figure 21. c-control chart for cracks in dying department of the Özer textile weaving factory.

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**.

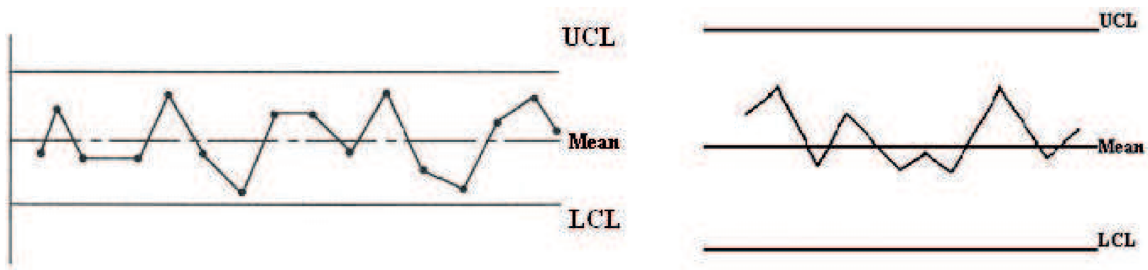

Figure 22. Two examples of a typical control chart.

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.

$\bar{x}$ 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

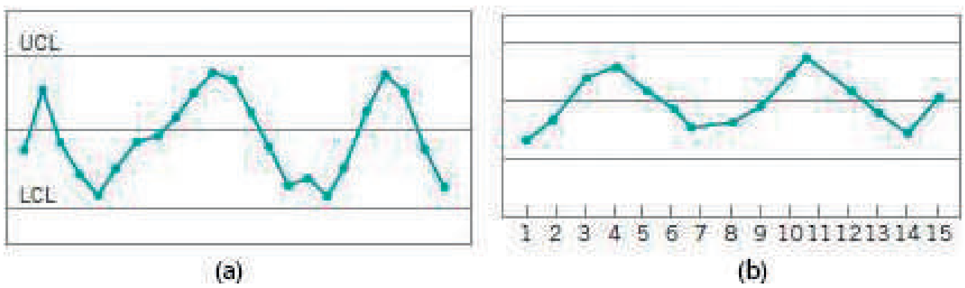

Figure 23. Two examples of control charts showing a cyclic pattern.

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 "over-control," 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.

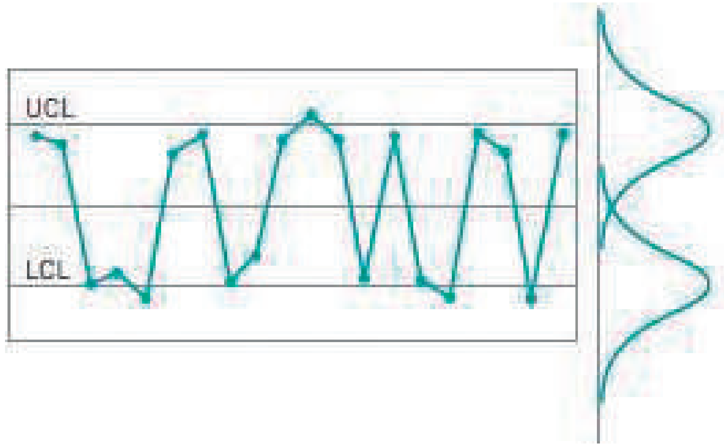

Figure 24. Example of a control chart showing a mixture pattern.

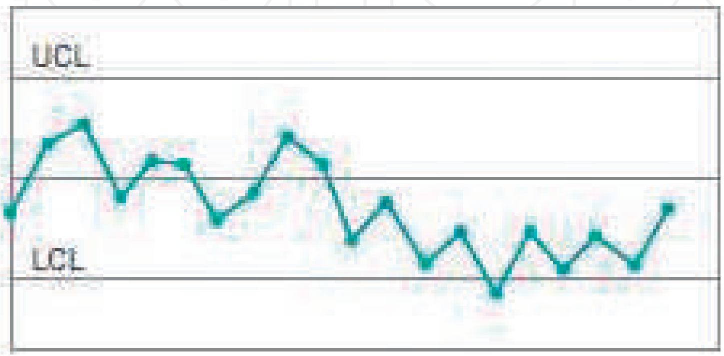

Figure 25. Example of a control chart showing a shift in process level pattern.

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.

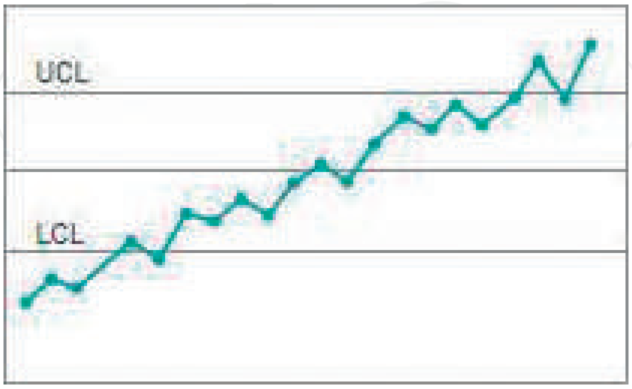

Figure 26. Example of a control chart showing a trend pattern.

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.

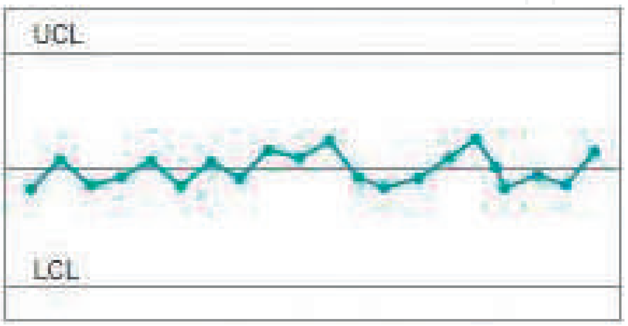

Figure 27. Example of a control chart showing a stratification pattern.

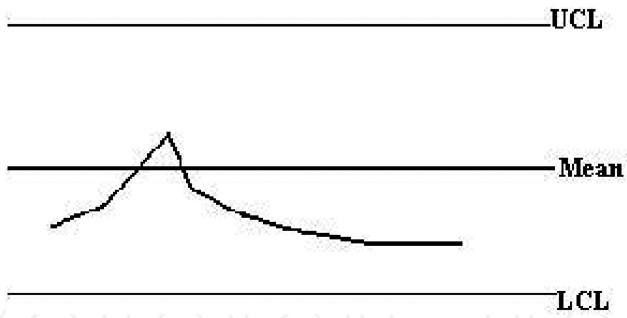

Figure 28. Example of a control chart showing an approach to LCL pattern.

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

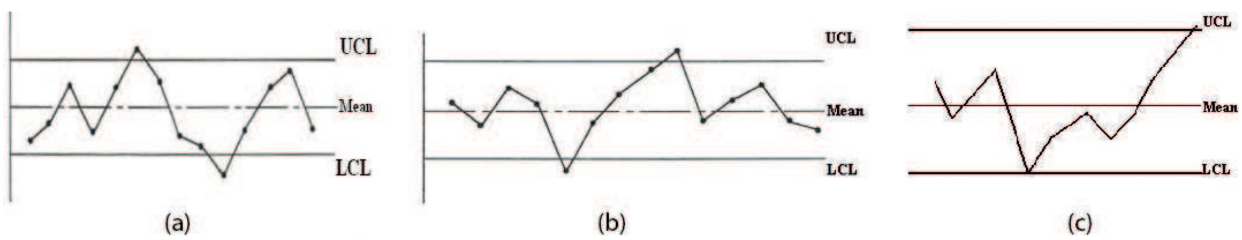

Figure 30. Examples of control charts showing point/points crossing the control limits.

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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 $\overline{x}$ 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.

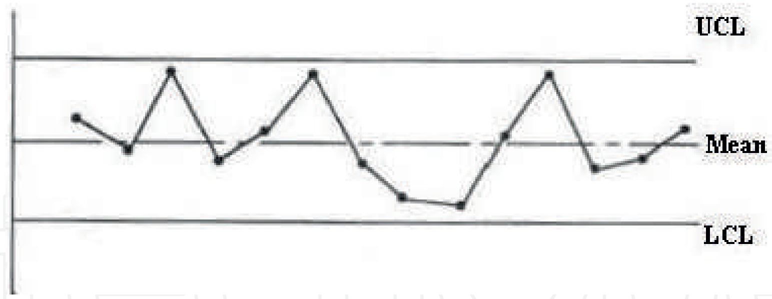

Figure 31. Example of a control chart showing many points that are very near to the control limits.

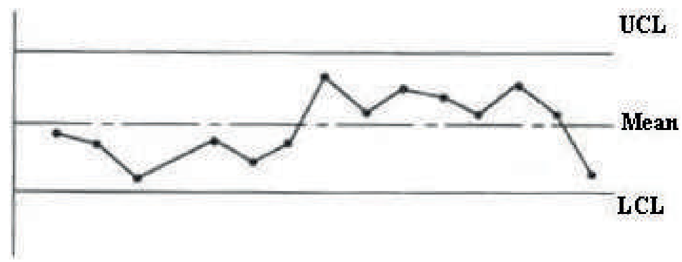

Figure 32. Example of a control chart showing points gathering around a value.

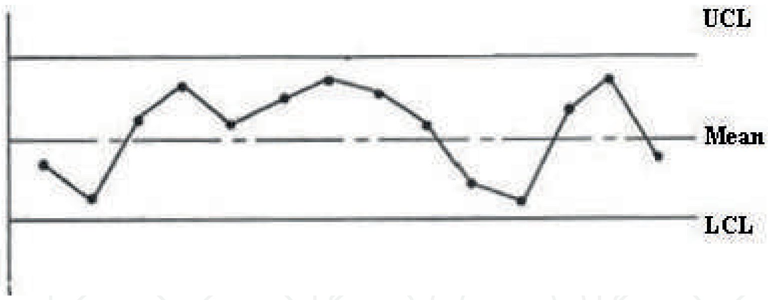

Figure 33. All of the consecutive 7 points are placed on one side of the center line.

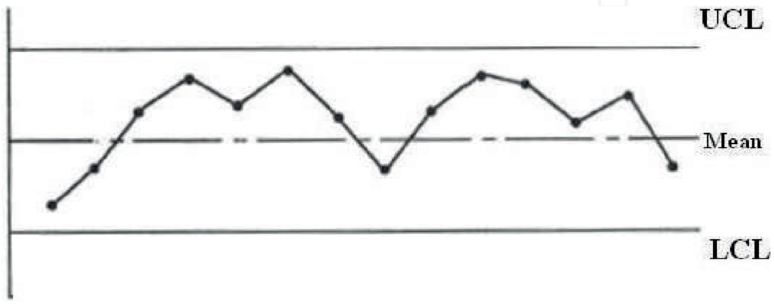

Figure 34. 10 out of 11 consecutive points that are placed on one side of the center line.

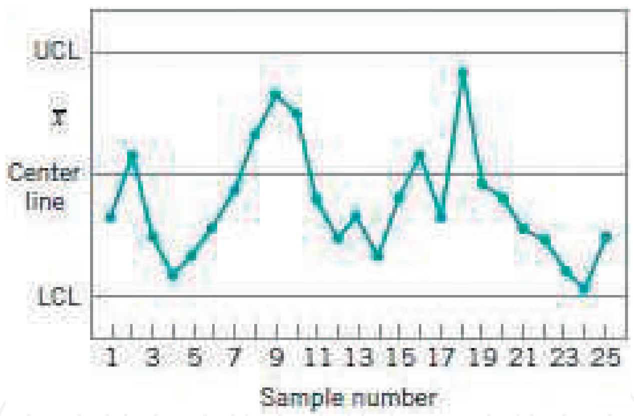

Figure 35. 19 out of 25 consecutive points are placed on one side of the center line.

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

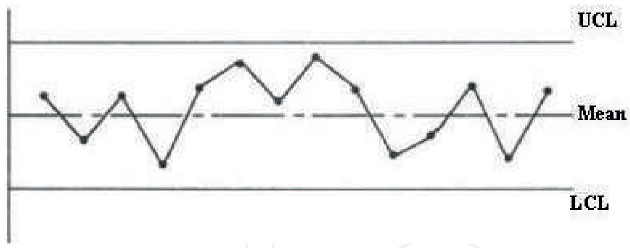

Figure 36. A run of 2 points out of 3 is near the control limits.

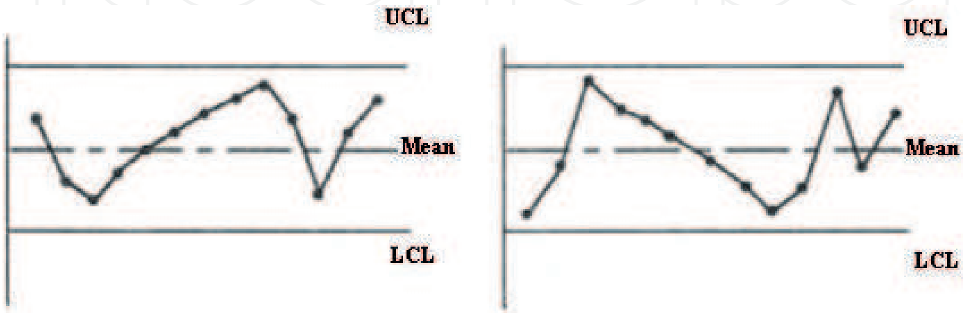

Figure 37. A run of 7 points rises or falls.

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.

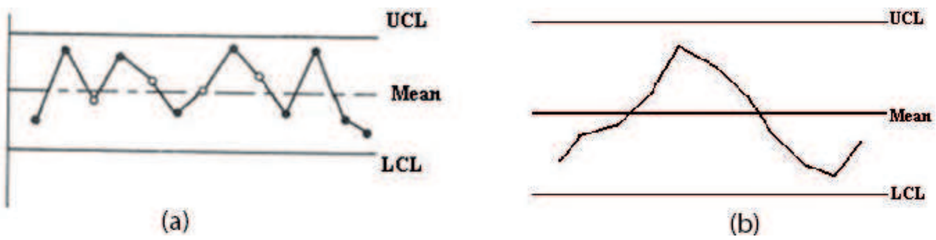

Figure 38. Less than 2/3 of points lie in the middle 1/3 of the control limits.

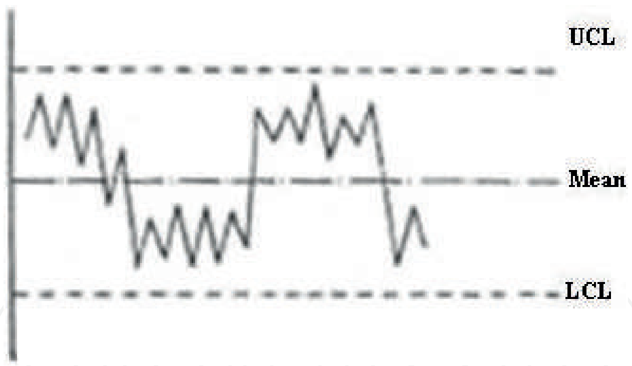

Figure 39. Example of clear shifts for different periods.

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 $\overline{x}$ 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 $\bar{X}$ 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].

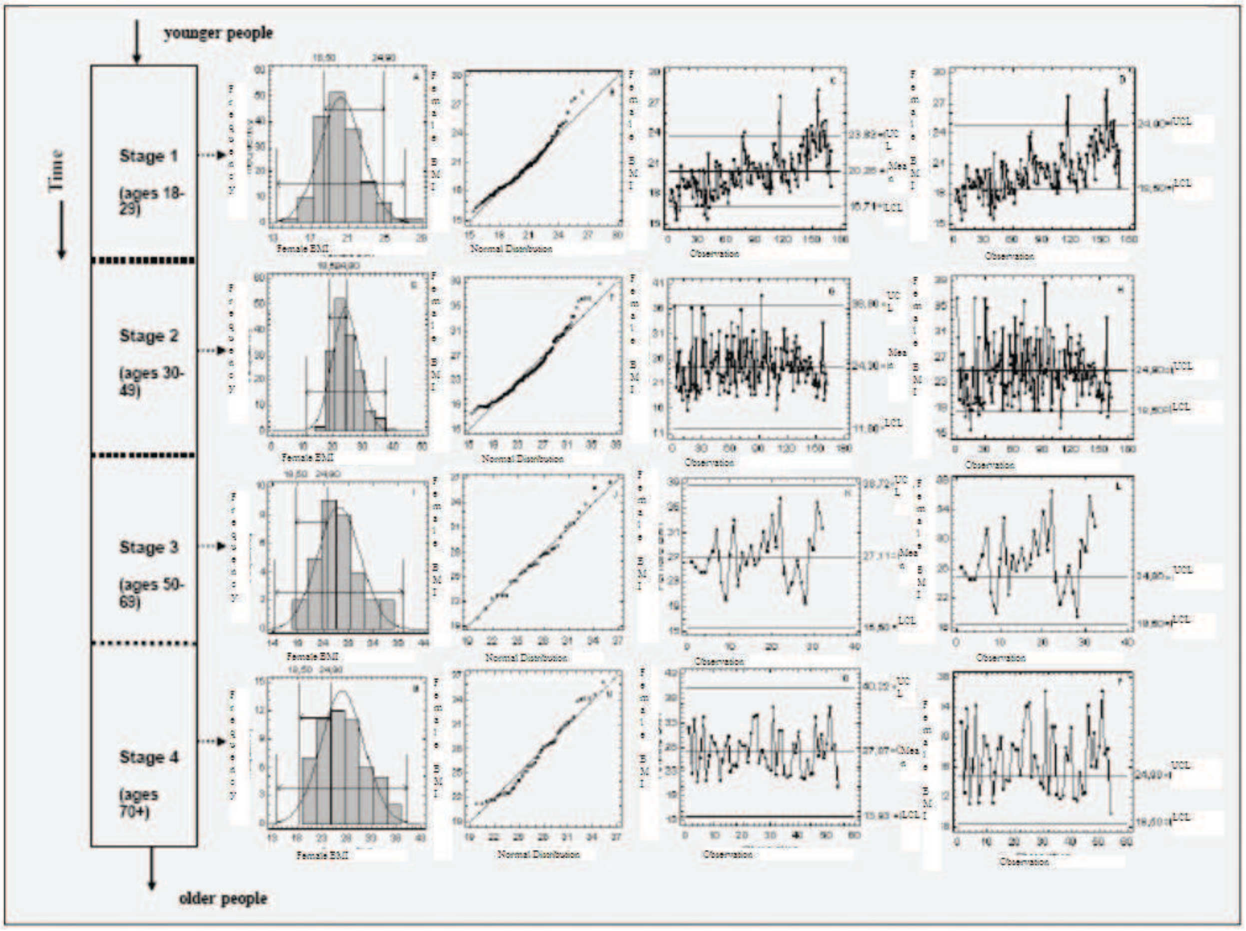

Figure 40. Mean BMI increase in females by age.

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 r-out-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 ($\overline{x}$), 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]

Factors for Constructing Variables Control Charts

Observations in Sample, n	Chart for Averages: Factors for Control Limits			Chart for Averages: Factors for Center Line		Chart for Standard Deviations: Factors for Control Limits				Factors for Center Line		Chart for Ranges: Factors for Control Limits				
	A	A_2	A_3	c_4	$1/c_4$	B_3	B_4	B_5	B_6	d_2	$1/d_2$	d_3	D_1	D_2	D_3	D_4
2	2.121	1.880	2.659	0.7979	1.2533	0	3.267	0	2.606	1.128	0.8865	0.853	0	3.686	0	3.267
3	1.732	1.023	1.954	0.8862	1.1284	0	2.568	0	2.276	1.693	0.5907	0.888	0	4.358	0	2.574
4	1.500	0.729	1.628	0.9213	1.0854	0	2.266	0	2.088	2.059	0.4857	0.880	0	4.698	0	2.282
5	1.342	0.577	1.427	0.9400	1.0638	0	2.089	0	1.964	2.326	0.4299	0.864	0	4.918	0	2.114
6	1.225	0.483	1.287	0.9515	1.0510	0.030	1.970	0.029	1.874	2.534	0.3946	0.848	0	5.078	0	2.004
7	1.134	0.419	1.182	0.9594	1.0423	0.118	1.882	0.113	1.806	2.704	0.3698	0.833	0.204	5.204	0.076	1.924
8	1.061	0.373	1.099	0.9650	1.0363	0.185	1.815	0.179	1.751	2.847	0.3512	0.820	0.388	5.306	0.136	1.864
9	1.000	0.337	1.032	0.9693	1.0317	0.239	1.761	0.232	1.707	2.970	0.3367	0.808	0.547	5.393	0.184	1.816
10	0.949	0.308	0.975	0.9727	1.0281	0.284	1.716	0.276	1.669	3.078	0.3249	0.797	0.687	5.469	0.223	1.777
11	0.905	0.285	0.927	0.9754	1.0252	0.321	1.679	0.313	1.637	3.173	0.3152	0.787	0.811	5.535	0.256	1.744
12	0.866	0.266	0.886	0.9776	1.0229	0.354	1.646	0.346	1.610	3.258	0.3069	0.778	0.922	5.594	0.283	1.717
13	0.832	0.249	0.850	0.9794	1.0210	0.382	1.618	0.374	1.585	3.336	0.2998	0.770	1.025	5.647	0.307	1.693
14	0.802	0.235	0.817	0.9810	1.0194	0.406	1.594	0.399	1.563	3.407	0.2935	0.763	1.118	5.696	0.328	1.672
15	0.775	0.223	0.789	0.9823	1.0180	0.428	1.572	0.421	1.544	3.472	0.2880	0.756	1.203	5.741	0.347	1.653
16	0.750	0.212	0.763	0.9835	1.0168	0.448	1.552	0.440	1.526	3.532	0.2831	0.750	1.282	5.782	0.363	1.637
17	0.728	0.203	0.739	0.9845	1.0157	0.466	1.534	0.458	1.511	3.588	0.2787	0.744	1.356	5.820	0.378	1.622
18	0.707	0.194	0.718	0.9854	1.0148	0.482	1.518	0.475	1.496	3.640	0.2747	0.739	1.424	5.856	0.391	1.608
19	0.688	0.187	0.698	0.9862	1.0140	0.497	1.503	0.490	1.483	3.689	0.2711	0.734	1.487	5.891	0.403	1.597
20	0.671	0.180	0.680	0.9869	1.0133	0.510	1.490	0.504	1.470	3.735	0.2677	0.729	1.549	5.921	0.415	1.585
21	0.655	0.173	0.663	0.9876	1.0126	0.523	1.477	0.516	1.459	3.778	0.2647	0.724	1.605	5.951	0.425	1.575
22	0.640	0.167	0.647	0.9882	1.0119	0.534	1.466	0.528	1.448	3.819	0.2618	0.720	1.659	5.979	0.434	1.566
23	0.626	0.162	0.633	0.9887	1.0114	0.545	1.455	0.539	1.438	3.858	0.2592	0.716	1.710	6.006	0.443	1.557
24	0.612	0.157	0.619	0.9892	1.0109	0.555	1.445	0.549	1.429	3.895	0.2567	0.712	1.759	6.031	0.451	1.548
25	0.600	0.153	0.606	0.9896	1.0105	0.565	1.435	0.559	1.420	3.931	0.2544	0.708	1.806	6.056	0.459	1.541

For $n > 25$.

$$A = \frac{3}{\sqrt{n}} \quad A_3 = \frac{3}{c_4\sqrt{n}} \quad c_4 \cong \frac{4(n-1)}{4n-3}$$

$$B_3 = 1 - \frac{3}{c_4\sqrt{2(n-1)}} \quad B_4 = 1 + \frac{3}{c_4\sqrt{2(n-1)}}$$

$$B_5 = c_4 - \frac{3}{\sqrt{2(n-1)}} \quad B_6 = c_4 + \frac{3}{\sqrt{2(n-1)}}$$

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