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Uvajanje informacijskih tehnologij z namenom izboljšanja sistema za upravljanje s kakovostjo

Implementation of Information Technology for the Purpose of Quality Management System Improvement

Aleksandar Vujović - Zdravko Krivokapić
(University of Montenegro, Podgorica, Montenegro)

V tem prispevku je predstavljena programska oprema za nadzor neusklajenosti sistema za upravljanje s kakovostjo z namenom uskladiti jih s standardom JUS ISO 9001:2001. Prav tako je treba ugotoviti in izpostaviti področje, na katerem pride do največ neusklajenosti. Podane so tudi natančne analize za vsako individualno področje in definirani predlogi za popravna oziroma preventivna dejanja, ki izboljšujejo sistem za upravljanje s kakovostjo, glede na pridobljene rezultate in opravljene raziskave na tem področju.

(Ključne besede: oprema programska, zagotavljanje kakovosti, neusklajenosti)

In this paper software for the macro-control of Quality management system (QMS) nonconformities, with the aim to classify them according to the JUS ISO 9001:2001 standard's areas and to mark those areas in which the major part of the nonconformities has emerged, is described. Detailed analyses for each respective area and the defined proposals for corrective and preventive actions for improving the QMS, based on the obtained results and on the inspection of the identified area, are given.

(Keywords: software, quality assurance, nonconformity)

0 INTRODUCTION

Market requirements in the 21st century will be characterized by a large variety and a relatively small demand for products. Effort that is more active is necessary for the development and the application of standards, and this conditions producers to adjust their products and processes by defined norms. The customer is in a privileged position and has a large assortment of products and services that should meet a customer's specific requirements.

Such conditions for operations require additional and permanent efforts, both on the part of the management and on the part of the employees in organizations, in order to improve processes and products as well. For such purposes, it is necessary to know how to manage processes in organizations along with the aim to meet the target defined in advance, which is confirmed by the following quotation:

What is necessary to learn (which is not easy) is the skill to "manage" the process that leads to the solution of problem – instead to manage people that work to solve such problem. (Alan Bloch).

The area for improvements within organizations is the control of nonconformities and, within that framework, the process to discover or to anticipate the possibilities for the emergence of nonconformities, as well as the application of corrective and preventive actions. In addition, the JUS ISO 9001:2001 standard imposes on organizations a requirement that relates to the control of nonconforming products. Consultants, certification and accreditation authorities have the need to manage QMS nonconformities in addition to the control of nonconforming products in organizations. That is why this paper is oriented toward the software that will support the macro-control of QMS nonconformities.

1 THE NEED FOR NONCONFORMITIES MACRO-CONTROL

The emergence of nonconformities in the quality management system and in the very business system in general represents a permanent danger for an organization, its operations, its image within the marketplace and its financial performance. These are the conditions that have encouraged the authors

of this paper to begin research into the control of nonconformities as the basis for the model for improving the quality management system as the most advanced form of business management. The research has its aim to develop a model for improving QMS, based on **real** nonconformities' control. Such nonconformities have been identified, based on the **objective findings provided by external auditors** of both the quality system and the quality management system, which resulted from their working visits to organizations within the country and within the neighboring countries. Based on 1150 nonconformities, which were found in more than 350 organizations, the analysis was performed and the preventative actions were defined with the aim of decreasing the number of corrective actions and with the aim to create a system based on the "ZERO defect" principle.

As a support to data analysis and to the development of the model for improving QMS, applicable software has been developed. In line with the principles of software engineering [1], on the one hand, and with the necessities this work imposes, on the other hand, the process of software development was conducted, having full respect for Deming's P-D-C-A philosophy (P-Plan, D-Do, C-Check, A-Action), through the phases presented in Figure 1.

Identifying future customers and defining their requirements were the starting points for the development of such software, and all with the aim of anticipating the emergence of nonconformities, to define corrective and preventive actions and to improve QMS. The appearance of nonconformities within the quality management system is in relation to:

- system auditors, who aim to detect nonconformities while performing checks, to evaluate the process capacity and the harmony of the system with the standard requirements;
- consultants, who give advice with the aim to harmonize operations with the principles presented in the standards;
- employees in organizations, who maintain, re-evaluate and improve the quality management system via the process of nonconformity control.

2 APPLICABLE SOFTWARE WORKING OUT FOR QMS IMPROVEMENT

From the point of view of the software application, the above stated three groups were observed as future users. By observing the identified customer, on the one hand, and the elements for nonconformities control, on the other hand, while defining the project task, the following requirements, which the software has to meet, have been presented:

- to enable real-time inspection of standards, as the basis for the control and the harmonization of the quality management system;
- to enable the acquisition of nonconformities;
- to present nonconformities, depending on the specified standard requirement;
- to present nonconformities depending on the size and the activity of a company and on the standard requirement as well;
- to point to the most burdened points with respect to the frequency of nonconformities the emergence of particular points of the standard, and to the size of the company according to which such nonconformities are presented;

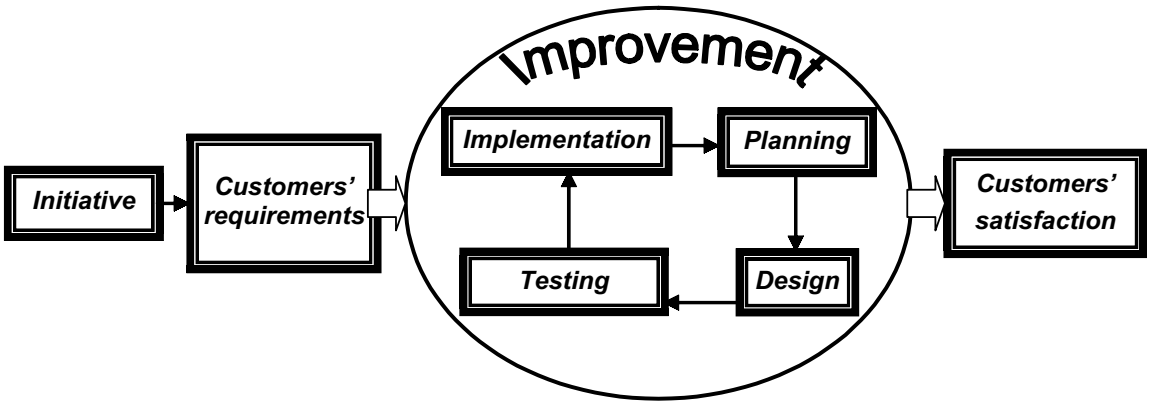


Fig. 1. *Software development activities*

- to generate a sequence of numerous corrective actions for the elimination of nonconformities, based on findings resulting from controls in certain areas of the standard;
- to suggest preventive actions intended for particular areas of the standard;
- to be cheap;
- to be compatible with the most frequently used hardware and software configurations;
- to be appropriate for broad usage and to be adapted for users that are not familiar with a computer.

The software is based on a database, the structure of which is shown in Figure 2.

The concept "to learn via mistakes" was the starting point for a thorough consideration of the structural database and the application design.

The causes for such mistakes, which result in knowledge, have been identified, based on the nonconformities defined by the performed analysis.

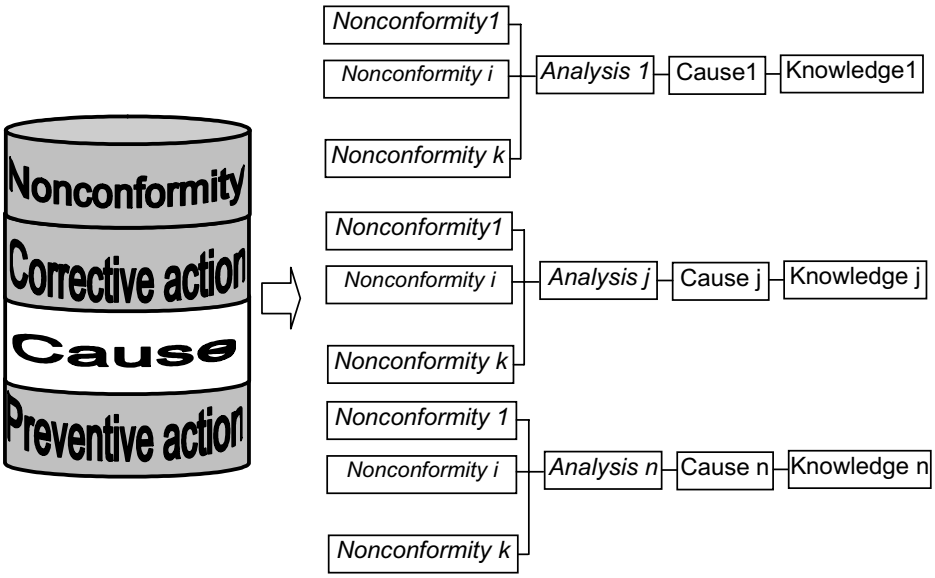


Fig. 2. *DB structure and approach data treatment*

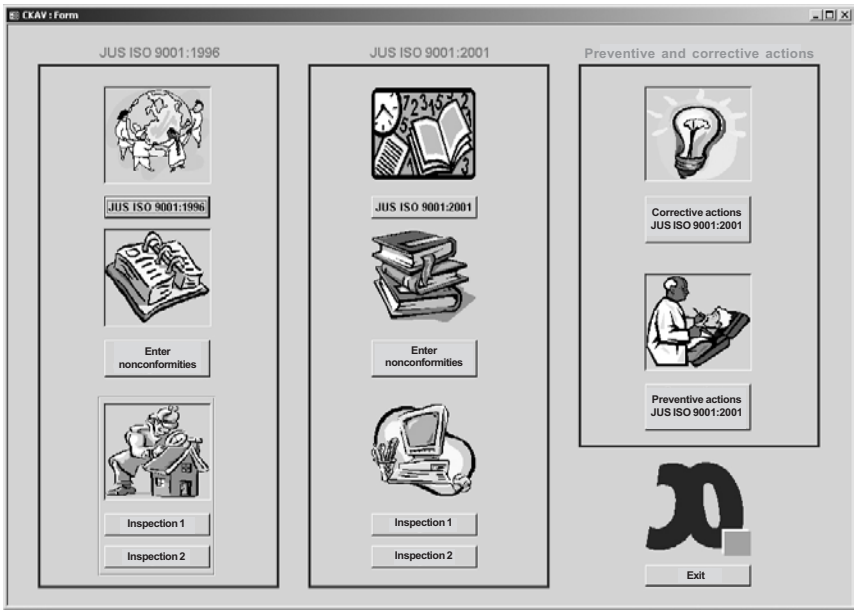


Fig. 3. *Appearance of the starting form*

All the nonconformities were divided into groups, depending on the standard requirements, i.e., on the area of such a standard in which the requirements have been specified. In addition, the grouping was carried out in relation to the activities and the size of the respective organization.

Gathered and grouped data were then analyzed so as to give a clear picture of the specificities of the nonconformities' emergence, depending on the standard requirements and on the type of company, and in order to create the basis for defining corrective and preventive actions, i.e., to generate knowledge.

The starting display form of the software is presented in Figure 3 [3].

For the purposes of this work the following analyses were carried out for each standard:

- The analysis of nonconformity frequency in relation to the standard requirement,
- The analysis of nonconformity frequency in relation to the standard requirement and to the activity and the size of the company.

The analyses carried out in such a manner gives the results that enable the inspection of nonconformity sequence of the order per defined criteria, i.e., the points which are most burdened from the point of view of nonconformities' emergence are identified.

This is indicated by numerical data, and the numerical data is the number of nonconformities per stated separation criteria. Such critical points represent the elements to be improved, and their priorities are defined with the number of identified nonconformities.

In addition, this analysis also results in alphabetical data that can be used for knowledge generation. It is a clearly presented sequence of original textual presentations of nonconformities and corrective actions, wherein the program users can find them or can use them as the support for the completion of their activities

In addition to the analysis relating to the new version of the standard, the analysis of the previous version was performed, based on the same criteria. The results obtained were used for knowledge generation, i.e., for defining preventative actions based on the correlation table in JUS ISO 9001:2001. Figure 3 shows the application has been divided into three parts. The first part relates to the quality system JUS ISO 9001:1996 standards and the second part relates to the quality management system JUS ISO 9001:2001 standard. The third part relates to the review and the usage of the proposed corrective and preventive actions for the new version of the JUS ISO 9001 standard.

3 SOFTWARE APPLICATION RESULTS

Based on the results obtained from the presented software, which are given in Figure 4, the identification of the five most burdened areas of the standard was done from the point of view of the nonconformities' emergence

The picture reflects the areas in which detailed analyses will be carried out, and for JUS ISO 9001:2001 they are as follows:

- Requirement 4.2 - the requirement that relates to the documentation;

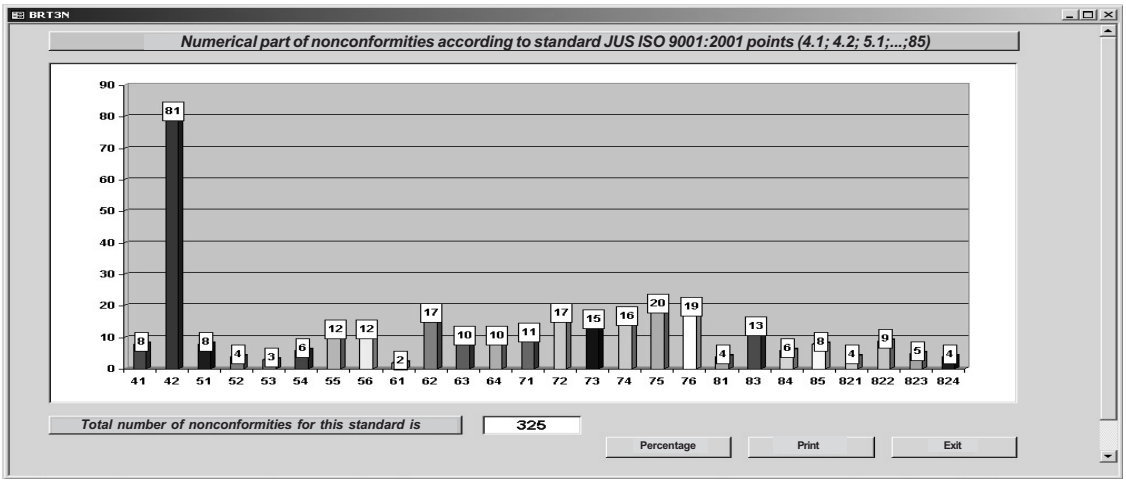
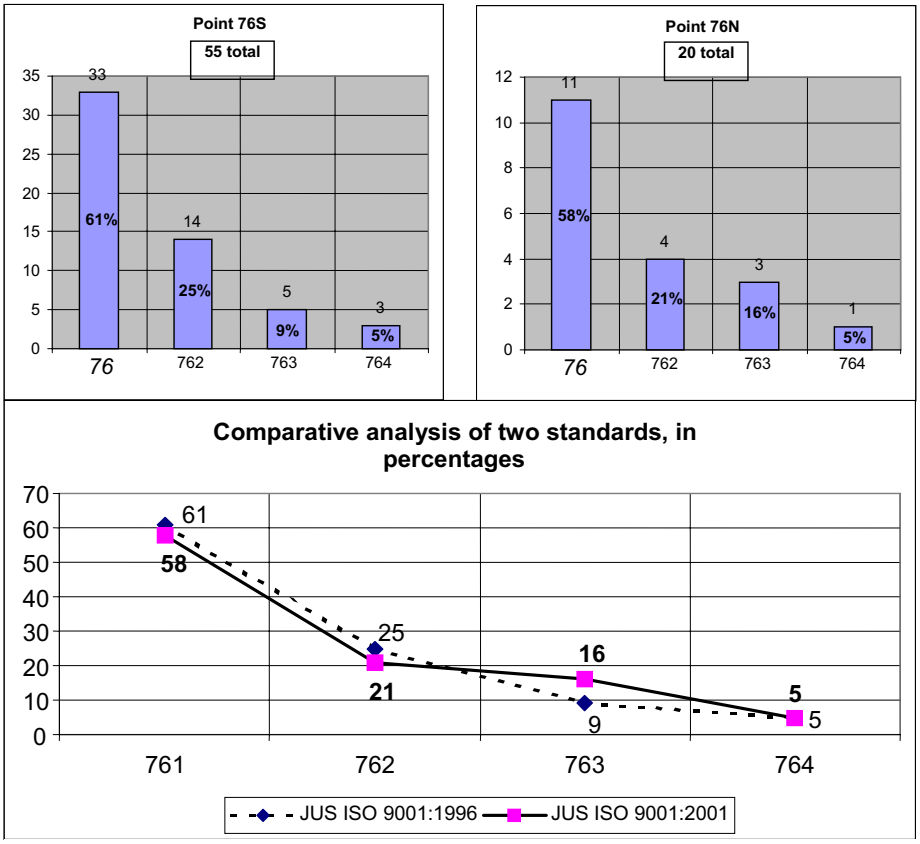


Fig. 4. *Histogram*

- Requirement 6.2 - the requirement that relates to the human resources;
- Requirement 7.2 - the requirement that relates to the customer;
- Requirement 7.5 - the requirement that relates to the production and servicing,
- Requirement 7.6 - the requirement that relates to the control of the surveillance and measurement devices.

The JUS ISO 9001:2001 standard has been used as the basis or the starting point for the analysis and the requirements that have been identified as the most critical and of highest priority from the point of view of the nonconformities' emergence in support of the improvement. An accurate picture of the weaknesses in organizations, i.e., of places where the advancement should be done for the purpose of improving the overall quality management system's performance is acquired in such a manner and through the current standard. As the support in the course to reach improvement within the actual and priority places, the experiences with nonconformities resulting from the old standard are added to the basis in order to create as real a picture as possible and to define the history and the tendencies in the emergence of the nonconformities, i.e., in the system's weak points, and to define as good a preventive actions as possible. For the purpose of the previously mentioned, the nonconformities derived from the previous version of the JUS ISO 9001:2001 standard were identified and presented in parallel diagrams, and all for the needs of the defined critical requirements of the mentioned standard. This paper presents only the completed analysis for point 7.5 (Figure 5).

The picture reflects that the emergence of the new standard has brought aggravations in the



Legend:
***761** – etaloning or verifying, and the records thereof*
***762** – identifying measuring equipment, for the purpose of etaloning status designating*
***763** – adjustment protection*
***764** – protection against damage or malfunction*

Fig. 5. *Analysis of requirement 7.6*

parts of the production and servicing processes management. At the same time, the improvement can be noticed in the part of the validation process in production and servicing. The reasons for the worse production and servicing processes management can be found in the chaotic organizational structures within our companies and in the disorientation during the ownership transformation processes, which again influences the quality of the mentioned processes as well. In addition, the improvement in the part of the validation is the consequence of increased competitiveness within the market place that forces organizations to improve their validation processes for the purpose of survival and regardless of the obvious problems inside those organizations. Other elements that relate to the identification, consistency, the property of customers and the maintenance of products, keep the same trend, as was the one in the previous standard.

Therefore, we have two elements in this case (751 and 752), that supplement each other by their nature and that are completely unlike as regards our circumstances. That is why it is necessary to act by preventive actions that have been proposed for this case and for the purpose of improving the situation, and especially for the case of production and servicing processes management.

The proposals of preventive actions are as follows:

- Absolute respect for the process approach in the part of the quality management system with the aim to overcome organizational and ownership transformations and to create a sense of private ownership for employees, both at the level of processes and activities, independently of current organizational and ownership structures within organizations;
- Introduction of information technologies based on modern and, at the same time, cheap and easily available database models, for the purposes of identifying and the consistency of products;
- Permanent analyzing of reports on rejects and customers' complaints, as well as re-evaluating and presenting the given results, along with adequate incentives for, or with assigning responsibilities to, the employees in such sectors.

The analysis and other points of the standard can be found in corresponding literature [3].

5 CONCLUSION

The basis for software functioning aimed at the support to QMS is composed of a database that contains 1150 nonconformities originating from more than 350 organizations. The nonconformities were provided, based on the available reports in two certified authorities that have the biggest number of certificates issued.

Query-based data selection and their analysis point out that the emergence of new versions of the JUS ISO 9001 standard did not significantly change the statuses within the systems.

The software enables the review of nonconformities and the review of corrective and preventive actions that are the result of analyses being carried out within the identified areas. The results indicate a particularly disturbing situation in the area of documents management and of the records of the quality management system. In addition, the significant number of nonconformities within the management of processes relating to the customers contributes to the previous thesis, regardless of the very core of new standard and of the approach it requires being exactly the respect for demands and the satisfaction of customers. On the other hand, if a part of the findings resulted from an evaluation of the quality management system is taken into consideration, it can be concluded that the evaluators do not often point out the essential nonconformities. Namely, the very evaluations speak more of deviations that should not be equated with nonconformities, whereas the nonconformities represent a higher category that should primarily reflect the dissatisfaction of customers or the poor quality of products.

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Authors' Address: Aleksandar Vujović
Prof. Dr. Zdravko Krivokapić
University of Montenegro
Faculty of Mechanical Eng.
Cetinski put bb
Podgorica, Montenegro

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