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QUALITY SYSTEM CONDITION FOR SUCCESSFUL BUSINESS AND COMPETITIVENESS

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ASSOCIATION FOR QUALITY AND STANDARDIZATION OF SERBIA

VIII INTERNATIONAL SCIENTIFIC CONFERENCE

QUALITY SYSTEM CONDITION FOR SUCCESSFUL BUSINESS AND COMPETITIVENESS

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PREFACE

Dear Colleagues, Ladies and Gentlemen,

I take great pleasure in welcoming you to the 22nd National and 8th International Scientific Conference on QUALITY SYSTEM CONDITION FOR SUCCESSFUL BUSINESS AND COMPETITIVENESS, organized by the Association for Quality and Standardization of Serbia.

In the past period, we have successfully organized 21 national and 7 international quality conferences where a large number of papers were published, with a large number of authors and co-authors and most importantly, with a large number of participants

This year, the organization of the conference got a completely different character due to the COVID-19 pandemic, so we organized the On line conference. The decision on the manner in which the conference will be organized was made only 15 days before the event, bearing in mind that at that time Government made a regulation to ban gatherings of more than 5 people indoors (in this case in the conference hall).

This year we are organizing the 22nd National and 8th International Scientific Conference in cooperation with:

- Faculty of Veterinary Medicine, Belgrade University co-organizer
- Quality Centre, Faculty of Engineering Sciences, Kragujevac University
- Quality Centre, Faculty of Mechanical Engineering, University of Montenegro, Podgorica
- Middle and South East European Countries Quality Initiative
- Shumadia Academy of professional studies,

with the support of

- Ministry of Economy of the Republic of Serbia
- Accreditation Body of Serbia
- Serbian Association of Employers
- Institute for Standardization of Serbia

The sponsor of the conference is Trayal Corporation from Kruševac

A number of papers have been submitted for this conference, which have been published in this proceedings, but the emphasis is on round tables, which are expected to be attended by a larger number of participants.

- THE FUTURE OF REMOTE AUDIT where the current practice and future directions of development of these new audit methods and techniques of verification would be pointed out.
- CORONAVIRUS PANDEMIC AND CRISIS MANAGEMENT, with the main goal of understanding the aspects of crisis management in the context of a coronavirus pandemic, as well as the consequences of the pandemic on the economic and financial system
- FOOD SUPPLY CHAIN IN THE CONDITIONS OF THE COVID-19 PANDEMIC, which will discuss
 the global food crisis in the world and its consequences, which were further deepened in
 2020 by the SARS-Cov-2 pandemic (Covid-19) and finding possible solutions for the period
 ahead
- FUTURE CONCEPTS OF STANDARDS FOR MANAGEMENT SYSTEMS with the aim of presenting the future concept of development of the ISO 9001 series of standards bearing in mind that the draft future concept of standards for management systems provides framework topics to be addressed in the future by ISO 9000 series standards and organizations applying standards for management systems.

This year, as well as every subsequent year, we will give recognition to those who have contributed to the success of the conference.

This year, as every next year, we will award prizes to deserving members for their contribution to the work of the Association as well as to the improvement of the quality infrastructure in Serbia

The success of a conference depends on all the participants, therefore, I take the opportunity to thank all the authors and co-authors of the papers, the co-organizer, the general sponsor, other sponsors and donors, media patrons, as well as all the participants from Serbia and abroad.

I would like to wish us successful work and a good time at the largest gathering devoted to quality.

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Yours sincerely,

Professor Zoran Punoševac, PhD Organizing Committee Chairman

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QUALITY SYSTEM CONDITION FOR SUCCESSFUL BUSINESS AND COMPETITIVENESS

COMPARATIVE ANALYSIS OF 8D METHOD AND REQUIREMENTS OF QUALITY MANAGEMENT SYSTEM

Maja Mutavdžija, mag.ing.traff.¹
Sanja Zladić, dipl.ing.²
doc.dr.sc. Ana Globočnik Žunac.³

Abstract: Nonconformity as such is a significant challenge for every organization because is the consequence of variability in the organizational process. Decreasing customer satisfaction could lead to a decreasing in organizational reputation which, in the long term, could be extremely dangerous for the organization. ISO 9001:2015 norm on the quality management system puts different kinds of requirements that are related to nonconformity management and which organization must involve in the decision when it comes to dealing whit nonconformity. Besides, ensuring accordance with such requirements could be a challenge for the organization because approach to the solving problem that is not systematic could lead to partial solutions. One of the ways for dealing nonconformities is the 8D method. In this paper, the authors compare requirements that ISO 9001:2015 puts on the organization when comes to nonconformity management and 8D method steps.

Keywords: non-conformities, complaints, analysis of the causes of the problem, quality management system

JEL Classification: L29

1. INTERDUCTION

One of the requirements that ISO EN 9001:2015 puts on quality management systems is managing inconsistent outputs which are described in 8.7. point. Norm ISO 9001:2015 on the organizational management system puts also requirement related to describing how non-compliance appeared and also to describe actions related to the solving problem or root cause of the problem. Accordingly, to the requirement, the organization must define procedures that will be taken when non-compliance appeared and also procedures that will be taken when the customer reports non-compliance with the product or service that he bought.

Non-compliance in the process as the result may have a decrease in the efficiency and effectiveness of the process as well as decreasing in cost-effectiveness. Furthermore, one of the main reasons for decreasing effectiveness, efficiency, and cost-effectiveness of the process is the process instability.

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Process instability is the result of different kinds of variations that may appear in the process.⁴ Accordingly, the organization must investigate possible causes of the variations that result in non-compliance of the product or service, as well as an organization, must conduct a risk assessment that is related to the identifying all risks that may in future as the result have appearing of new non-compliances in the process. It should be highlighted that identifying the root cause of the problem and creating measures for future preventing of the incident in the process could lead to the development of the sustainable success of the organization.⁵

Reclamation that costumer have are one of opportunity for the organization to conduct improvements and also to discover places in the process and features that current product or service have that could be improved. Reclamation as such for the organization means that customer is not fully satisfied whit product or service so current satisfaction of costumer must be improved because there is the risk that customer will go to the competition.⁶

When non-compliance appears in the process this may lead to the appearance of cost for poor quality. Poor quality costs are all costs that organizations have and there are related whit dealing whit non-compliance of product or service that is delivered to the customer. In poor quality, the cost may be included costs that are related to the corrective actions that the organization is conducting because of the non-compliance. The organization places a larger amount of products on the market that have some kind of non-compliance there is also the possibility of endangering the health of the costumers that will buy such a product. Furthermore, there is also risk related to the increasing in poor quality costs because the organization must withdraw all non-compliance products from the market. So, because of the complexity of dealing whit non-compliances, there is a need of using a method that will be in accordance whit requirements of the ISO EN 9001:2015 and will result in dealing whit non-compliance products.

In this paper, the authors describe the 8D method for a scientific approach in non-compliance solving. In the paper, the authors find that the 8D method is following whit requirements that ISO 9001:2015 puts on the organizations.

2. METODOLOGY

For conducting research in this paper authors use secondary research in which they compare requirements that ISO EN 9001:2015 puts on the organizational quality management system and it's related to the dealing whit non-compliance and improvements in the process. After identifying all requirements of the ISO 9001:2015, whit secondary research authors identify all steps of the 8D method and compare them whit requirements of ISO 9001:2015. The main aim of the research is to show the importance of dealing with whit non-compliances and conducting continuous process improvements. Furthermore, the paper aims to compare the 8D method whit requirements of ISO 9001:2015 requirements.

3. NONCONFORMITY MANAGEMENT

Nonconformity is the product, service, or activity that has been conducted but that is not in accordance with whit requirements that law or norm puts on that product, service, or activity. Furthermore, nonconformity in most cases is a result of process variations. According to the ISO EN 9000:2018 nonconformity is non-compliance whit the requirements that are placed on the product or services. On the other hand, nonconformity showed also customer dissatisfaction whit the product or service whit product or service from the organization. So, nonconformity as the result has non-effectiveness because the organization is not conducted planed goal. Whit non-effectiveness and not meeting goals, the organization must invest more resources to meet planned goals that mean the organization is not efficient. Whit noneffective and nonefficiency, the organization is dealing with whit decreasing cost-effectiveness.

Nonconformity management is one of the main requirements that ISO 9001:2015 puts on the quality management system and its related to the root cause analysis of the problem that as result have nonconformity as well as the creating and conducting measures that are related to the improvement in the process to prevent future risks that may result in nonconformity. ¹⁰ Furthermore, Nonconformity management is imperative because of fact that nonconformity as the result may have decreasing of organizational repentance as well as the possibility to customer substitute organizational products and services whit products and services from the competitors.

In point 8.7.1. ISO 9001:205 norm is highlighting that the organization must conduct all measures that are necessary for managing nonconformity. Furthermore, all measures must be aimed at the root cause of the problem so the problem will not appear in the future as well as conducting all measures that are related to the product recall.¹¹ So, it is necessary for the organization to create procedures for managing all nonconformity and also procedures that will be aimed at decreasing damage for all interested parties. All product recall for the organization may result in increased costs of poor quality that may endanger organizational success in the future.¹² After procedures that are aimed at product recall and decreasing damage to the costumers has been conducted, the organization must conduct an analysis of root cause and also create measures that will result in decreasing damage. When conducting all measures, the organization must document every step that is made. Documenting of measures and their effectiveness and efficiency is one of the main requirements of ISO 9001:2015.¹³ For creating such measures and procedures, organizations can use a different kind of tools such as the Pareto diagram, Ishikawa diagram, brainstorming, control carts, etc.

The need for root cause analysis arises from the requirements that ISO 9001:2015 describe in point 10.2.1. in which is described that organization must create measures and procedures that are aimed at the supervision of the nonconformity and actions that are made for nonconformity management. ¹⁴ In other words, the organization must identify all problems and consequences that arise from nonconformity and create measures for decreasing damage for the customer and all interested

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⁴ Buntak, K., Sesar, V., & Kovačić, M. (2016). Bussness process controlling. XVII nacionalni i V međunarodni naučno stručni skup "Sistem kvaliteta uslov za uspešno poslovanje i konkurenntost".

⁵ Buntak, K., Kovačić, M., & Mutavdžija, M. (2019). Continuous process improvement as a foundation for sustainable organizational development. 20th International Symposium on Quality - QUALITY - YESTERDAY, TODAY, TOMORROW.

⁶Tari, J. J., & Sabater, V. (2004). Quality tools and techniques: are they necessary for quality management? International journal of production economics, str. 267-280.

⁷ Oppermann, M., Sauer, W., & Wohlrabe, H. (2004). Optimization of quality costs. Robotics and Computer-Integrated Manufacturing, str. 135-140.

⁸ ISO, S. 9000. (2018). Quality management systems. Fundamentals and vocabulary (ISO 9000: 2015). Brussels: European Committee for Standardization.

⁹ Buntak, K., Sesar, V., & Kovačić, M. (2016). Bussness process controlling. XVII nacionalni i V međunarodni naučno stručni skup "Sistem kvaliteta uslov za uspešno poslovanje i konkurenntost"

¹⁰ Percarpio, K. B., Watts, B. V., & Weeks, W. B. (2008). The effectiveness of root cause analysis: what does the literature tell us? The Joint Commission Journal on Quality and Patient Safety, str. 391-398

¹¹ ISO, E. N. 9001. (2015). Quality management systems. Requirements. Brussels: European Committee for Standardization.

¹² Magno, F. (2012). Managing product recalls: The effects of time, responsible vs. opportunistic recall management and blame on consumers' attitudes. Procedia-Social and Behavioral Sciences, str. 1309-1315

¹³ ISO, E. N. 9001. (2015). Quality management systems. Requirements. Brussels: European Committee for Standardization.

¹⁴ Ibid.

If organization identify the larger problem that may endanger business continuity, it is necessary to create procedures that will ensure business continuity and which will ensure all resources and measures that are important for ensuring recovery from the problem.¹⁷ It should be highlighted that every organization must put special attention to the risks and risk assessment that as the result could have nonconformity or decreasing in customer satisfaction. Whit this approach organization is preventing future problems that may result in creating nonconformity and also create an approach that is based on risk assessment. To additionally decrease the possibility of arising risks, it is recommended to involve interested parties in risk assessment and to look at risk from the aspect of the customer.¹⁸ Because of the requirements that ISO 9001:2015 puts on the quality management of the organization, it is necessary for the organization to create and implement a systematic approach to managing nonconformity and also for a system approach to the creating measures related to the decreasing damage to the costumers and organization itself.

4. SYSTEM APPROACH TO THE NONCONFORMITY MANAGEMENT

System approach to the nonconformity management implies fulfillment of the requirements that ISO 9001:2015 puts on the organization, and are related to the communication whit all interested parties which are affected whit the problem or which reported nonconformity. One of the system-based approaches to the nonconformity root cause analysis is the 8D method. 8D method is an approach that is created during World War 2 within military norm 1520 – corrective actions and nonconformity. The method was first used in 1987. Within automobile organizations in the USA, and today is often used in the automobile industry. ¹⁹ 8D is an acronym for eight disciplines that are incorporated within the method and which are described in Table 1.

Table 1: 8D method phases

Discipline	Description	
D0 – planning	In this phase, the organization conduct preparation for the project of root cause analysis. So, in this phase, the organization defines all information that is important for the root cause analysis such as information from customer service, from costumer and all interesting parties that are related to the nonconformity.	
D1 - Team creation	In the first phase of the 8D project, the organization creates an 8D team that consists of different kinds of experts from different areas such as quality, customer service, manufacturing department in the organization, etc.	
D2 – Problem definition	In the second phase of the project, the 8D team creates a definition of the problem that occurred in the organization. Problem definition is related to the creating problem statement that is in accordance whit the nonconformity that the customer reported. The problem must be described as accurately as possible.	

¹⁵ Gupta, P., & Varkey, P. (2009). Developing a tool for assessing competency in root cause analysis. The Joint Commission Journal on Quality and Patient Safety, str. 36-42.

¹⁶ ISO, E. N. 9001. (2015). Quality management systems. Requirements. Brussels: European Committee for Standardization

¹⁷ Buntak, K., Kovačić, M., & Sesar, V. (2019). The importance of identifying opportunities and risks in enshuring business continuity. 4th International Scientific Conference on Economic and Social Development "Sustainble Turist Destinations"

¹⁸ Dănescu, T., Prozan, M., & Dănescu, A. C. (2014). Non-conformity risks-theoretical and practical connotations. Procedia Economics and Finance, str. 993-1001.

¹⁹ Biban, L. K., & Dhounchak, D. (2017). 8D Methodology and Its Application. JETIR.

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D3 – Actions for limitation of damage	The main goal of actions for limitation of damage is preventing further spreading of the problem to all other interested parties. Some of the examples of such actions is a product recall. Defined actions are in accordance whit identified risk and identified risk should be a review after actions for damage prevention are done. Furthermore, it is necessary to establish communication whit all interested parties and to communicate all defining measures that are aimed at decreasing damage.
D4 – Root cause analysis	In the fourth step in 8D, the team must analyze the root cause to identify possible causes of the problem. For root, cause analysis the organization team can use different kinds of tools such as Pareto diagram, Ishikawa diagram, brainstorming, etc.
D5 – Validation of measures	In this phase, after the organization team recognizes root cause, corrective actions are defined. Before measures are implemented in the process it is necessary to validate such measures to ensure their efficiency and effectiveness.
D6 – Implementing measures	The sixth phase is related to the implementation of measures that are defined in the fifth phase. It should be highlighted that all implemented measures should be aimed at updating all procedures that are used in the process and also to educate all employees that are involved in the process. This approach will as the result have a decreasing risk of repetition of the problem in the future.
D7 – defining preventive actions	After corrective actions are deployed, the organization must create preventive actions to prevent future occurrences of similar problems in the process. All defined measures must be reviewed through the aspect of their effectiveness and efficiency.
D8 – Closing project	The last phase is related to the closing of the project and to rewarding all project members.

Source: Author

All steps that are described in Table 1 must be conducted whit in accordance with step 1 to step 8. The organization team is not allowed to skip one of the steps because skipping will as the result have a partial solution to the problem. Furthermore, the organizational 8D team must document all steps and results of the step and in the last create an 8D report. It should be highlighted that 8D is a team approach to problem-solving and the organization must create and obtain synergy in the team as well as ensure management support.

ISO 9001:2015 norm on the organization puts a different kind of the requirements that are described in the third chapter. In accordance with whit that, the 8D method is one of the ways of problem-solving that is in accordance whit described requirements. Furthermore, Table 2 is shown a comparison between requirements that ISO 9001:2015 puts on the quality management system of

8D phase	ISO 9001:2015 point in which requirement is described	Short description
D0 – planning	8.2.1	In D0 phase of the 8D method problem solving in which organization collection all information related to the problem that customer report. This step is in accordance with whit point 8.2.1. of the ISO 9001:2015. Furthermore, in the mentioned point, ISO 9001:2015 on quality management system puts requirement that is related to the managing product that customer report as non-compilated whit the requirement as well as the places in which such product must be stored.

	14	Tuju Mutuvuziju, Sarija Ziarre, 12. a. s s s s s s s
D1 – Team creation	7.2.	The team that the organization creates and will be in charge of problem-solving whit the 8D method must have different competences and knowledge from different areas. Requirements that are related to the competence of the team and employees are described in point 7.2. Furthermore, the competence of the team and organization as a whole is one of the principles of the quality managed organization.
D2 – problem description	8.7.2, 7.4.,	In this step problem is precisions described which are the requirement that norm ISO 9001:2015 puts on the quality management system in point 8.7.2. The exact problem description is a precondition for a system approach to problem-solving as well as the nonconformity solving. Precisions problem description often means good communication whit the costumers so customers can describe what is exactly wrong whit the product or service. Furthermore, the organization must communicate problems whit other interested parties whit different media channels. This is a requirement that norm ISO 9001:2015 is describing in point 7.4.
D3 – actions for limitation of damage	10.1, 10.2.1	In this step are conducted risk assessment as well as the defining measures that will be aimed at decreasing damage to the problem that is occurred. ISO 9001:2015 norm in point 10.2.1 the described requirement that is related to conducting all measures that are important for damage limitation. In point 10.1. ISO 9001:2015 norm defining requirement related to the correcting, preventing, and decreasing of unwanted repercussions of the problem. So, D3 is in accordance with whit described requirement.
D4 – root cause analysis	10.1, 10.2.1	In this step, the organization is providing roo cause analysis. Requirements that norm puts of the organizational quality management system are described in point 10.1. of ISO 9001:201: norm in which is described that the organization must analyze the root cause of the problem a well as all unwanted repercussions Furthermore, in point 10.2.1. are described requirements that are related to the measures for supervision of conducted steps for analyses of the problem.
D5 – validation of the measures	10.2.1,	ISO 9001:2015 norm in point 10.2.1. on the quality management system of the organization puts requirement related to the evaluating of a measures that are created for problem-solvin i.e. corrective actions.

D6 – implementing measures	9.1.1, 9.1.3, 10.2.2.	In this step, the organization is implementing steps that are created in D5. This is related to creating control points in the process that will be used for the monitoring of the efficiency and effectiveness of the implemented measures. Furthermore, in point 9.1.3. ISO 9001:2015 norm on the organizational quality management system puts requirements related to the imperative of identification are defined measures good i.e. does measures as the result have improvements. In point 10.2.2. ISO 9001:2015 norm puts requirements related to the monitoring of the conducted corrective measures. So, D6 is in the accordance whit requirements of the ISO 9001:2015.
D7 – defining preventive measures	10.1,	Quality management system based on the ISO 9001:2015 norm is based on the risk approach which means that organization must provide risk assessment and to create and conduct all measures that are appropriated and in correlation whit the risk level. ISO 9001:2015 norm in point 10.1. on organization puts requirements related to the improvement's so in the future, there is significantly lower risk and the possibility of occurrence of the problem. So, an organization in D7 create preventive measures based on the risks and risk evaluation and created measures are related to the decreasing possibility of occurrence of new problems.

Source: Author

It should be highlighted that D8 of the 8D discipline is not described in Table 2 because motivation and human potential management policies are defined by every organization itself. So, ISO 9001:2015 is not explicitly defining requirements related to the rewarding of the employees.

5. CONCLUSION

This paper is based on secondary research and within it is conducted a comparative analysis between requirements that ISO 9001:2015 puts on the quality management system in the organization and phases i.e. 8D disciplines. In research, authors find accordance with 8D whit requirements of ISO 9001:2015 norm in points that are aimed at requirements for nonconformity management. Nonconformity management is one of the main requirements that ISO 9001:2015 highlights and it is especially important for obtaining relations whit costumers and obtain the reputation that organizations have on the market. Furthermore, 8D is one method that an organization can use for the non-compliance management and for analyzing root cause that as the result have lower satisfaction of the customer.

Managing nonconformities is important because nonconformity products as the result may have to decrease in the satisfaction of the costumers and also the possibility of endangering their quality of life and life as such. Furthermore, nonconformity is the possibility to improve product or service and also to make products or services better. Through secondary research, authors find that man papers are describing methods for nonconformity management and for root cause analysis but there is a lack of papers that highlight possibilities of using the 8D method for nonconformity management and solving costumer's problem. Also, many papers are describing individual tools.

Usage of individual tools for root cause analysis could lead to partial solutions and partial solutions mean the possibility of a new occurrence of the nonconformity in the process.

So, all organizations that have a quality management system that is certificated whit ISO 9001:2015 norm are advised to use the 8D method as the scientifically and systematic approach for nonconformity management. Usage of 8D is in accordance with whit requirements that ISO 9001:2015 norm puts on the quality management system and also summarizes that requirements in a methodological and logical approach.

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ACCREDITATION BODY OF SERBIA

The Accreditation Body of Serbia (ATS) as a national accreditation body was founded by the Republic of Serbia and is located in Belgrade.

Pursuant to the Law on Accreditation, ATS has a task to assess the competence of conformity assessment bodies (CABs) to perform testing, calibration, inspection, and certification of products, management systems and persons.

ATS activities are oriented to the upgrade of its system of operation in order to maintain and extend the scope of signed multilateral agreements (MLAs) and the accreditation system that was put in place. This will increase the level of efficiency of accreditation procedures in all fields of conformity assessment and provision of safety of goods and services in our country and abroad.



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ATS performs the following activities:

- determine the competence of conformity assessment bodies performing testing, calibration, inspection, certification of products, certification of management systems and certification of persons;
- determine the competence to perform other conformity assessment activities;
- set forth and publish the Rules of Accreditation that shall be based on the relevant Serbian, international and European standards and documents of the international and European organisations for accreditation;
- keep a public directory of accredited conformity assessment bodies;
- participate in the work of international and European organisations for accreditation;
- organise and deliver accreditation-oriented training to assessors;
- organise seminars and training courses, and promote the importance and role of accreditation;
- preparation and issue of informants, publications and newsletters in the field of accreditation

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