

ANALYSIS OF NONCONFORMITIES AT QUALITY AUDITS

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Abstract:

This paper deals with implementation of requirements of standard ISO 9001. Quality management systems in accordance with requirements of standard ISO 9001 are implemented and accepted in broad number of companies in Croatia. First organizations that implemented these requirements were production companies from industry. Authors investigate differences at implementing requirements of standard ISO 9001 at organizations dealing with different kind of production companies. Using statistical tests, requirements of quality management system are determined, which have significant number of non-conformities at monitored organizations. Data are obtained from actual internal and external quality audits at Croatian factories. Analysis of internal and external quality audits results was used to determine those quality management system requirements that were difficult to implement. Investigation includes 25 Croatian companies, with different scopes of activity, number of employees and type of ownership. Quality management systems of these companies were monitored in detail for four years. Internal audit reports were collected from companies, and author himself performed external audits at companies that were included in this investigation. Findings of more than one hundred quality audits are included. These data are analysed to determine influential parameters to occurring of non-conformities at quality management systems. Non-conformities that were issued at audits are presented according to requirements of standard ISO 9001.

Keywords: Quality, Audit, Analysis

1. INTRODUCTION

Numerous Croatian companies accepted and implemented Quality Management Systems in accordance to requirements defined in standard ISO 9001. Many of these companies have certified their quality management systems. Level of fulfillment of quality management system requirements is evaluated by quality audit. After years of implementation of quality management systems requirements, analysis is performed to determine which requirements are most difficult to implement. There were Internal and external quality audits monitored in this investigation. When auditor establish that requirement is not fulfilled, non-conformity is issued. Internal audit reports were collected from companies, and author himself performed external audits at companies that were included in this investigation. Non-conformities that were issued at audits are presented related to requirements of standard ISO 9001. Investigation was

performed at Croatian companies, with different scopes of activity and type of ownership. Quality management systems of these companies were monitored in detail for four years. This data are analyzed to determine influence of type of activity and ownership to non-conformities at quality management systems. To simplify analysis, requirements of standard ISO 9001 are grouped and identified as presented at table 1.

Table 1: Group of requirements

Group of requirements	Clause of standard	Group of requirements	Clause of standard
4A	4.1 4.2.1	7E	7.5.1 7.5.2
4B	4.2.2 4.2.3	7F	7.5.3
4C	4.2.4	7G	7.5.4
5	5 6.1	7H	7.5.5
6A	6.2	7I	7.6
6B	6.3 6.4	8A	8.2.2 8.2.3
7A	7.1	8B	8.2.4
7B	7.2 8.2.1	8C	8.3
7C	7.3	8D	8.4
7D	7.4	8E	8.5

2. AUDIT FINDINGS

2.1 Analysis related to company type

First companies that implemented ISO 9001 requirements in Croatia, were production companies [1]. Later, when revision of ISO 9001:2000 was issued service companies, started to implement ISO 9001 requirements. It continued with ISO 9001:2008 revision. In this investigation, companies are divided to service companies, metal dealing production companies, and all other production companies that will be named Production 2. Analysis is performed to determine are there significant differences between service organizations, metal production and production 2 companies related to non-conformities which were determined at internal and external quality audits. Pareto analysis, Spearman rank correlation and Chi square analysis are made to determine influence of type of company to implementation of requirements of quality management system.

Example of results of performed audits are presented at figure 1 where percentage of nonconformities (related to total number of non-conformities) from internal audits at service organizations is displayed. Only groups of requirements with high percentage of non-conformities are presented at figure 1.

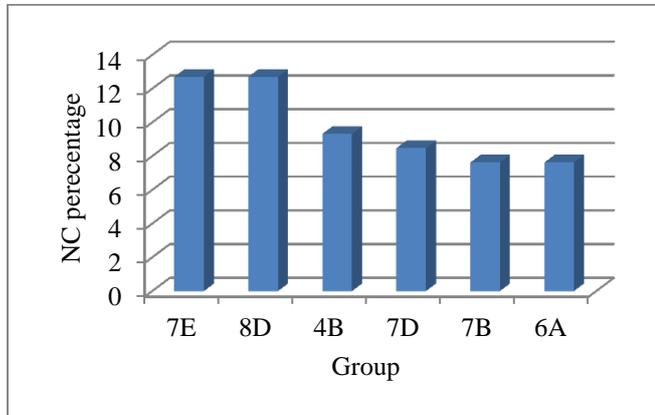


Figure1: Example of non-conformities at internal audits

Group of requirements with most number of non-conformities at internal audits were noticed at group of requirements 7E which is related to Realization of production or service. These kind of non-conformities are most often at internal audits because they are easy to notice and internal auditors are familiar with requirements at realization process. Same reason is for large number of non-conformities at requirements related to document control (4B). Also at service organizations significant number of non-conformities was noticed at group 8D, which is related to Statistical techniques. This is expected due to fact that statistical techniques usually are not applied in service organizations in such extent as in production organizations [2]. Internal auditors noticed non-conformities related to evaluation of suppliers and customer satisfaction measurement techniques.

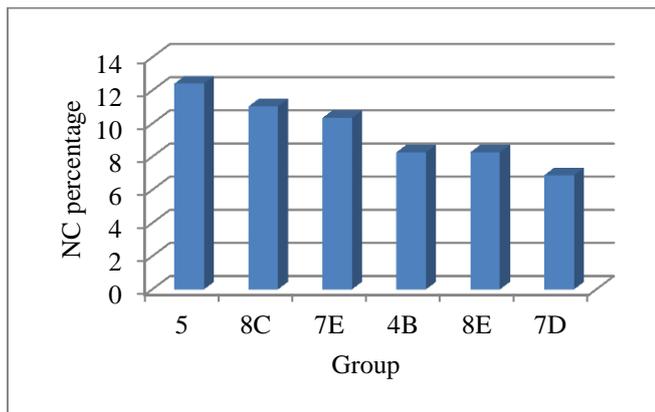


Figure 2: Example of non-conformities at external audits

External audits have a little bit different results. Beside already mentioned requirements, non-conformities are noticed mainly at requirements related to management responsibility (5). Clearly, reason for this is that internal auditors were not resolute enough to determine mistakes at

their own management. External auditors did not have this problem. Also requirements related to non-conforming products (8C) and corrective and preventive actions (8E) were noticed as those with high number of non-conformities. Reason for this was that external auditors noticed problems with determining of cause of problem when issuing corrective or preventive action. Also there were problems with documenting non-conforming services at service organizations. Internal auditors overlooked that.

Comparing results from internal and external audits to determine level of differences in evaluation of quality management systems, is performed by Spearman rank correlation [3].

$$r_s = 1 - \frac{6 \sum_{i=1}^N d_i^2}{N^3 - N} \tag{1}$$

Where is

r_s - correlation coefficient

d_i - differences between ranks

N - number of ranks

Results show that between internal audits, coefficient is relatively high, from 0,53 to 0,72. Between external audits coefficient is also significant, and it has value from 0,61 to 0,77. Results between internal and external audits related to type of production show coefficient from 0,13 to 0,63. Coefficient 0,13 which show really weak relation is determined at comparing results from internal audits at metal production and external audits at service companies.

Finally Chi square test is performed to determine influence of type of companies to non-conformities at audits. Chi square value is calculated as defined by [3]:

$$\chi^2 = \sum_{i=1}^r \sum_{j=1}^k \frac{(O_{ij} - E_{ij})^2}{E_{ij}} \tag{2}$$

Where

χ^2 is value of chi square test

O_{ij} are observed frequencies

E_{ij} are expected frequencies

Results of performed chi square test related to type of company are presented at table 2. Results show very weak influence at only one requirement (7C) where calculated probability was $p=0,054$. Results for other requirements show there is no influence of company type to audit findings.

Group of requirements 4C, 6B, 7A and 7B did not have appropriate data to perform correct Chi square test. Observed frequencies should be higher than 5 for at least 20 % cases.

Table 2: Chi square test results related to company type

Groups	χ^2 - test	p
4A	1,918	0,383
4B	2,079	0,355
4C	-	-
5	1,174	0,559
6A	1,798	0,408
6B	-	-
7A	-	-
7B	1,924	0,382
7C	5,844	0,054
7D	2,665	0,264
7E	0,860	0,650
7F	0,900	0,638
7G	-	-
7H	0,353	0,838
7I	4,345	0,114
8A	2,370	0,306
8B	3,322	0,190
8C	4,684	0,096
8D	4,787	0,090
8E	0,599	0,744

2.2 Analysis related to type of ownership

There are still number of companies in Croatia that are state owned. Analysis is performed comparing results from internal and external audits at state owned companies and private companies.

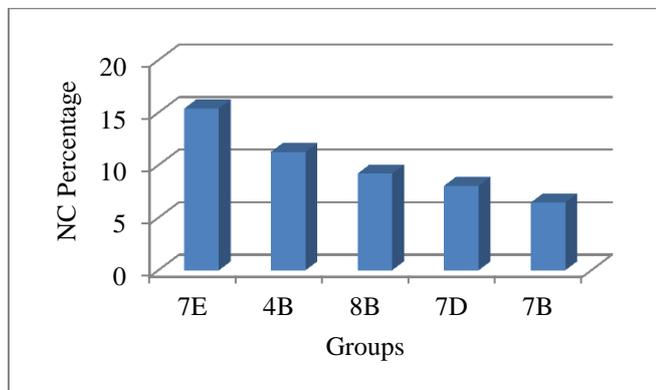


Figure 3: Internal audits related to type of ownership

Requirement with significant number of non-conformities at internal audits in private and state owned companies was requirement related to document control (4B) and for requirement related to realization of product (7E). Reason is similar to situation at analysis for type of production. Requirement for control of product (8B) has significant percentage of non-conformities and it is related to criteria of acceptance which was not correctly defined. Internal audits at private companies resulted with significant number of non-conformities related to purchasing (7D). Main reasons for this are weaknesses in evaluation of suppliers which was performed just formally, and at some cases not at all. Results of external audits, again, show weaknesses at management responsibility and at control of non-conformities and corrective and preventive actions.

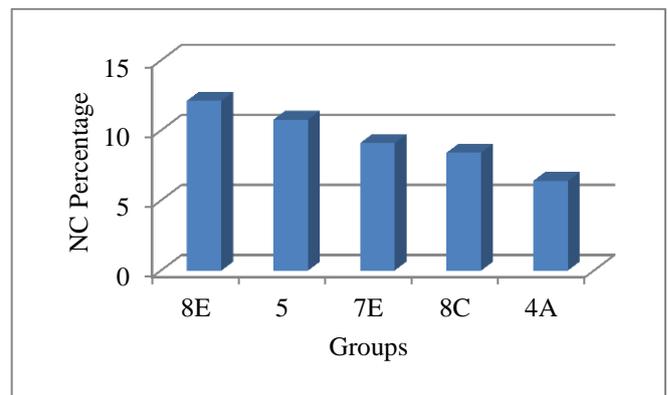


Figure 4: External audits related to type of property

Similar to analysis related to type of company external audits show significant number of non-conformities for group of requirements (8E, 5, 7E and 8C). Requirements related to process identification (4A) were also found with significant percentage of non-conformities.

Results of performed Spearman rank correlation test related to type of property, show that between internal and external audits coefficient got values from 0,19 to 0,57. Coefficient 0,19 show weak relation, and it is determined at comparing results from external audits at state owned companies and internal audits at private companies. These results are presented at table 3.

Table 3: Spearman rank correlation for type of property

Audit	Type of property	Internal		External	
		Privat	State	Privat	State
Internal	Privat	1	-	-	-
	State	0,59	1	-	-
External	Privat	0,41	0,19	1	-
	State	0,48	0,57	0,74	1

Table 4 present results of Chi square test for found non-conformities at internal and external audits related to type of ownership at monitored companies

Table 4: Chi square test related to type of ownership

Grupe	χ^2 - test	p
4A	1,302	0,254
4B	1,306	0,253
4C	-	-
5	0,071	0,790
6A	1,561	0,211
6B	-	-
7A	-	-
7B	3,331	0,068
7C	0,123	0,726
7D	2,394	0,122
7E	13,887	0,0002
7F	0,653	0,420
7G	-	-
7H	6,009	0,014
7I	1,968	0,161
8A	2,231	0,135
8B	0,348	0,555
8C	5,201	0,002
8D	1,605	0,205
8E	5,780	0,016

Significant influence to results of internal and external audits related to type of ownership was found at four groups of quality management system requirements (7E, 7H, 8C and 8E). Compared to analysis for type of company, this is higher influence, where only one group of requirements showed weak influence.

3. CONCLUSION

Quality management systems according to requirements of standard ISO 9001, are widely implemented, and most of companies have certified their quality management systems. For Croatian companies, it is important to determine which requirements of standard are difficult to implement, and these are requirements with significant number of non-conformities found at quality audits. Result of analysis is that companies should pay a lot of effort to enhance improvement process. Additional training should be performed due to better understanding of corrective and preventive actions requirements and control of non-conforming products or services. Management should be more involved to quality management system and should accept that without management commitment, there is no successful quality management system. Employees should be educated to proper handling of documents, especially at production area. There is influence of type of ownership to implementation of quality management system. Data obtained from this investigation could help implementation of ISO 9001 requirements in Croatian companies.

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