

## ASSESSMENT OF USE OF INFORMATION OBTAINED FROM QMS AUDIT, FOR THE PURPOSE OF IMPROVEMENT PROCESSES AND PRODUCTS

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### SUMMARY

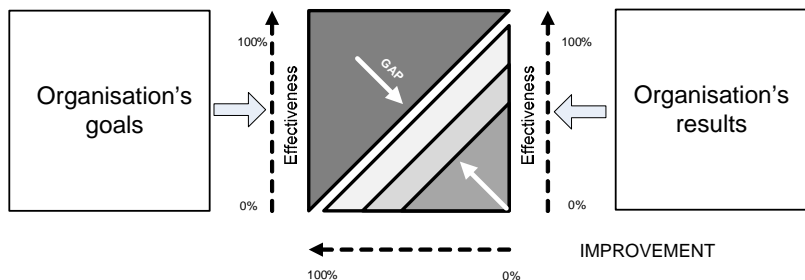
*The article presents analysis results of the third-party audits documentation from one of the world's leading certification bodies. The research uses a documentation resulting from 110 certification audits conducted in 2008. These results have been compared to the results of internal audits carried out in 80 production and service companies, ranked as small and medium businesses. The research allowed to evaluate the level of use of information gained from the internal audits in order to improve the company management effectiveness.*

**Keywords:** quality, management, audit, improvement

### 1. INTRODUCTION

Quality systems have undergone evolution from quality control through quality assurance to quality management. Quality control was focused on the proper course of processing operations. The 1980s marked a breakthrough in the way quality was perceived. In that period a quality domination could be observed in Japan. Juran already in 1966 forecast that Japan would become a quality leader in the upcoming two decades [1]. The economic successes of Japan resulted in works on quality assurance, and next quality management systems. The assumption of the first edition of ISO series 9000 was to create a system in which the customer's requirements would be predictable, and their fulfilment would be ensured owing to the establishment of procedures guiding the employees through all management areas that influence customer satisfaction. The effectiveness of this system was guaranteed by systematic audits enabling elimination of inconsistencies and potential inconsistencies understood as a departure from the established procedures required by the standard. The major amendment of ISO 9001 as of 2000 changed the assumptions of quality systems, which became closer to the concept of TQM. They were based on eight pillars among which the customer focus and continuous improvement were considered the most important. Such an approach allowed taking decisions on the basis of facts. The amendment of ISO 9001 in 2008 did not introduce any significant changes to the concept of standards. It was based on the decisions taken by the working group ISO/TC176/IAF ISO 9001 Auditing Practice Group at a meeting which was held in 2003, in Sydney, Australia. In the new edition the requirements which frequently provoked interpretation discussions were specified more precisely. At the meeting it was established that both effectiveness and improvement may be presented as a cyclic process, in which QMS elements are used to analyse data and next, to make changes and undertake initiatives. They ensure continuous improvement [2]. The adopted assumption

emphasizes the relationship with the strategic, business or financial goals of an organization. The effectiveness of a system, including a QMS, is measured by a gap between the targets and results of an organization (Fig. 1). This gap should be treated as an indicator of business effectiveness. Both the goals adopted by an organisation and the obtained business results should be analysed and provide a basis for undertaking improvement initiatives. So understood quality management system requires an audit to be treated as a tool which allows improving the system, management and manufacturing processes as well as a product or service by identifying the gaps between the targets set at the company's strategic level and the obtained results. The assumptions of an audit, a tool used to maintain conformity of the quality system with the requirements of the standard and the established system, is to identify departures and areas requiring improvement.



A gap indicates the effectiveness of a system. The smaller the gap, the greater convergence of the results and goals.

Figure 1. Effectiveness of the QMS as a measure of gap between organizations objectives and results.

In the last two revisions of ISO 9001 standards, attention has been paid to the use of audit information to improve the system of management, processes and products/services. The functioning of an organisation on the market involves risk. The risk that an organization is exposed to may be related to the strategy, organization, conformity, operating activity or data loss. A tool which reduces the probability of the increased risk related to business activity is a system audit – understood as an internal audit of the second and third party. In order to be deemed effective, each audit should bring an added value to the audited processes/systems. The effectiveness of external audits is higher compared to internal ones. This results from insufficient preparation of internal auditors and the fact that they have less experience in QMS auditing [6].

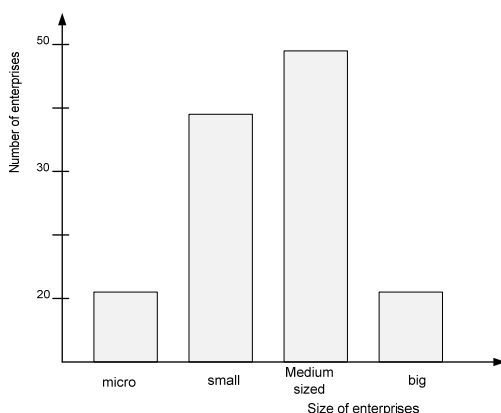
## 2. CONDUCTED STUDIES

The studies included analysis of documentation from preliminary, certification, control and recertification audits conducted by a selected accredited certification body. The analysed documentation concerned the audits conducted in 2009. The post-audit documentation from an external unit was analysed with regard to the following problems:

- ✓ Is there a dependence between the type of an organisation's activity and the number of identified inconsistencies and areas to be improved?
- ✓ Does the type of business activity influence the kind of inconsistencies and areas requiring improvement identified with regard to a particular paragraph of the standard?
- ✓ Is there a dependence between the size of an enterprise and the number of discovered inconsistencies and areas to be improved?
- ✓ Is there a relationship between the size of an enterprise and the number of inconsistencies and areas to be improved identified with regard to a particular paragraph of the standard?
- ✓ Do auditors have preferences regarding particular paragraphs of the standard?

The analysis took into consideration the kind of nonconformity and the paragraph of the standard to which it referred. The studies included 274 cases of nonconformity discovered during audits and 326 cases identified during audits as areas requiring improvement. The studies covered audits conducted by independent certification bodies in 110 enterprises. In order to establish whether the auditors had any preferences regarding particular paragraphs of the standard, the issues raised by professional auditors of the certification body were selected from among the collected cases of non-conformity and areas to be improved. Three auditors who had conducted minimum 10 audits were chosen.

The analysis did not take into account the inconsistencies quoted by contract auditors in nonconformity reports. The nonconformity reports and audit reports were analysed from the point of view of the type of business activity (service and production firms) as well as the size of an enterprise. The analysed enterprises were classified according to the number of employees into micro-enterprises (up to 10 employees), small (up to 50 employees), medium-sized (up to 250 employees) and big firms employing 250 people. The population subjected to investigations included 28 service enterprises and 36 production ones. There were 12 micro-enterprises, 39 small, 48 medium-sized and 11 big firms. The number of enterprises was selected so that the sample would be representative with regard to the number of economically active enterprises of particular size [4]. The structure of population in terms of the size of enterprises has been presented in Fig. 2.



*Figure 2 The division of enterprises in the analysed population according to size*

The obtained research results were compared to the results of internal audits. Documentation from internal audits provided by 43 economic subjects representing small (27 micro and small) and medium-sized enterprises was available for analysis. The analysed nonconformity reports (NC) and areas requiring improvement (ARI) identified in audit reports were classified according to the type of enterprise activity falling into two categories – service sector firms and production companies. The areas to be improved quoted in audit reports were assigned to the requirements of the standard. The results of research have been given in Tables 1 and 2.

The quoted results indicate that the highest number of inconsistencies were connected with the requirements contained in paragraph 8 of the standard – Measurements and improvement. Service-providing enterprises had more such inconsistencies than production ones.

Similar numbers of inconsistencies were identified for paragraph 7 of the standard – Product processing. In this case, however, more cases of nonconformity were noted in production enterprises. Inconsistencies regarding the requirements of paragraph 4 (general requirements and requirements concerning nonconformity documentation) account for 11.3% of the total number of inconsistencies in service enterprises, and 7.74% in production ones. As for areas requiring improvement, there were 8.71% of cases in service companies and 11% in production ones.

The discovered inconsistencies and areas to be improved were classified according to the size of enterprises. The results have been presented in Table 3.

*Table 1 Classification of inconsistencies and areas requiring improvement according to the frequency of occurrence with regard to the type of activity and the requirements of the standard.*

Classification of enterprises/paragraph of the standard	According to the type of activity			
	Services		Production	
	NC [%]	ARI [%]	NC [%]	ARI [%]
4. Quality management system	11,30	8,71	7,74	11,00
5. Responsibility of managers	5,14	6,85	4,76	7,26
6. Management of resources	5,36	5,39	8,85	6,02
7. Product processing	10,20	13,48	13,49	11,69
8. Measurement, analysis, improvement	19,56	13,12	13,50	15,49
TOTAL:	51,56	47,55	48,54	52,45
Legend: NC – nonconformity, ARI – areas requiring improvement				

Source: own study

*Table 2 Division of inconsistencies and areas to be improved according to the frequency of occurrence with regard to paragraph 8 of ISO 9001:2008 standard*

Classification of enterprises/paragraph of the standard:	According to the type of activity			
	Services		Production	
	NC [%]	ARI [%]	NC [%]	ARI [%]
8 Measurements, analysis and improvement	17,56	16,60	12,50	13,49
8.1 General provisions	0,00	0,21	0,30	0,41
8.2 Monitoring and measurements	0,30	0,00	0,00	0,00
8.2.1 Customer satisfaction	2,98	2,49	1,49	2,90
8.2.2 Internal audit	3,57	3,73	2,38	2,70
8.2.3 Process monitoring and measurements	2,08	2,07	2,08	1,24
8.2.4 Product monitoring and measurements	1,79	0,00	2,08	1,04
8.3 Supervision over nonconforming product	0,89	1,04	0,30	1,66
8.4 Data analysis	0,60	1,45	0,00	1,24
8.5 Improvement	0,60	0,62	0,00	0,41
8.5.1 Continuous improvement	0,30	0,41	0,00	0,21
8.5.2 Corrective measures	2,98	2,90	2,38	1,04
8.5.3 Preventive measures	1,49	1,66	1,49	0,62
Where: NC – nonconformity, ARI – areas requiring improvement				

Source: own study

The highest number of inconsistencies was noted in small and medium-sized enterprises. They were related to the paragraph of the standard regarding measurements, analysis and improvement (30.1%) and product processing (26.8%). Similar tendencies were observed in case of areas requiring improvement. The highest number of inconsistencies and areas to be improved were recorded in small (45.8%) and medium-sized enterprises (30.1%). For micro

and big enterprises these values ranged from 7.3 to 14.0%, both in case of inconsistencies and areas to be improved. The difficulties encountered by small enterprises in the area of measurements, analysis and improvement concerned chiefly the monitoring of a product (2.7%), audit and process monitoring (2.4% each). In the case of medium-sized enterprises, the majority of inconsistencies were discovered in the area of corrective measures (2.4%), customer satisfaction monitoring (2.1%) as well as audits and process monitoring (1.5% each). Similar tendencies were observed in areas requiring improvement.

Table 3 Division of inconsistencies and areas to be improved according to the frequency of occurrence and the size of enterprises.

Paragraph of the standard	Classification of enterprises according to their size Values expressed in [%]							
	Micro		Small		Medium-sized		Big	
	NC	ARI	NC	ARI	NC	ARI	NC	ARI
4. Quality management system	3,9	1,5	6,8	8,1	5,7	8,5	2,7	1,7
5. Responsibility of managers	1,8	1,7	5,1	6,0	3,9	5,4	1,2	1,0
6 Management of resources	2,1	0,6	4,8	4,6	4,2	5,4	1,2	0,8
7 Product processing	2,7	1,5	14,6	10,2	7,1	12,0	2,4	1,0
8 Measurement, analysis and improvement	3,6	3,1	14,6	15,1	9,2	9,1	2,7	2,7
	14,0	8,3	45,8	44,0	30,1	40,5	10,1	7,3

Source: own study

The studies revealed the existence of preferences among the auditors with regard to the fields in which inconsistencies or areas to be improved were identified. Due to the number of conducted preliminary, certification, control and recertification audits, from among twelve auditors were selected the ones who conducted minimum ten audits. They were marked with „X”, „Y” and „Z” symbols. The studies were based on nonconformity (NC) analysis and improvement recommendations (ARI). When evaluating the auditors, relative values were taken into consideration. The results have been shown in the form of values representing the percentage of inconsistencies/areas to be improved per one audit. Average values of nonconformity (NC) and areas to be improved (ARI) for „X”, „Y”, and „Z” have been presented in Fig. 3.

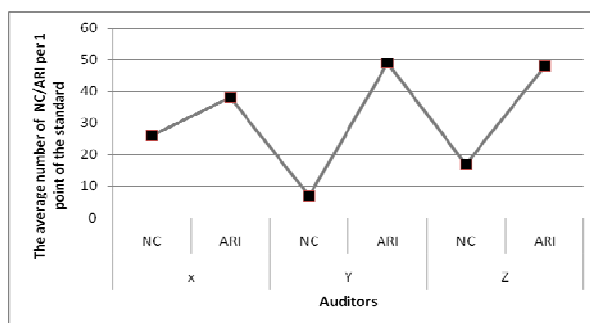


Figure 3 The average number of inconsistencies and areas requiring improvement identified by the analysed auditors per 1 paragraph of the standard.

Source: own study

The results were compared with the ones obtained on the basis of internal audits documentation. It was found that the first party auditors most frequently raised the question of inconsistencies related to supervision over documentation. A characteristic approach is the planning of audits from the point of view of fulfilling the requirements of the standard, and not from the process perspective. This results from insufficient improvement of auditing skills. Among the internal auditors subjected to analysis, in 84.5% of cases the training was run by a QMS representative. Only in 7.5% of cases the auditors participated in skill improvement workshops. The training run by specialist units was attended by a mere 15.5% of auditors.

### **3. CONCLUSIONS**

On the basis of the conducted studies the following is concluded:

1. No significant dependencies between the type of enterprise activity and the number of discovered inconsistencies and areas requiring improvement was found. The exception is the paragraph of the standard regarding measurements, analysis and improvement - here the difference in the number of inconsistencies between service and industrial enterprises was more than 5%.
2. There is a relationship between the size of an enterprise and the number of discovered inconsistencies and areas to be improved. The most inconsistencies and areas requiring improvement were identified in small and medium-sized enterprises, and the fewest – in micro and small companies.
3. No dependencies between the size of an entity and the inconsistencies and areas requiring improvement with regard to a particular paragraph of the standard were found. Irrespective of the size of an enterprise, the highest number of inconsistencies and areas to be improved regarded measurements, analysis and improvement, whereas the lowest number concerned the responsibility of managers and management of resources.
4. The analysis of the auditors' preferences revealed that the inconsistencies and areas requiring improvement which they had identified in most cases referred to the paragraph of the standard regarding measurements, analysis and improvement.
5. The analysis of internal audits documentation shows that audits are not conducted from the process perspective, but are focused on the fulfilment of requirements contained in particular paragraphs of the standard. This may result from insufficient preparation of internal auditors to conduct audits according to the process approach.
6. The vast majority of inconsistencies identified during internal audits concerned supervision over documentation. Few of them referred to the analysis of data, the use of information in management processes and problem identification tools.
7. The above conclusions are significant within the scope of conducted investigations.

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